UNITED STATES DISTRICT COURT
DISTRICT OF KANSAS

TIMOTHY JOHNSON,	§	
	§	
Plaintiff	§	**CASE NO.: 2:14-cv-02044-KHV-KGS**
	§	
v.	§	
	§	
3M COMPANY; AND ARIZANT HEALTHCARE, INC.,	§	**JURY TRIAL DEMANDED**
	§	
	§	
Defendants.	§	

PLAINTIFF'S FIRST AMENDED ORIGINAL COMPLAINT

COMES NOW, Plaintiff, TIMOTHY JOHNSON ("Mr. Johnson" or "Plaintiff") and files this, his First Amended Complaint, against Defendants 3M Company and Arizant Healthcare, Inc. (jointly "Defendants") and would respectfully show the following:

I. INTRODUCTION

1. This is a product liability personal injury case stemming from the design, manufacture, marketing, and maintenance of the Bair Hugger Forced Air Warming device ("Bair Hugger FAW"). As a direct result of the use of Bair Hugger FAW during his knee replacement surgery, Plaintiff suffered grievous harm, incurred significant medical bills, and continues to suffer to this day.

2. Defendants knew about the risks the Bair Hugger FAW poses to patients, particularly patients such as Plaintiff undergoing implantation surgeries. Despite this knowledge, which Defendants enjoyed for a least the last fifteen years, no attempt has been made to redesign their product or warn healthcare providers of the risks inherent in using a Bair Hugger FAW in an implantation surgery. In fact, Defendants have taken every step to conceal and discredit any scientific studies which might undermine their sales.

II. PARTIES

3. Plaintiff is a citizen of the State of Kansas and resides in Johnson County, Kansas.

4. Defendant 3M Company ("3M") is a corporation organized under the laws of the State of Delaware doing business in the State of Kansas. 3M has made an appearance in this case through its counsel.

5. Defendant Arizant Healthcare, Inc. ("Arizant") is a corporation organized under the laws of the State of Delaware doing business in the State of Minnesota. Arizant has made an appearance in this case through its counsel.

III. JURISDICTION AND VENUE

6. The Court has jurisdiction over this suit because it involves a controversy between parties of diverse citizenship and the amount in controversy exceeds $75,000. 28 U.S.C. § 1332(a).

7. Defendants have had continuous and systematic contacts with the state of Kansas sufficient to establish general jurisdiction over said Defendants.

8. The causes of action alleged herein arose from or relate to the contacts of Defendants to the State of Kansas, thereby conferring specific jurisdiction with respect to said Defendants.

9. The assumption of jurisdiction over Defendants will not offend traditional notions of fair play and substantial justice and is consistent with the constitutional requirements of due process.

10. Venue is proper in this District because a substantial portion of the acts and omissions that form the basis of this suit occurred in this district.

IV. FACTUAL BACKGROUND

11. On September 29, 2010 Plaintiff Johnson underwent surgery at The University of Kansas Hospital for the purpose of receiving a right total knee arthroplasty (TKA).

12. During his surgery, Plaintiff's anesthesiologist used a Bair Hugger Forced Air Warming device (hereinafter "Bair Hugger FAW") on him.

13. Plaintiff sustained a periprosthetic infection during his knee replacement surgery due to the introduction of contaminants unto his open surgical site by the Bair Hugger FAW.

14. Plaintiff's infection contained Methicillin-resistant Staphylococcus Aureus (MRSA) which was introduced as a result of the Bair Hugger FAW.

15. Plaintiff learned that his injuries were the result of the Bair Hugger FAW within the two year period prior to initiating this lawsuit. Specifically, Plaintiff learned his injuries were the result of the Bair Hugger FAW in 2013.

16. The Bair Hugger FAW is designed, manufactured, and marketed by Defendants 3M Company and Arizant Healthcare, Inc.

17. More than 50,000 Bair Hugger FAW units are currently in use across the country.

18. The Bair Hugger FAW consists of a portable heater/blower connected by a flexible hose to a disposable blanket that is positioned over (or in some cases under) surgical patients. The system warms patients during surgery by blowing hot air on a patients' exposed skin.

19. The hot air produced by Bair Hugger FAW accumulates under the surgical drape covering the patient and escapes from under the surgical drape below the level of the surgical table or at the head end of the surgical table. This escaped air creates air flow currents that flow against the downward air flow of the operating room. As this warmed air rises, it deposits

bacteria from the floor of the surgical room into the surgical site.

20. At some point between 2002 and 2009 Defendants reduced the efficiency of the air filtration of Bair Hugger FAW blowers. This action reduced the safety of such blowers.

21. As a result of these actions by Defendants, the internal airflow paths of Bair Hugger FAW blowers become contaminated with pathogens.

22. The pathogens contaminating the internal airflow paths of Bair Hugger FAW blowers incubate and proliferate therein.

23. These pathogens are then expelled from the interior of the Bair Hugger FAW blower by the outward airflow, travel through the hose into the disposable blanket and escape into the operating room.

24. Defendants have been aware of the pathogenic contamination of the airflow paths of Bair Hugger FAW blowers since at least 2009.

25. Defendants have actively and aggressively marketed the Bair Hugger FAW as safe in both general and orthopedic surgeries despite their knowledge to the contrary.

26. In a communication to the Food and Drug Administration ("FDA") in September 2000, Defendants represented that the Bair Hugger FAW's filtration system meets HEPA ("High Efficiency Particulate Air") Standards. This statement was false at the time Defendants made it and it remains false today. To meet HEPA standards, an air filter must be capable of removing 99.97% of all particles 0.3 microns or large. The filter of the Bair Hugger FAW, which is marketed as HEPA compliant, is only capable of removing les that 65% of all such particles. When Defendants made these misrepresentations, Defendants had actual knowledge of their falsity.

27. In June of 1997, in a letter to the FDA, Defendants admitted that "air blown intraoperatively across the surgical wound may result in airborne contamination." Defendants

countered this flaw in their products by misrepresenting to the FDA that the risk of contamination by air flow is obviated because all "Bair Hugger Blankets designed for use in the operating room feature a tape barrier which prevent (sic) air from migrating toward the surgical site." This ameliorative statement by Defendants is false on a number of fronts. First, a number of Bair Hugger blankets marketed as safe for use in surgeries do not utilize a taped edge at all. Instead, those blankets blow contaminated air directly toward the surgical field. Second, the statement that the taped barrier would contain the contaminated air is false because it ignores the fact that the heated air from the Bair Hugger FAW rises against the general downward airflow of the operating theatre. The presence of a tape edge would do nothing to prevent the fact that the Bair Hugger FAW facilitates the movement of pathogens from the floor of the operating room to the surgical site. When Defendants made these misrepresentations, they had actual knowledge of their falsity.

28. In their website, www.FAWFact.com (last visited November 11, 2013), Defendants make the following misrepresentations:

a. Contamination mobilized by the convection currents generated by the Bair Hugger FAW cannot reach the surgical site because "[a]ir velocity within the operating theatre is may times stronger than that of the forced-air warming blanket;

b. "The air emerging from the blanket is directed downward by the surgical drape and emerges under the operating room table and is drawn away through the laminar system's return air inlets;"

c. "It's been suggested that warm air rising above the Bair Hugger blanket could interfere with the downward laminar flow toward the surgical site. It should be noted that the Bair Hugger warming unit delivers less than one percent of the airflow of a laminar flow system and the momentum of the downward air is far greater than the upward momentum imparted to the air above the blanket."

29. The statements in the preceding paragraph are false and intentionally misleading. Through these statements, Defendants disguise the fact that the issue is not the strength of the

airflow in a laminar system but the heat of the air generated by the Bair Hugger FAW. The cold air circulated with the operating room, having a higher density than the air heated by the Bair Hugger FAW, falls to the floor which forces the contaminated air at the floor of the operating room, now warmed by the waste heat from the Bair Hugger FAW, to rise into the sterile field and the surgical site. The heated air rises, it is not "drawn away" as Defendants' posit in their advertisement.

30. In an advertisement that appeared in multiple medical publications as early as 2010, available online at http://www.fawfacts.com/_asset/zn062p/ (last visited November 11, 2013), Defendants made the following false and deliberately misleading claims:

> "While simple logic makes it clear that forced air warming has no impact on laminar conditions, science also supports this. A forced air warming blanket delivers less than one percent of the airflow of a laminar flow system and therefore is unable to affect laminar flow ventilation systems."

As published scientific research, before and after this statement, has demonstrated, this statement is untrue. The exhaust generated by the Bair Hugger FAW creates convective airflow patterns that do disrupt the laminar flow of the operating theater.

31. In a communication that appeared in *Healthcare Purchasing News* in July of 2012, Defendants' public relations and communications specialist Greta Deutsch stated "some conductive-warming manufacturers have alleged that forced-air warming increases bacterial contamination of operating rooms or interrupts laminar airflow. These accusations have no factual basis." Again, this statement ignores numerous published studies documenting the adverse effects the Bair Hugger FAW has on laminar airflow.

32. In a marketing video produced by Defendants and available online at http://www.youtube.com/watch?v=0j9w5brozV4 (last visited November 11, 2013), Defendants make the following misrepresentations:

a. "3M Bair Hugger forced-air warming does NOT influence the effectiveness of a laminar flow system";

b. Claims by conductive warming manufacturers that Bair Hugger disrupts laminar flow are "inaccurate and irresponsible;"

c. Laminar airflow is stronger than the convective currents created by the Bair Hugger FAW.

Each of these statements is false and willfully ignore published studies to the contrary.

33. The publication of numerous peer-reviewed studies documenting and revealing the critical safety shortcomings of the Bair Hugger FAW should have prompted Defendants to redesign or discontinue their product. Instead, those criticisms only caused Defendants to amplify their efforts to champion the Bair Hugger FAW. These publications include, but are not limited to, the following:

a. Albrecht M, Leaper D et al. Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room. *Am J Infect Control* 2011;39:321-8;

b. Leaper D et al. Forced-air warming: a source of airborne contamination in the operating room? *Orthopedic Rev*. 2009;1(2):e28;

c. McGovern et al. Forced-air warming and ultra-clean ventilation do not mix. *J Bone and Joint Surg-Br*. 2011;93(11):1537-1544;

d. Legg et al. Do forced air patient-warming devices disrupt unidirectional downward airflow? *J Bone and Joint Surg-Br*. 2012;94-B:254-6;

e. Belani et al. Patient warming excess heat: The effects on orthopedic operating room ventilation performance. *Anesthesia & Analgesia* 2012 (prepublication on-line) 2013;117(2):406-411; and

f. Dasari et al. Effect of forced air warming on the performance of operating theatre laminar flow ventilation. *Anaesthesia* 2012;67:244-249.

34. Separately and in conjunction with each other, the net effects of these misrepresentations was to mislead healthcare providers about the safety of the Bair Hugger FAW for use in surgical procedures. Defendants were aware of the falsity of their

misrepresentations at the time those misrepresentations were authored.

35. As each study confirms the dangers the Bair Hugger FAW poses to surgical patients, Defendants do nothing to alter the design of the machine nor do they make any effort to warn physicians. To do so would be against their closely guarded economic interests.

36. Plaintiffs' physicians' relied upon the above representations and advertisements to Plaintiff's detriment. Any reasonable and competent physician would not use a Bair Hugger FAW in an orthopedic implant surgery if they were fully apprised of the dangers and risks associated with doing so. However, through misrepresentations to the public, the medical community, and the FDA, Defendants actively concealed the infection causing propensity of the Bair Hugger FAW in orthopedic implant surgeries.

37. As a direct and proximate result of the failure of Defendants' Bair Hugger FAW to maintain the sterility of the surgical area and the Defendants' wrongful conduct in designing, manufacturing, and marketing this dangerous product, Plaintiff sustained and continues to suffer economic damages (including medical and hospital expenses), severe and permanent injuries, pain, suffering, and emotional distress. Plaintiff has sustained and will continue to sustain damages in an amount to be proven at trial.

V. CAUSES OF ACTION

COUNT I - NEGLIGENCE

38. Plaintiff represents and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

39. Defendants owed Plaintiff a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling Bair Hugger FAW.

40. Defendants failed to exercise due care under the circumstances and therefore breached this duty in the following nonexclusive ways:

a. Failing to properly and thoroughly test Bair Hugger FAW before releasing the device to market;

b. Failing to properly and thoroughly analyze the data resulting from the pre-market tests of the Bair Hugger FAW;

c. Failing to conduct sufficient post-market testing and surveillance of the Bair Hugger FAW;

d. Designing, manufacturing, marketing, advertising, distributing, and selling the Bair Hugger FAW to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of the Bair Hugger FAW and without proper instructions to avoid the harm which could foreseeably occur as a result of using the device;

e. Failing to exercise due care when advertising and promoting the Bair Hugger FAW; and

f. Negligently continuing to manufacture, market, advertise, and distribute the Bair Hugger FAW after Defendants knew or should have known of its adverse effects.

41. Plaintiff was injured as a direct and proximate result of Defendants' actions, omissions, and misrepresentations. Plaintiff has incurred and will continue to incur expenses as a result of using the Bair Hugger FAW.

COUNT II - VIOLATION OF THE KANSAS CONSUMER PROTECTION ACT

42. Plaintiff represents and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

43. Under the Kansas Consumer Protection Act ("KCPA"), Kan. Stat. Ann. § 50-623, *et seq.*, Plaintiff is a consumer, Kan. Stat. Ann. § 50-624(b) and the Defendants are suppliers, Kan. Stat. Ann. § 50-624(l).

44. Under the KCPA, no supplier shall engage in any deceptive act or practice in connection with a consumer transaction and deceptive acts include, but are not limited to the willful failure to state a material fact, or the willful concealment, suppression or omission of a

material fact. Kan. Stat. Ann. § 50-626(b)(3).

45. Defendants violated the KCPA by engaging in acts and practices by willfully failing and refusing to timely report information that reasonably suggested the Bair Hugger FAW, like that used on Plaintiff, may cause or contribute to death or serious injury when used in implantation surgeries.

46. Defendants violated the KCPA, among other ways, through the following:

a. Representing knowingly or with reason to know that the Bair Hugger FAW has approval, characteristics, uses, or benefits that it does not have;

b. Representing knowingly or with reason to know that the Bair Hugger FAW and its filtration system is of a particular standard, qualify, or grade when it differs materially from that representation;

c. Representing knowingly or with reason to know that the Bair Hugger FAW has uses, benefits, or characteristics that have been otherwise proven incorrect;

d. Falsely stating, knowingly or with reason to know, that services or repairs are not needed.

47. The Defendants' violations of the KCPA, whether individually or in combination, caused or contribute to cause Plaintiff's injuries and damages as forth herein.

48. Under the KCPA, Plaintiff is entitled to recover his actual damages and entitled to recover his reasonable attorneys' fees from the Defendants.

COUNT III - STRICT LIABILITY

49. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

50. Defendants, or entities under their control, were responsible for the design,

manufacture, assembly, marketing, selling and/or distribution of the Bair Hugger FAW used in Plaintiff's surgery.

51. The propensity of the Bair Hugger FAW to cause convention currents that disrupt the generally downward airflow of the operating room makes the Bair Hugger FAW dangerous when used in the way it is ordinarily used and is dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchased it, with the ordinary knowledge common to the community as to its characteristics.

52. In the alternative, the propensity of the Bair Hugger FAW's internal air flow passageways, including its non-HEPA compliant filter, to become contaminated with pathogens makes the Bair Hugger FAW dangerous when used in the way it is ordinarily used and is dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchased it, with the ordinary knowledge common to the community as to its characteristics.

53. The Bair Hugger FAW system used on Plaintiff by his physicians was defective and unsafe for its intended purposes at the time it left the control of Defendants and at the time it was sold.

54. Plaintiff therefore invokes the doctrine of strict liability in Section 402A, Restatement of the Law of Torts, 2d, and as adopted by the Supreme Court of Kansas.

55. Specifically, Bair Hugger FAW is defective in its design of formulation in that it is not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design.

56. Plaintiff and his physicians were unaware of the significant hazards and defects in Bair Hugger FAW. The Bair Hugger FAW system was unreasonably dangerous and/or not reasonably safe in that it was more dangerous than would be reasonably contemplated by the

ordinary patient or physician. During the period that Plaintiff and his physicians used the Bair Hugger FAW system, it was used in a manner that was intended by Defendants. At the time Plaintiff was warmed by the Bair Hugger FAW system, it was represented to be safe and free from latent defects.

A. DEFECTIVE WARNING

57. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

58. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce Bair Hugger FAW and in doing so, directly advertised or marketed the product to the FDA, health care professionals, and consumers, or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of Bair Hugger FAW.

59. Defendants failed to adequately warn health care professionals and the public, including Plaintiff and his physician, of the true risks of Bair Hugger FAW, including that Bair Hugger FAW would circulate contaminated air in the operating room and that the vented heat from Bair Hugger FAW would mobilize floor air contaminated with pathogens into the surgical site, causing deep joint infections, and requiring further treatment, including surgery and/or amputation.

60. Defendants failed to provide timely and reasonable warnings regarding the safety and efficacy of Bair Hugger. Had they done so, proper warnings would have been heeded and no health care professional, including Plaintiff's physicians, would have used Bair Hugger FAW and no patient, including Plaintiff, would have allowed use of Bair Hugger FAW.

61. Bair Hugger FAW, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released

into the stream of commerce by Defendants, was defective due to inadequate post-marketing warnings and/or instructions because Defendants failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiff, and continue to aggressively promote Bair Hugger FAW.

62. Defendants failed to perform or otherwise facilitate adequate testing, failed to reveal or concealed testing and research data, or selectively and misleadingly revealed or analyzed testing and research data.

63. The defective warnings or instructions provided in association with the Bair Hugger FAW constitute a producing cause of Plaintiff's injuries.

64. The failure to provide timely and reasonable warnings, instructions, and information regarding Bair Hugger FAW to Plaintiff and/or his physician rendered the Bair Hugger unreasonably dangerous. As a direct result of Defendants' conduct, Plaintiff has suffered and continues to suffer serious and permanent non-economic and economic injuries. Defendants are liable to Plaintiff in an amount to be determined at trial.

B. DEFECTIVE DESIGN AND MANUFACTURE

65. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

66. While engaged in the manufacture and sale of the Bair Hugger, Defendants manufactured and sold Bair Hugger FAW to consumers within the stream of commerce. Defendants intended and expected that the Bair Hugger so introduced and passed on in the course of trade would ultimately reach a consumer or user in the condition in which it was originally sold.

67. The design of the Bair Hugger FAWs and/or its component parts, make the Bair Hugger FAW unreasonably dangerous, taking into consideration the utility of the device and the

risk involved in its use.

68. At all times relevant to this action, an economically and technologically feasible safer alternative design existed, which in reasonable medical probability:

a. Would have prevented or significantly reduced the risk of Plaintiff's infection and subsequent amputation; and

b. Would not have impaired the utility of the device.

69. Specifically, Bair Hugger FAW is defective in its design of formulation in that it is not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design. Bair Hugger FAW is defective in design in that it lacks efficacy, poses a greater likelihood to injury and is more dangerous than other available devices indicated for the same conditions and uses.

70. If the design defects were known at the time of manufacture, a reasonable person would have concluded that the utility of Bair Hugger FAW did not outweigh its risks.

71. The defective condition of the Bair Hugger FAW system rendered it unreasonably dangerous and/or not reasonably safe and the Bair Hugger FAW system was in this defective condition at the time it left the hands of the Defendants. The Bair Hugger FAW system was expected to and did reach Plaintiff and his physicians without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied, and otherwise released into the stream of commerce.

72. Defendants are strictly liable to Plaintiff for designing, manufacturing, and placing into the stream of commerce the Bair Hugger FAW system, which was unreasonably dangerous for its reasonably foreseeable uses because of its design defects.

73. Defendants knew or should have known of the danger associated with the use of the Bair Hugger FAW, as well as the defective nature of Bair Hugger FAW, but have continued

to design, manufacture, sell, distribute, market, promote, and/or supply Bair Hugger FAW so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by Bair Hugger FAW.

74. The defective design and manufacture of the Bair Hugger FAW was a cause of Plaintiff's injuries.

75. As a direct result of Defendants' conduct, Plaintiff has suffered and continues to suffer serious and permanent non-economic and economic injuries and Defendants are liable to Plaintiff in an amount to be determined at trial.

COUNT IV—BREACH OF EXPRESS WARRANTY

76. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

77. Defendants advertised, labeled, marketed and promoted Bair Hugger FAW, representing the quality to health care professionals, the FDA, Plaintiff, and the public in such a way as to induce its purchase or use, thereby making an express warranty that Bair Hugger FAW would conform to the representations. More specifically, Defendants represented that Bair Hugger FAW was safe and effective for use by individuals such as Plaintiff or that it was safe and effective to use during Plaintiff's surgery.

78. The representations, as set forth above, contained or constituted affirmations of fact or promises made by Defendants to the buyer that related to the goods and became part of the basis of the bargain, creating an express warranty that the goods would conform to the affirmations of fact or promises.

79. The Bair Hugger FAW system did not conform to the representations made by Defendants in that the Bair Hugger FAW system was not safe and effective, was not safe and effective for use by individuals such as Plaintiff, and/or was not safe and effective to treat

individuals such as Plaintiff.

80. At all relevant times, the Bair Hugger FAW system was used on Plaintiff by his physicians for the purpose and in the manner intended by Defendants.

81. Plaintiff and Plaintiff's physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

82. The breach of warranty was a proximate cause in bringing about Plaintiff's injuries.

83. As direct result of Defendant' conduct, Plaintiff has suffered and continues to suffer serious and permanent non-economic and economic injuries and Defendants are liable to Plaintiff in an amount to be determined at trial.

COUNT V—BREACH OF IMPLIED WARRANTY

84. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

85. The Bair Hugger FAW system was not reasonably fit for the ordinary purposes for which such goods are used and did not meet the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manner. Nor was the Bair Hugger FAW system minimally safe for its intended purposes.

86. At all relevant times, the Bair Hugger FAW system was used on Plaintiff's by his physicians for the purpose and in the manner intended by Defendants.

87. Plaintiff and Plaintiff's physician, by the use of reasonable care, would not have discovered the breached warranty and realized its danger.

88. Defendants' breach of the implied warranty was a proximate cause in bringing about Plaintiff's injuries.

89. As direct results of Defendants' conduct, Plaintiff has suffered and continues to

suffer serious and permanent non-economic and economic injuries and Defendants are liable to Plaintiff in an amount to be determined at trial.

COUNT VI—NEGLIGENT MISREPRESENTATION

90. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

91. Defendants made misrepresentations with respect to Bair Hugger FAW including, but not limited to, the following particulars:

a. Defendants represented through the labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that Bair Hugger FAW has been tested and found to be safe and effective for the warming of patients during orthopedic implant surgery; and

b. Defendants represented that Bair Hugger FAW was safer than other patient warming systems.

92. Defendants did not exercise reasonable care or competence in obtaining or communicating the information to the public regarding the characteristics and qualities of Bair Hugger FAW.

93. Plaintiff and his physicians did, in fact, rely upon the representations.

94. Plaintiff and his physicians justifiably relied upon the representations.

95. Defendants' misrepresentations evidence their callous, reckless, and willful indifference to the health, safety, and welfare of their consumers, including Plaintiff.

96. Plaintiff was injured as a direct and proximate result of Defendants' actions, omissions, and misrepresentations.

97. Plaintiff has incurred and will continue to incur expenses as a result of using the Bair Hugger FAW system.

COUNT VII—FRAUDULENT MISREPRESENTATION

98. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

99. Defendants made fraudulent misrepresentations with respect to Bair Hugger FAW including, but not limited to, the following particulars:

a. Defendants represented through the labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that Bair Hugger FAW had been tested and found to be safe and effective for warming patients undergoing orthopedic implant surgery; and

b. Defendants represented that Bair Hugger FAW was safe and safer than other alternative patient warming devices.

100. Defendants knew that their representations were false, yet they willfully, wantonly, and recklessly disregarded their obligation to provide truthful representations regarding the safety and risks of Bair Hugger FAW to consumers, including Plaintiff, and the medical community.

101. The representations were made by Defendants with the intent that doctors and patients, including Plaintiff, rely upon them.

102. Defendants' representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of Bair Hugger FAW.

103. Plaintiff and his physicians did in fact rely upon the representations. In the absence of Defendants' representations, the Bair Hugger FAW would not be used in implantation surgeries such as the one at issue in this case.

104. Defendants' fraudulent representations evidence their callous, reckless, and willful indifference to the health, safety, and welfare of consumers, including Plaintiff.

105. Plaintiff was injured as a direct and proximate result of Defendants' actions, omissions, and misrepresentations. Plaintiff has incurred and will continue to incur expenses as a result of using Bair Hugger FAW.

106. Defendants acted with oppression, fraud, and malice towards Plaintiff, who accordingly requests that the trier of fact, in the exercise of its sound discretion, award additional damages for the sake of example and for the purpose of punishing Defendants for their conduct, in an amount sufficiently large to be an example to others and to deter these Defendants and others from engaging in similar conduct in the future.

COUNT VIII—FRAUDULENT CONCEALMENT

107. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

108. Defendants fraudulently concealed information with respect to Bair Hugger FAW including, but not limited to, the following particulars:

a. Defendants represented through the labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that Bair Hugger FAW was safe and fraudulently withheld and concealed information about the substantial risk of using Bair Hugger FAW; and

b. Defendants represented that Bair Hugger FAW was safe and safer than other alternative systems and fraudulently concealed information that demonstrated that Bair Hugger FAW was not safer than alternatives available on the market.

109. Defendants had sole access to material facts concerning the dangers and unreasonable risks of Bair Hugger FAW.

110. The concealment of information by Defendants about the risks of Bair Hugger FAW was intentional, and the representations made by Defendants were known

by Defendants to be false.

111. The concealment of information and the misrepresentations about Bair Hugger FAW were made by Defendants with the intent that doctors and patients, including Plaintiff and his doctors, rely upon them.

112. Plaintiff and his physicians relied upon the representations and were unaware of the substantial risks of Bair Hugger FAW which Defendants concealed from the public, including Plaintiff and his physicians.

113. Plaintiff was injured as a direct and proximate result of Defendants' actions omissions, and misrepresentations. Plaintiff has incurred and will continue to incur expenses as a result of using the Bair Hugger FAW system.

114. Defendants acted with oppression, fraud, and malice towards Plaintiff, who accordingly requests that the trier of fact, in the exercise of its sound discretion, award additional damages for the sake of example and for the purpose of punishing Defendants for their conduct, in an amount sufficiently large to be an example to others and to deter these Defendants and others from engaging in similar conduct in the future.

VI. PUNITIVE DAMAGES

115. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

116. Defendants' acts or omissions described above, when viewed from the standpoint of the Defendants at the time of the act or omission, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to Plaintiff and the community at large.

117. Defendants' acts or omissions, as described herein, were performed with a realization of the imminence of danger and were performed with reckless disregard or

complete indifference to the probable result.

118. Defendants had actual, subjective awareness of the risks involved in the above described acts or omissions, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of Plaintiff and the community at large.

119. Based on the facts stated herein, Plaintiff requests that punitive damages be awarded to Plaintiff from Defendants.

VII. DAMAGES

120. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

121. As a direct and proximate result of the occurrence made the basis of this lawsuit, Plaintiff was caused to suffer personal injuries and has incurred the following damages:

a. Reasonable medical care and expenses in the past;

b. Reasonable and necessary medical care and expenses that will, in all reasonable probability, be incurred in the future;

c. Physical pain and suffering in the past;

d. Physical pain and suffering in the future;

e. Physical impairment in the past;

f. Physical impairment that , in all reasonable probability, will be suffered in the future;

g. Loss of earnings in the past;

h. Loss of earning capacity that, in all reasonable probability, will be incurred in the future;

i. Disfigurement in the past;

j. Disfigurement in the future;

k. Mental anguish in the past;

l. Mental anguish in the future;

m. Cost of medical monitoring and prevention in the future;

n. Reasonable and necessary attorney's fees in prosecuting this action (*See* KAN. STAT. ANN. §50-6,101(c)); and

o. Punitive damages.

122. Plaintiff seeks all elements of said damages permitted under law from the Defendants in an amount that Plaintiff would show he is entitled to at the time of trial.

PRAYER

WHEREFORE, PREMISES CONSIDERED, Plaintiff respectfully prays that Defendants be cited to appear and answer herein, and that upon a final hearing of the cause, judgment be entered for Plaintiff against Defendants, jointly and severally, for damages in an amount within the jurisdictional limits of the Court; together with pre-judgment interest at the maximum rate allowed by law; post-judgment interest at the legal rate, costs of court; exemplary damages, and such other and further relief to which Plaintiff may be entitled at law or in equity.

A JURY TRIAL IS DEMANDED ON ALL ISSUES.

Respectfully submitted,

KENNEDY HODGES, L.L.P.

By: /s/ David W. Hodges
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CERTIFICATE OF SERVICE

I certify that on April 22, 2014 a true copy of the foregoing instrument was served on all parties of record by email via the District of Kansas's CM/ECF system.

/s/ Gabriel A. Assaad
Gabriel A. Assaad