UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA

William McCormick,

Plaintiff,

vs.

Civil Action No.:

3M COMPANY, a Delaware corporation,

Defendant.

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff, William McCormick, by and through Plaintiff's undersigned attorneys brings this Complaint against Defendant 3M COMPANY and alleges as follows:

This is an action for damages relating to Defendant's design, development, testing, assembling, manufacturing, packaging, promoting, marketing, distribution, supplying and/or selling the defective device sold under the trade names of Bair Hugger Forced Air Warming device (hereinafter "Bair Hugger", or "Defective Device").

I. PARTIES

1. At all times relevant to this action, Plaintiff was a resident of Forsyth County, Georgia.

2. 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.

II. JURISDICTION AND VENUE

3. This Court has jurisdiction pursuant to 28 U.S.C. § 1332, as complete diversity exists between Plaintiff and Defendant, and the amount in controversy exceeds \$75,000. Defendant are subject to *in personam* jurisdiction in this court, and venue is proper within this district pursuant to 28 U.S.C. § 1391, as a substantial number of the events, actions, or omissions giving rise to the Plaintiff's claims occurred in this district. At all times relevant to this matter, Defendant 3M Company ("3M") conducted substantial business in this district. Defendant did (and do) business within the state of Minnesota and have had substantial, continuous, and systematic contacts with the state of Minnesota, have consented to jurisdiction in the state of Minnesota, and/or committed a tort in whole or in part in the state of Minnesota, and sold the defective devices in the District of Minnesota, and many other states, against thousands of Plaintiff's, including Plaintiff herein, as more fully set forth below. On information and belief, Defendant also marketed, advertised, and sold the defective devices in the District of Minnesota, and many other states, made material omissions and representations in each of these districts, and breached warranties in these districts.

III. SUMMARY OF THE CASE

4. The Defendant, directly or through its agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed and sold the Bair Hugger.

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

6. On or about February 18, 2014, the Bair Hugger was used on Plaintiff during the course of Plaintiff's total knee replacement surgery.

7. Because the Bair Hugger was used, contaminants were introduced to Plaintiff's open surgical wound, resulting in an infection.

CASE 0:16-cv-00360 Document 1 Filed 02/12/16 Page 3 of 24

8. Due to the infection, Plaintiff needed multiple additional surgical procedures to remove the implant and clean the infected area within less than six months from the original implant surgery, and Plaintiff continues to suffer substantial damages, including but not limited to impaired mobility.

9. Plaintiff now suffers and will continue to suffer from permanent damages as a result of the Bair Hugger-induced infection.

10. The Defendant concealed and continues to conceal its knowledge of the Bair Hugger's unreasonably dangerous risks from Plaintiff, other consumers, and the medical community.

11. The Defendant failed to conduct adequate and sufficient post-marketing surveillance after it began marketing, advertising, distributing and selling the Bair Hugger.

12. As a result of the Defendant's 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.

IV. FACTUAL BACKGROUND

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

14. 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.

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

CASE 0:16-cv-00360 Document 1 Filed 02/12/16 Page 4 of 24

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

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

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

19. 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.

20. The Defendant has been aware of the pathogenic contamination of the airflow paths of Bair Hugger blowers since at least 2009.

21. The Defendant has actively and aggressively marketed the Bair Hugger as safe in both general and orthopedic surgeries despite its knowledge to the contrary.

22. In a communication to the Food and Drug Administration ("FDA") in September 2000, Defendant represented that the Bair Hugger's filtration system meets HEPA ("High Efficiency Particulate Air") Standards. This statement was false at the time Defendant 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 larger. The filter of the Bair Hugger, which is marketed as HEPA compliant, is only capable of removing less than 65% of all such particles. When the Defendant made these representations, it had actual knowledge of their falsity.

23. In June of 1997, in a letter to the FDA, the Defendant admitted that "air blown intraoperatively across the surgical wound may result in airborne contamination." The Defendant addressed this flaw in its products by making further misrepresentations to the FDA when it stated that the risk of contamination by air flow is obviated because all "Bair Hugger

CASE 0:16-cv-00360 Document 1 Filed 02/12/16 Page 5 of 24

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 Defendant 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 Defendant made these representations, it had actual knowledge of their falsity.

24. On its website, www.fawfacts.com/laminar_airflow/ (last visited July 17, 2015),

the Defendant makes 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."
- 25. The statements in the preceding paragraph are false and intentionally misleading.

Through these statements, the Defendant disguised 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

CASE 0:16-cv-00360 Document 1 Filed 02/12/16 Page 6 of 24

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 Defendant falsely claim in advertisements.

26. 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 July 17, 2015), the Defendant 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 creates convective airflow patterns which disrupt the laminar flow of the operating theater.

27. In a communication that appeared in *Healthcare Purchasing News* in July of 2012, the Defendant's 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.

28. The publication of numerous peer-reviewed studies identifying and documenting the critical safety shortcomings of the Bair Hugger should have prompted the Defendant to redesign or discontinue the product. Instead, those criticisms only caused the Defendant to amplify 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. *Anaesthesia* 2012;67:244-249.

29. The effect of these misrepresentations was to mislead healthcare providers about the safety of the Bair Hugger for use in surgical procedures. The Defendant were aware of the falsity of these misrepresentations at the time those misrepresentations were authored.

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

31. Plaintiffs' physicians relied upon the above representations and advertisements to Plaintiff's detriment. Any reasonable and competent physician would not use a Bair Hugger 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, the Defendant actively and knowingly concealed the propensity of these devices to cause infection in orthopedic implant surgeries.

32. As a result of the failure of the Defendant's Bair Hugger to maintain the sterility

CASE 0:16-cv-00360 Document 1 Filed 02/12/16 Page 8 of 24

of the surgical area and the Defendant's 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 Defendant's acts, omissions and misrepresentations.

V. CAUSES OF ACTION

COUNT ONE - NEGLIGENCE

33. Plaintiff restates the allegations set forth above as if fully rewritten herein, and further alleges as follows:

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

35. The Defendant 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 Defendant knew or should have known of its adverse effects.

36. As a direct and proximate result of the Defendant's actions, omissions and misrepresentations, Plaintiff suffered an infection, requiring two additional surgical procedures to clean the infected area and remove the knee 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 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.

37. 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. Defendant's conduct warrants, if allowed by the Court upon motion, an award of punitive damages against Defendant in an amount appropriate to punish the Defendant and deter them from similar conduct in the future.

COUNT TWO - VIOLATION OF MINNESOTA'S CONSUMER PROTECTION AND DECEPTIVE TRADE PRACTICES LAWS

38. Plaintiff restates the allegations set forth above as if fully rewritten herein, and further alleges as follows:

39. The Defendant have violated and continue to violate Minnesota Consumer Protection statutes, Minn. Stat. §§ 325F.67; 325F.69 and Minnesota's Deceptive Trade Practices statutes, Minn. Stat. §§ 325D.44.

CASE 0:16-cv-00360 Document 1 Filed 02/12/16 Page 10 of 24

40. The Defendant is a corporation who intentionally sells merchandise, including the Bair Hugger, to consumers, including consumers in Minnesota. The Defendant made false statements in advertisements for the Bair Hugger, in violation of Minn. Stat. § 325F.67.

41. In advertising the Bair Hugger through various means in Minnesota, including but not limited to television, radio, internet, the products label, pamphlets and letters, the Defendant made material assertions, representations, or statements of fact which are untrue, deceptive, or misleading.

42. Similarly, the Defendant also acted with, used, or employed fraud, false pretense, false promise, misrepresentation, misleading statements or deceptive practices with the intent that consumers, including Plaintiff, rely on said statements or actions in connection with the sale of the merchandise, in violation of Minn. Stat. § 325F.69.

43. Defendant violated the Minnesota consumer protection laws through, *inter alia*, the following:

- a. Representing through statements and advertisements that the Bair Hugger has approval, characteristics, uses, or benefits that it does not have;
- b. Representing through statements and advertisements that the Bair Hugger and its filtration system is of a particular standard, qualify, or grade when it differs materially from that representation;
- c. Representing through statements and advertisement that the Bair Hugger 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.

44. As a direct and proximate result of the Defendant's actions, omissions, and misrepresentations, Plaintiff suffered an infection, requiring two additional surgical procedures

CASE 0:16-cv-00360 Document 1 Filed 02/12/16 Page 11 of 24

to clean the infected area and remove the knee 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 qualify 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.

45. 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. Defendant's conduct warrants, if allowed by the Court upon motion, an award of punitive damages against Defendant in an amount appropriate to punish the Defendant and deter them from similar conduct in the future.

COUNT THREE - STRICT LIABILITY

46. Plaintiff restates the allegations set forth above as if fully rewritten herein, and further alleges as follows:

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

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

49. The Defendant designed, manufactured, sold, distributed, supplied, marketed or promoted the Bair Hugger, which was expected to reach and did in fact reach consumers,

CASE 0:16-cv-00360 Document 1 Filed 02/12/16 Page 12 of 24

including Plaintiff, without substantial change in the condition in which it was manufactured and sold by the Defendant.

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

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.

A. Strict Liability - Failure to Warn

53. Plaintiff restates the allegations set forth above as if fully rewritten herein, and further alleges as follows:

54. Because the Defendant 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, it had a duty to warn of the risks associated with the use of the Bair Hugger.

55. Defendant 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,

CASE 0:16-cv-00360 Document 1 Filed 02/12/16 Page 13 of 24

causing deep joint infections, and requiring further treatment, including surgery or amputation.

56. Defendant failed to provide timely and reasonable warnings regarding the safety and efficacy of the Bair Hugger. Had it 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.

57. 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.

58. As a direct and proximate result of the Defendant's actions, omissions and misrepresentations, Plaintiff suffered an infection, requiring additional surgical procedures to clean the infected area and/or remove the knee 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.

59. The Defendant's 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. Defendant's conduct warrants, if allowed by the Court upon motion, an award of punitive damages against Defendant in an amount appropriate to punish the Defendant and deter them from similar conduct in the future.

B. Strict Liability - Defective Design and Manufacture

60. Plaintiff restates the allegations set forth above as if fully rewritten here, and further alleges as follows:

61. 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.

62. 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

63. 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.

64. 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 Defendant. 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.

65. Defendant 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

CASE 0:16-cv-00360 Document 1 Filed 02/12/16 Page 15 of 24

maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by Bair Hugger.

66. As a direct and proximate result of the Defendant's actions, omissions and misrepresentations, Plaintiff suffered an infection, requiring additional surgical procedures to clean the infected area and/or remove the knee 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.

67. 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. Defendant's conduct warrants, if allowed by the Court upon motion, an award of punitive damages against Defendant in an amount appropriate to punish the Defendant and deter them from similar conduct in the future.

COUNT FOUR - BREACH OF EXPRESS WARRANTY

68. Plaintiff restates the allegations set forth above as if fully rewritten herein, and further alleges as follows:

69. The Defendant expressly represented to Plaintiff and other consumers and the medical community that the Bair Hugger was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested.

CASE 0:16-cv-00360 Document 1 Filed 02/12/16 Page 16 of 24

70. The Bair Hugger does not conform to the Defendant's express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injury.

71. At all relevant times, the Bair Hugger did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

72. Plaintiff, other consumers, and the medical community reasonably relied upon the Defendant's express warranties for the Bair Hugger.

73. At all relevant times, the Bair Hugger was used on Plaintiff by Plaintiff's physicians for the purpose and in the manner intended by Defendant.

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

75. As a direct and proximate result of the Defendant's actions, omissions and misrepresentations, Plaintiff suffered an infection, requiring additional surgical procedures to clean the infected area and/or remove the knee 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.

76. 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. Defendant's conduct warrants, if allowed by the

CASE 0:16-cv-00360 Document 1 Filed 02/12/16 Page 17 of 24

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

COUNT FIVE - BREACH OF IMPLIED WARRANTY

77. Plaintiff restates the allegations set forth above as if fully rewritten herein, and further alleges as follows:

78. The Defendant designed, manufactured, distributed, advertised, promoted and sold the Bair Hugger.

79. At all relevant times, the Defendant 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.

80. The Defendant was aware that consumers, including Plaintiff, would use the Bair Hugger for treatment in conjunction with orthopedic surgical procedures.

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

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

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

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

85. As a direct and proximate result of the Defendant's actions, omissions and misrepresentations, Plaintiff suffered an infection, requiring additional surgical procedures to clean the infected area and/or remove the knee implant. Consequently, Plaintiff suffered

CASE 0:16-cv-00360 Document 1 Filed 02/12/16 Page 18 of 24

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.

86. 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. Defendant's conduct warrants, if allowed by the Court upon motion, an award of punitive damages against Defendant in an amount appropriate to punish the Defendant and deter them from similar conduct in the future.

COUNT SIX - NEGLIGENT MISREPRESENTATION

87. Plaintiff restates the allegations set forth above as if fully rewritten herein, and further alleges as follows:

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

- a. The Defendant 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 Defendant represented the Bair Hugger was safer than other patient warming systems.
- 89. Defendant did not exercise reasonable care or competence in obtaining or

CASE 0:16-cv-00360 Document 1 Filed 02/12/16 Page 19 of 24

communicating the information to the public regarding the characteristics and qualities of the Bair Hugger.

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

91. As a direct and proximate result of the Defendant's actions, omissions and misrepresentations, Plaintiff suffered an infection, requiring additional surgical procedures to clean the infected area and/or remove the knee 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.

92. 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. Defendant's conduct warrants, if allowed by the Court upon motion, an award of punitive damages against Defendant in an amount appropriate to punish the Defendant and deter them from similar conduct in the future.

COUNT SEVEN - FRAUDULENT MISREPRESENTATION

93. Plaintiff restates the allegations set forth above as if fully rewritten herein, and further alleges as follows:

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

- a. The Defendant 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 Defendant represented Bair Hugger was safer than other patient warming systems.

95. Defendant knew that these representations were false, yet it willfully, wantonly, and recklessly disregarded its obligation to provide truthful representations regarding the safety and risks of Bair Hugger to consumers, including Plaintiff, and the medical community.

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

97. The Defendant's 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.

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

99. The Defendant's fraudulent representations evidence a callous, reckless, and willful indifference to the health, safety, and welfare of consumers, including Plaintiff.

100. As a direct and proximate result of the Defendant's actions, omissions and misrepresentations, Plaintiff suffered an infection, requiring additional surgical procedures to clean the infected area and/or remove the knee 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

CASE 0:16-cv-00360 Document 1 Filed 02/12/16 Page 21 of 24

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.

101. 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. Defendant's conduct warrants, if allowed by the Court upon motion, an award of punitive damages against Defendant in an amount appropriate to punish the Defendant and deter them from similar conduct in the future.

COUNTH EIGHT - FRAUDULENT CONCEALMENT

102. Plaintiff restates the allegations set forth above as if fully rewritten herein, and further alleges as follows:

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

- a. The Defendant 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 Defendant 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.

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

105. The concealment of information by the Defendant about the risks of the Bair Hugger was intentional, and the representations made by Defendant were known by the

CASE 0:16-cv-00360 Document 1 Filed 02/12/16 Page 22 of 24

Defendant to be false.

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

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

108. As a direct and proximate result of the Defendant's actions, omissions and misrepresentations, Plaintiff suffered an infection, requiring additional surgical procedures to clean the infected area and/or remove the knee 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.

109. 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. Defendant's conduct warrants, if allowed by the Court upon motion, an award of punitive damages against Defendant in an amount appropriate to punish the Defendant and deter them from similar conduct in the future.

PRAYER FOR RELIEF

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

- For an award of compensatory damages in excess of Seventy-Five Thousand Dollars (\$75,000.00);
- 2. If allowed by the Court upon motion, an award of punitive damages in the amount to be proven at the time of trial, and sufficient to punish the Defendant or to deter the Defendant and others from repeating the injurious conduct alleged herein;
- For pre-judgment and post-judgment interest on the above general and special damages;
- 4. For costs of this suit and attorneys' fees;
- 5. For all other relief that Plaintiff may be entitled to at equity or at law; and
- 6. 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.

Respectfully Submitted,

DATED this 12th day of February, 2016.

MESHBESHER & SPENCE, LTD

/s/ Genevieve M. Zimmerman Genevieve M. Zimmerman (MN #330292) Anthony J. Nemo (MN #221351) Ashleigh E. Raso (MN #0393353) 1616 Park Avenue Minneapolis, MN 55404 Phone: (612) 339-9121 Email: gzimmerman@meshbesher.com tnemo@meshbesher.com araso@meshbesher.com

AND

THE OLINDE FIRM, LLC.

/s/ Wesley G. Barr_

Wesley G. Barr (LA #32332) 400 Poydras Street, Suite 1980 New Orleans, LA 70130 Tel: (504) 587-1440 Fax: (504) 5871577 Email: <u>wbarr@olindefirm.com</u>

ATTORNEYS FOR PLAINTIFF

CASE 0:16-cv-00360 Document 1-1 Filed 02/12/16 Page 1 of 1 CIVIL COVER SHEET

JS 44 (Rev. 12/12)

di.

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

purpose of minimumB int them at				*				
I. (a) PLAINTIFFS William McCormick			DEFENDANTS 3M COMPANY, A Delaware Corporation.					
(b) County of Residence of First Listed Plaintiff <u>Forsyth</u> (EXCEPT IN U.S. PLAINTIFF CASES)				County of Residence of First Listed Defendant <u>Ramsey</u> (IN U.S. PLAINTIFF CASES ONLY) NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.				
Meshbesher & Sp	merman, Esq. Ashle	igh E. Raso, Esq.		Attorneys (If Known)				
II. BASIS OF JURISDI	CTION (Place an "X" in Or	ne Box Only)			RINCIPA	L PARTIES (Place an "X" in One Box for Pla and One Box for Defendant)	intiff
□ 1 U.S. Government Plaintiff			(For Diversity Cases Only) PTF DEF Citizen of This State 1 I Incorporated or Principal Place 4 X 4 of Business In This State					
2 U.S. Government Defendant			Citizen of Another State X 2 Icorporated and Principal Place of Business In Another State 5 5 5 Citizen or Subject of a Image: State sta					
· · · · · · · · · · · · · · · · · · ·				gn Country				
IV. NATURE OF SUIT		ly) RTS	FOR	FEITURE/PENALTY	BAN	NKRUPTCY	OTHER STATUTES	
 Ito Insurance I20 Marine I30 Miller Act I40 Negotiable Instrument I50 Recovery of Overpayment & Enforcement of Judgment I51 Medicare Act I52 Recovery of Defaulted Student Loans (Excludes Veterans) I53 Recovery of Overpayment of Veteran's Benefits I60 Stockholders' Suits I90 Other Contract I95 Contract Product Liability I96 Franchise 	PERSONAL INJURY 310 Airplane 315 Airplane Product Liability 320 Assault, Libel &	PERSONAL INJUR 365 Personal Injury - Product Liability 367 Health Care/ Pharmaceutical Personal Injury Product Liability 368 Asbestos Personal Injury Product Liability PERSONAL PROPEI 370 Other Personal 371 Truth in Lending 380 Other Personal Property Damage 385 Property Damage 385 Property Damage 385 Property Damage 463 Alien Detainee 463 Alien Detainee 510 Motions to Vacata Sentence 530 General	Y □ 625] □ 690 f □ 690 f □ 710 [□ 720 [□ 740 [□ 751 [□ 790 [NS □ a □	Drug Related Seizure of Property 21 USC 881	□ 422 Appe □ 423 With □ 820 Copy □ 830 Pates □ 840 Trad □ 861 HIA □ 862 Blac □ 863 DIW □ 865 RS1 □ 870 Taxe □ 870 Taxe □ 871 IRS- 26 U 26 U	eal 28 USC 158 ddrawal JSC 157 RTY RIGHTS wrights nt teemark <u>SECURITY</u> (1395ff) k Lung (923) ('C/DIWW (405(g)) D Title XVI	 375 False Claims Act 400 State Reapportionment 410 Antitrust 430 Banks and Banking 450 Commerce 460 Deportation 470 Racketeer Influenced a Corrupt Organizations 480 Consumer Credit 490 Cable/Sat TV 850 Securities/Commoditie Exchange 891 Agricultural Acts 893 Environmental Matters 895 Freedom of Informatio Act 896 Arbitration 899 Administrative Proced Act/Review or Appeal Agency Decision 950 Constitutionality of State Statutes 	s/ s n ure
V. ORIGIN (Place an "X" i	n One Box Only)	· · · · · · · · · · · · · · · · · · ·						
	ate Court	Appellate Court	□ 4 Reinst Reope	ened Anoth (specif	er District	☐ 6 Multidistr Litigation		
VI. CAUSE OF ACTION	DN 28 U.S.C. 1332 Brief description of ca Health Care/Phar	maceutical Person	al Injury F	Product Liability	<u></u>		if demonded is complaint	
VII. REQUESTED IN COMPLAINT:	CHECK IF THIS UNDER RULE 2	IS A CLASS ACTIO 3, F.R.Cv.P.		MAND \$ 5,000.00		JURY DEMAND:	if demanded in complaint: XI Yes □ No	
VIII. RELATED CAS IF ANY	E(S) (See instructions):	10000	loan N. Er		DOCK	ET NUMBER M	DL 2666 (15-md-2666)	
DATE 02/12/2016	signature of attorney of record /s/ Genevieve M. Zimmerman							
FOR OFFICE USE ONLY								
RECEIPT # A	MOUNT	APPLYING IFP		JUDGE _		MAG. JUI	DGE	