

CAUSE NO. _____

TOMMY WALTON,

Plaintiff

v.

**3M COMPANY; ARIZANT
HEALTHCARE, INC.; AND
ROBERT PRESTERA,**

Defendants.

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IN THE DISTRICT COURT

HARRIS COUNTY, TEXAS

_____ **JUDICIAL DISTRICT**

PLAINTIFF'S ORIGINAL PETITION

Plaintiff Tommy Walton (‘Mr. Walton’ or ‘Plaintiff’) files this, his Original Petition, against Defendants 3M Company, Arizant Healthcare, Inc. and Robert Prestera (jointly ‘Defendants’) and would respectfully show the following:

I. DISCOVERY LEVEL

1. Plaintiff intends to conduct discovery be conducted under Discovery Level 3.
2. Plaintiff seeks monetary relief in excess of \$1,000,000 and hereby pleads out of the expedited action process of Rule 169.

II. PARTIES

3. Plaintiff is a citizen of the State of Texas and resides in Sabine County, Texas.
4. Defendant 3M Company (‘3M’) is a corporation organized under the

laws of the State of Delaware doing business in the State of Texas. 3M engages or has engaged in business in this State and may be served by serving its registered agent, CT Corporation System, at its registered address, 350 N. St. Paul St., Suite 2900, Dallas, Texas 75201.

5. Defendant Arizant Healthcare, Inc. (“Arizant”) is a corporation organized under the laws of the State of Delaware doing business in the State of Texas. Arizant engages or has engaged in business in this State and may be served by serving its registered agent, CT Corporation System, at its registered address, 350 North St. Paul St., Suite 2900, Dallas, Texas 75201.

6. Defendant Robert Prestera (“Mr. Pestera”) is a citizen of the State of Texas and resides in Katy, Texas. Mr. Pestera may be served process at his residential address 23726 Shadow Creek Ct., Katy, Texas 77494.

III. JURISDICTION AND VENUE

7. The Court has jurisdiction over this action because the amount in controversy exceeds the minimum jurisdictional limits of the Court and because all Defendants do business or reside in this state.

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

9. The causes of action alleged herein arose from or relate to the contacts of Defendants to the State of Texas, thereby conferring specific

jurisdiction with respect to said Defendants.

10. 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.

11. Defendants engaged in activities constituting business in the state of Texas as provided by Section 17.042 of the Texas Civil Practice and Remedies Code, in that said Defendants committed a tort in whole or in part in Texas.

12. Venue for this action is permissive in Harris County, Texas, under TEX. CIV. PRAC. & REM. CODE § 15.002, for the reason that all or a substantial part of the events or omissions giving rise to this lawsuit occurred in this county.

IV. FACTUAL BACKGROUND

13. On or about March 15, 2011 Plaintiff Walton underwent surgery at Houston Orthopedic Surgical Hospital for the purpose of implanting a prosthetic right hip.

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

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

16. Plaintiff sustained a periprosthetic infection during his hip replacement surgery due to the introduction of contaminants into his open surgical

site by the Bair Hugger FAW.

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

18. 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 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. Furthermore, the internal airflow paths of Bair Hugger FAW blowers have become contaminated with pathogens.

21. The pathogens contaminating the internal airflow paths of Bair Hugger FAW blowers incubate and proliferate therein resulting in further contamination of the surgical site.

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

23. Defendant Pretera is a district sales manager for Defendants 3M and Arizant. In that capacity Defendant Pretera supplied Houston Orthopedic Surgical Hospital with the Bair Hugger FAW used on Plaintiff.

24. Defendant Pretera works from an office in Katy, Texas.

25. Defendant Pretera failed to inform Houston Orthopedic Surgical Hospital or the Plaintiff of the risks inherent in using the Bair Hugger FAW, including the machines' propensity to cause infections in implant surgeries.

26. Defendant Pretera represented to Houston Orthopedic Surgical Hospital and the public that the Bair Hugger FAW was safe for use in implant surgeries when it is not.

27. 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. As a result, Plaintiff has sustained and will continue to sustain damages in an amount to be proven at trial.

V. CAUSES OF ACTION

COUNT I-NEGLIGENCE

28. Plaintiff represents and incorporates by reference all other paragraphs

of this Petition as if fully set forth herein.

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

30. 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.

31. 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-TEXAS DECEPTIVE TRADE PRACTICES ACT

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

33. Plaintiff was a consumer of the Bair Hugger FAW. Defendants, through written and oral statements to Plaintiff misled Plaintiff and his physicians to believe that the Bair Hugger FAW was safe and fit for the purposes intended when used under ordinary conditions and in an ordinary manner. Plaintiff and his physicians relied on those statements to Plaintiff's detriment.

34. Defendants are in violation of Chapter 17 of the Texas Business and Commerce Code, i.e., the Texas Deceptive Trade Practices Act in the following circumstances:

- a. Breach of express or implied warranty which resulted in Plaintiff's economic damages and mental anguish. TEX. BUS. & COM. CODE § 17.50(a)(2);
- b. Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have or that a person has a sponsorship, approval, status, affiliation, or connection which they do not. TEX. BUS. & COM. CODE § 17.46(5);
- c. Representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another. TEX. BUS. & COM. CODE § 17.46(7);

- d. Failing to disclose information concerning goods or services which was known at the time of the transaction if such failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed. TEX. BUS. & COM. CODE § 17.46(24).

COUNT III-- PRODUCTS LIABILITY: FAILURE TO WARN

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

36. 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.

37. 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.

38. 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.

39. Defendants failed to provide timely and reasonable instructions and training concerning the safe and effective use of Bair Hugger FAW to Plaintiff's physician.

40. 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.

41. 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.

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

43. 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.

COUNT IV—PRODUCTS LIABILITY: MANUFACTURING AND DESIGN DEFECTS

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

45. Defendants are the researcher, developer, manufacturer, distributor, marketer, promoter, supplier, and seller of Bair Hugger FAW, which is defective and unreasonably dangerous.

46. 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.

47. The Bair Hugger FAW system used by Plaintiff and 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. More specifically, because Bair Hugger FAW system was defectively designed, manufactured, marketed it is unreasonably dangerous.

48. 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 Texas.

49. 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.

50. There was a safer alternative design than the one actually employed by Defendants. Such safer alternative design, in reasonable probability would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the Bair Hugger FAW system's utility. This safer alternative design was both economically and technologically feasible at the time the product left the control of each of the Defendants by the application of existing or reasonably achievable scientific knowledge.

51. 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.

52. 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.

53. 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 warned by the Bair Hugger FAW system, it was represented to be safe and free from latent defects.

54. 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.

55. 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.

56. The defective design and manufacture of the Bair Hugger FAW was a producing cause of Plaintiffs' injuries.

57. 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 V—BREACH OF EXPRESS WARRANTY

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

59. 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 Plaintiffs' surgery.

60. 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.

61. 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.

62. 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.

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

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

65. As direct result of Defendant's 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—BREACH OF IMPLIED WARRANTY

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

67. 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.

68. 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.

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

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

71. 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 VII—NEGLIGENT MISREPRESENTATION

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

73. 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.

74. 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.

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

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

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

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

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

COUNT VIII—FRAUDULENT MISREPRESENTATION

80. Plaintiff repeats and incorporates by reference all other paragraphs of

this Petition as if fully set forth herein.

81. 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 safer than other alternative patient warming devices.

82. 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.

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

84. 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 and/or its related consumables.

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

86. Defendants' fraudulent representations evidence their callous,

reckless, and willful indifference to the health, safety, and welfare of consumers, including Plaintiff.

87. 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.

88. 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 IX—FRAUDULENT CONCEALMENT

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

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

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

92. 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.

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

94. 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.

95. 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.

96. 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. EXEMPLARY DAMAGES

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

98. 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.

99. 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.

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

VII. DAMAGES

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

102. 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 attorneys' fees in prosecuting this action; and
- o. Exemplary damages.

103. 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.

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