IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

Larry Young,

Plaintiff,

v.

3M COMPANY and ARIZANT HEALTHCARE, INC.,

Defendants.

Case No. _____

COMPLAINT AND
DEMAND FOR JURY TRIAL

Plaintiff, Larry Young, brings this Complaint against Defendants 3M Company ("3M") and Arizant Healthcare, Inc. ("Arizant") (hereinafter referred to collectively as "Defendants"), for injuries caused by Defendants' design, development, testing, assembling, manufacturing, packaging, promoting, marketing, distribution, supplying and/or selling the defective device sold under the trade name of Bair Hugger Forced Air Warming device (hereinafter "Bair Hugger" or "Defective Device").

I. INTRODUCTION

1. This is a product liability personal injury case stemming from the design, manufacture, marketing, sale and distribution of the Defective Device. As a result of the use of the Defective Device during his knee replacement surgery, Plaintiff suffered grievous harm, incurred significant medical bills, and continues to suffer.

2. Defendants knew about the risks the Defective Device poses to patient, particularly patients such as Plaintiff undergoing implantation surgeries. Despite this knowledge, no attempt has been made to redesign their product or warn healthcare providers of the risks inherent in

using the Defective Device in an implantation surgery. In fact, Defendants have taken every step to conceal and discredit any scientific studies that might undermine their sales.

II. PARTIES

3. Plaintiff is a citizen and resident of Cook County, Illinois.

4. Defendant 3M is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business located in Maplewood, Minnesota. 3M is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the Bair Hugger.

4. 3M engages or has engaged in the business in this State and may be served by serving its registered agent, CT Corporation System, 208 S. LaSalle St., Suite 814, Chicago, Illinois 60604

5. Defendant Arizant is a corporation organized and existing under the laws of the State of Delaware, with its headquarters located in Eden Prairie, MN. Arizant conducts business throughout the United States, including the State of Illinois, and is a wholly owned subsidiary of Defendant 3M. Arizant engages or has engaged in the business in this State and may be served by serving its registered agent, CT Corporation System, 208 S. LaSalle St., Suite 814, Chicago, Illinois 60604

III. JURISDICTION AND VENUE

6. This Honorable Court has jurisdiction over this matter because it involves an injury and conduct that occurred in Illinois and Plaintiff is an Illinois resident.

7. The Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 insofar as the parties are citizens of different states and the amount in controversy in this matter exceeds Seventy-Five Thousand Dollars ($75,000), exclusive of interest and costs.

8. Venue is proper in this jurisdiction pursuant to 28 U.S.C. § 1391 because a substantial number of the events, actions, or omissions giving rise to the Plaintiff's claims occurred in this district. Moreover, Defendants regularly solicited and engaged in business in this district. Defendants did (and do) business within the state of Illinois and have had substantial, continuous, and systematic contacts with the state of Illinois.

IV. FACTUAL ALLEGATIONS

9. The Defendants, directly, or through their agents, apparent agents, servants, or employees, designed, manufactured, marketed, advertised, distributed and sold the Bair Hugger.

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

11. The Bair Hugger 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 patient's exposed skin.

12. The hot air produced by Bair Hugger 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 can deposit bacteria from the floor of the surgical room into the surgical site.

13. Upon information and belief, at some point between 2002 and 2009 the Defendants reduced the efficiency of the air filtration of Bair Hugger blowers. This action reduced the safety of such blowers.

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

15. The contaminating pathogens incubate and proliferate within the internal airflow paths of Bair Hugger blowers.

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

17. Upon information and belief, the Defendants have been aware of the pathogenic contamination of the airflow paths of Bair Hugger blowers since at least 2009.

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

19. In June of 1997, in a letter to the Food and Drug Administration ("FDA"), the Defendants admitted that "air blown intraoperatively across the surgical wound may result in airborne contamination." The Defendants addressed this flaw in their products by making further misrepresentations to the FDA when they stated 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." That statement by the Defendants was and is patently false. 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. Also, 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 rises against the general downward airflow of the operating theatre. The presence of a tape edge does nothing to prevent the Bair Hugger from facilitating the movement of pathogens from the floor

of the operating room to the surgical site. When the Defendants made these representations, they had actual knowledge of their falsity.

20. In a communication to the FDA in September 2000, Defendants represented that the Bair Hugger's filtration system meets HEPA ("High Efficiency Particulate Air") Standards.

21. Upon information and belief Defendants' September 2000 statement was false at the time Defendants made it and remains false today. To meet HEPA standards, an air filter must be capable of removing 99.97% of all particles 0.3 microns or larger. The filter of the Bair Hugger, which is marketed as HEPA compliant, is capable of removing at most 65% of all such particles.

22. On Defendants' website, www.fawfacts.com/laminar_airflow/ (last visited September 2, 2015), the Defendants make the following misrepresentations:

a. Contamination mobilized by the convection currents generated by the Bair Hugger cannot reach the surgical site because "[a]ir velocity within the operating room is many times stronger than that of a 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."

23. Upon information and belief, these statements on Arizant's website, itemized in the preceding paragraph, are false and intentionally misleading. Through these statements, the 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. The cold air circulated with the operating

room, having a higher density than the air heated by the Bair Hugger, 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, to rise into the sterile field and the surgical site. The heated air rises, and is not "drawn away" as the Defendants falsely claim in their advertisement.

24. In an advertisement that appeared in multiple medical publications as early as 2010, available online at http://www.fawfacts.com/_asset/zn062p/AJIC.pdf (last visited September 2, 2015), the 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 has demonstrated, this statement is untrue. The exhaust generated by the Bair Hugger creates convective airflow patterns which disrupt the laminar flow of the operating theater.

25. In a communication that appeared in Healthcare Purchasing News in July of 2012, the 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 has on laminar airflow.

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

a. Albrecht M, et al. Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room. *Am J Infect Control* 2010; 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, P.D., et al. Forced-air warming and ultra-clean ventilation do not mix. *J Bone and Joint Surg-Br.* 2011;93-B(11):1537-1544;

d. Legg, A. 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, K., 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;

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

27. These misrepresentations mislead healthcare providers about the safety of the Bair Hugger for use in surgical procedures. The Defendants were aware of the falsity of their misrepresentations at the time those misrepresentations were authored.

28. Rather than alter the design of their product or warn physicians of the dangers associated with the Bair Hugger, as numerous studies confirm, the Defendants have chosen to "double down" on their efforts to promote their defective product.

29. Plaintiffs' physicians relied upon the above representations and advertisements to Plaintiff's detriment. However, through misrepresentations to the public, the medical community, and the FDA, the Defendants actively and knowingly concealed the propensity of these devices to cause infection in orthopedic implant surgeries.

30. As a result of the failure of the Defendants' Bair Hugger to maintain the sterility of the surgical area and the Defendants' wrongful conduct in designing, manufacturing, and marketing this defective product, Plaintiff and Plaintiff's physician were unaware, and could not

have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this complaint, and that those risks were the direct and proximate result of the Defendants' acts, omissions and misrepresentations.

V. PLAINTIFF'S SPECIFIC EXPERIENCE

31. As a result of the defective design of the Bair Hugger, Plaintiff has suffered and may continue to suffer severe and permanent personal injuries.

32. On June 14, 2013, Plaintiff underwent a left leg open reduction internal fixation at the University of Illinois Hospital in Chicago, Cook County, Illinois.

33. During his surgery, Plaintiff's anesthesiologist used a Bair Hugger on him.

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

34. Plaintiff subsequently experienced persistent pain and symptoms related to this deep infection. As a result of this infection, Plaintiff was forced to undergo a 2-stage revision with the first stage occurring November 7, 2013. A 3M forced air warming blanket was also utilized during this surgery.

35. Following this surgery, Plaintiff underwent further treatment, including hospitalization and antibiotic bead placements. Furthermore, Plaintiff had to endure multiple surgeries including the removal of the hardware.

36. Because the Bair Hugger was used, contaminants were introduced to Plaintiff's open surgical wound, resulting in a severe infection, multiple surgeries, permanent and ongoing injuries.

37. The Defendants concealed and continue to conceal their knowledge of the Bair Hugger's unreasonably dangerous risks from Plaintiff, other consumers, and the medical community.

38. The Defendants failed to conduct adequate and sufficient post-marketing surveillance after they began marketing, advertising, distributing and selling the Bair Hugger.

39. As a result of the Defendants' actions and inactions, Plaintiff was injured due to the use of the Bair Hugger, which has caused and will continue to cause Plaintiff's various injuries and damages. Accordingly, Plaintiff seeks compensatory damages.

VI. CAUSES OF ACTION

COUNT I - NEGLIGENCE

40. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

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

42. The Defendants failed to exercise due care under the circumstances and therefore breached this duty by:

a. Failing to properly and thoroughly test the Bair Hugger 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;

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

d. Designing, manufacturing, marketing, advertising, distributing, and selling the Bair Hugger to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of the Bair Hugger 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; and

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

43. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff suffered an infection, requiring additional treatment. Consequently, Plaintiff has suffered damages and incurred and will continue to incur medical expenses as a result of using the Bair Hugger.

44. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting condition and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage earning capacity.

45. The Defendants' conduct as described above was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff. Defendants' conduct warrants, if allowed by the Court upon motion, an award of punitive damages against Defendants in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

COUNT II - STRICT LIABILITY FAILURE TO WARN

46. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

47. The Defendants, or entities under their control, manufactured, sold, distributed, marketed or supplied the Bair Hugger in a defective and unreasonably dangerous condition to consumers, including Plaintiff.

48. Specifically, the Defendants failed to warn of the injuries suffered by Plaintiff as a result of using the Bair Hugger, and they introduced into the stream of commerce a defectively designed or manufactured product.

49. The Defendants designed, manufactured, sold, distributed, supplied, marketed or promoted the Bair Hugger, which was expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by the Defendants.

50. Plaintiff and Plaintiff's physicians used the Bair Hugger in a manner normally intended, recommended, promoted and marketed by the Defendants.

51. The Bair Hugger failed to perform safely when used by ordinary consumers, including Plaintiff, including when it was used as intended and in a reasonably foreseeable manner.

52. The propensity of the Bair Hugger's internal air flow passageways, including its non-HEPA compliant filter, to become contaminated with pathogens makes the Bair Hugger unreasonably 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. Because the Defendants researched, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce the Bair Hugger and in doing so, directly advertised or marketed the product to the

FDA, health care professionals, and consumers, or persons responsible for consumers, they had a duty to warn of the risks associated with the use of the Bair Hugger.

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

55. Defendants failed to provide timely and reasonable warnings regarding the safety and efficacy of the 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, and no patient, including Plaintiff, would have allowed use of the Bair Hugger.

56. The failure to provide timely and reasonable warnings, instructions, and information regarding the Bair Hugger to Plaintiff or Plaintiff's physician rendered the Bair Hugger unreasonably dangerous.

57. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff suffered an infection, requiring additional surgical procedures to clean the infected area and/or remove the orthopedic implant. Consequently, Plaintiff has suffered damages and incurred and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiff has also suffered and will continue to suffer diminished capacity of the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalizations, physician care,

monitoring, treatment, medications and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage earning capacity.

58. The Defendants' conduct described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff. Defendants' conduct warrants, if allowed by the Court upon motion, an award of punitive damages against Defendants in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

COUNT III - STRICT LIABILITY DEFECTIVE DESIGN AND MANUFACTURE

59. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

60. The Defendants, or entities under their control, manufactured, sold, distributed, marketed or supplied the Bair Hugger in a defective and unreasonably dangerous condition to consumers, including Plaintiff.

61. Specifically, the Defendants failed to warn of the injuries suffered by Plaintiff as a result of using the Bair Hugger, and they introduced into the stream of commerce a defectively designed or manufactured product.

62. The Defendants designed, manufactured, sold, distributed, supplied, marketed or promoted the Bair Hugger, which was expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by the Defendants.

63. Plaintiff and Plaintiff's physicians used the Bair Hugger in a manner normally intended, recommended, promoted and marketed by the Defendants.

64. The Bair Hugger failed to perform safely when used by ordinary consumers, including Plaintiff, including when it was used as intended and in a reasonably foreseeable manner.

65. The propensity of the Bair Hugger's internal air flow passageways, including its non-HEPA compliant filter, to become contaminated with pathogens makes the Bair Hugger unreasonably 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.

66. The design of the Bair Hugger or its component parts, makes the Bair Hugger unreasonably dangerous, taking into consideration the utility of the device and the risk involved in its use.

67. 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 injuries (including additional surgical procedures to clean the infected area and/or remove the implant); and

b. would not have impaired the utility of the device

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

69. The defective condition of the Bair Hugger rendered it unreasonably dangerous or not reasonably safe and the Bair Hugger was in this defective condition at the time it left the hands of the Defendants. The Bair Hugger was expected to and did reach Plaintiff and Plaintiff's 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.

70. Defendants knew or should have known of the danger associated with the use of the Bair Hugger, as well as the defective nature of the Bair Hugger, but have continued to design, manufacture, sell, distribute, market, promote, or supply the Bair Hugger 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.

71. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff suffered an infection, requiring additional surgical procedures to clean the infected area and/or remove the orthopedic implant. Consequently, Plaintiff has suffered damages and incurred and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss wages and wage earning capacity.

72. The Defendants' conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff. Defendants' conduct warrants, if allowed by the Court upon motion, an award of punitive damages against Defendants in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

COUNT IV - BREACH OF IMPLIED WARRANTY

73. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

74. The Defendants designed, manufactured, distributed, advertised, promoted and sold the Bair Hugger for use in sterile, surgical environments.

75. At all relevant times, the Defendants knew of the use for which the Bair Hugger was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

76. The Defendants were aware that consumers, including Plaintiff, would use the Bair Hugger for treatment in conjunction with orthopedic surgical procedures.

77. Plaintiff, Plaintiff's physician, and the medical community reasonably relied upon the judgment and sensibility of the Defendants to sell the Bair Hugger only if it was indeed of merchantable quality and safe and fit for its intended use.

78. The Defendants breached their implied warranty to consumers, including Plaintiff; the Bair Hugger was not of merchantable quality or safe and fit for its intended use.

79. Consumers, including Plaintiff, Plaintiff's physician, and the medical community reasonably relied upon the Defendants implied warranty for the Bair Hugger.

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

81. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff suffered an infection, requiring additional surgical procedures to clean the infected area and/or remove the orthopedic implant. Consequently, Plaintiff suffered damages and incurred and will continue to incur medical expenses as a result of using the Bair

Hugger. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage earning capacity.

82. The Defendant's conduct as described above was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff. Defendants' conduct warrants, if allowed by the Court upon motion, an award of punitive damages against Defendants in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

COUNT V - NEGLIGENT MISREPRESENTATION

83. Plaintiff restates the allegations set forth above as if fully rewritten herein.

84. The Defendants made negligent misrepresentations with respect to the Bair Hugger including, but not limited to, the following particulars:

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

b. The Defendants represented the Bair Hugger was safer than other patient warming systems.

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

86. Plaintiff and Plaintiff's physicians did, in fact, reasonably rely upon the representations.

87. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff suffered an infection, requiring additional surgical procedures to clean the infected area and/or remove the orthopedic implant. Consequently, Plaintiff has suffered damages and incurred and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage earning capacity.

88. Upon information and belief, the Defendants' conduct as described above was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff. Defendants' conduct warrants, if allowed by the Court upon motion, an award of punitive damages against Defendants in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

COUNT VI - FRAUDULENT MISREPRESENTATION

89. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

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

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

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

91. 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 to consumers, including Plaintiff, and the medical community.

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

93. The 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.

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

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

96. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff suffered an infection, requiring additional surgical procedures to clean the infected area and/or remove the orthopedic implant. Consequently, Plaintiff has suffered damaged and incurred and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiff has also suffered and will continue to suffer diminished capacity for

the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage earning capacity.

97. Upon information and belief, the Defendants' conduct as described above was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff. Defendants' conduct warrants, if allowed by the Court upon motion, an award of punitive damages against Defendants in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

COUNT VII - FRAUDULENT CONCEALMENT

98. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

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

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

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

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

101. The concealment of information by the Defendants about the risks of the Bair Hugger was intentional, and the representations made by Defendants were known by the Defendants to be false.

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

103. Plaintiff and Plaintiff's physicians relied upon the representations and were unaware of the substantial risks of the Bair Hugger which the Defendants concealed from the public, including Plaintiff and Plaintiff's physicians.

104. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff suffered an infection, requiring additional surgical procedures to clean the infected area and/or remove the orthopedic implant. Consequently, Plaintiff has suffered damaged and incurred and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage earning capacity.

105. The Defendants' conduct as described above was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff. Defendants' conduct warrants, if allowed by the Court

upon motion, an award of punitive damages against Defendants in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

DAMAGES

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

107. 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 n 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; and

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against the Defendants, jointly and/or severally, as follows:

1. For an award of compensatory damages in excess of Seventy-Five Thousand Dollars ($75,000.00);

2. For pre-judgment and post-judgment interest on the above general and special damages;

3. For all other relief that Plaintiff may be entitled to at equity or at law.

4. For such further and other relief that this Court deems just and equitable.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and issues so triable.

KP Law, LLC.

By: /s/ Rajesh Kanuru

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