IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

[redacted],	)	
	)	
Plaintiff,	)	
	)	Case No.:
v.	)	
	)	
WRIGHT MEDICAL TECHNOLOGY, INC.,	)	
WRIGHT MEDICAL GROUP, INC.,	)	
	)	
Defendants.	)	

_____/

COMPLAINT

Plaintiff [redacted] for his Complaint against Defendants WRIGHT MEDICAL TECHNOLOGY, INC. (hereafter "WMT"), WRIGHT MEDICAL GROUP, INC. (hereafter "WMG;" WMT and WMG collectively, "DEFENDANTS"), and alleges as follows:

INTRODUCTION, PARTIES, VENUE AND JURISDICTION

1. This is a lawsuit over defective hip implant components designed, manufactured, marketed, and sold within New Jersey by DEFENDANTS.

2. At all times relevant to this Complaint, Plaintiff [redacted] ("Plaintiff") resided in Burlington County, New Jersey.

3. At all times relevant to this Complaint, WMT was and is a corporation organized under the laws of the State of Delaware, with the principal offices located at 5677 Airline Road, Arlington, Tennessee.

4. At all times relevant to this Complaint, WMG was and is a corporation organized under the laws of the State of Delaware, with the principal offices located at 5677 Airline Road, Arlington, Tennessee.

5. WMT is a wholly owned subsidiary of WMG.

6. At all times relevant to this Complaint, DEFENDANTS were involved in the design, manufacture, marketing, and/or worldwide sales of medical products, including the orthopedic hip implant components at issue in this suit.

7. The components at issue in this case were marketed by DEFENDANTS as the "ProFemur" hip stem system (Hereafter referred to as "ProFemur System" or "Product"), including a ProFemur Plasma Z stem and a ProFemur modular neck.

8. The ProFemur is a registered trademark of DEFENDANTS.

9. Upon information and belief, at all times relevant to this complaint, DEFENDANTS routinely did business in Camden County, New Jersey, by marketing, selling, supplying and distributing DEFENDANTS' products to Cooper University Hospital in Camden County, New Jersey.

10. Plaintiff was implanted with DEFENDANTS' ProFemur System at Cooper University Hospital in Camden County, New Jersey.

11. DEFENDANTS did market, sell, supply and distribute, within Camden County, the products at issue in this Complaint.

12. Jurisdiction is proper in this Federal Court because the Plaintiff and Defendants are completely diverse and the amount in controversy is greater than $75,000.

13. Venue is proper in the Federal District of New Jersey in that at present and at all times relevant to this action, the actions underlying this suit took place in this District:

a) DEFENDANTS regularly did business in this District;
b) the product at issue was marketed, distributed, sold and supplied in this district;
c) the surgery to implant the product took place in this District;
d) DEFENDANTS' defective product injured Plaintiff in this District; and
e) Plaintiff's primary residence is in this District.

TOTAL HIP ARTHROPLASTY

14. Total Hip Arthroplasty (hereafter "THA") is the term used to describe surgery wherein a patient's natural hip anatomy is replaced with synthetic components. THA is also commonly referred to as "hip replacement surgery." A patient may need a THA for a variety of medical reasons including degenerative bone disease and avascular necrosis.

15. THA involves invasive and traumatic surgery in which a surgeon saws and removes a considerable portion of bone from the top of the femur. In place of the removed bone, the surgeon places a metal shaft, called a "stem," down into what remains of the femoral bone. The portion of the stem which is housed inside the femur may be affixed to the bone via use of bone cement or by a porous coating on the synthetic surface of the stem into which the natural bone will grow. The top of the synthetic metal stem, referred to as the "neck," is not housed inside the femur and remains completely exposed inside the body. A component called a "taper," which can roughly be described as similar to a metal sleeve, fits on top of, and around, the exposed neck of the stem. A synthetic ball, whether made of metal, plastic, or ceramic, is then attached on top of, and around, the taper.

16. The surgeon also replaces the anatomical hip socket, the acetabulum, with an artificial "cup." This cup is sometimes referred to as an "acetabular cup." To implant an acetabular cup, the surgeon removes bone from the natural acetabulum in an effort to create a new hip socket large enough to house the synthetic cup. The surgeon then places the synthetic

cup into the newly formed hip socket. The cup affixes to the bone either through the use of screws, bone cement, a porous metal coating on the back of the synthetic cup into which the natural bone will grow, or by a combination of the three.

17. Typically, the surgeon will then place a "liner" on the inside surface of the synthetic cup. This liner is the surface against which the synthetic ball will move, or articulate. The liner is made of plastic, metal, or ceramic.

18. A successful THA results in a hip prosthesis that should last 20+ years in a patient before having the articulating components (liner and ball) replaced. Femoral implants last even longer and most times never need replacing, at all.

REVISION HIP ARTHROPLASTY

19. If a hip prosthesis fails in a patient, the patient's surgeon may recommend a "revision" THA procedure in order to replace the failed hip components.

20. A revision THA is extremely traumatic to a patient, multitudes more so than a primary THA. The surgery is typically much longer, with greater blood loss, greater surgery difficulty, and greater mortality rate. The rehabilitation period for a revision THA can be much longer.

21. In most revision THA procedures, the synthetic components that must be replaced are either the acetabular cup or the femoral ball or both.

22. In a smaller number of revision THA procedures, a surgeon may find it necessary to replace the synthetic femoral stem, as well. This is especially the case where a patient suffers from a fracture of their synthetic stem.

23. The revision of a femoral stem is significantly more physically traumatic to a patient than the revision of an acetabular cup and/or ball. In order to remove the synthetic stem

from within the femur, the surgeon must create a large incision down the patient's thigh, then section and remove large sections of the femoral bone in order to get access to the femoral implant. This process of removing the bone around the implant can be likened to peeling a quartered banana. However, the patient's previously implanted femoral stem has fused with the bone in which it is embedded. This results in an extremely difficult surgery in which the surgeon must carefully separate ingrown bone from the artificial stem. Once the surgeon is able to access, remove, and replace the failed stem, the process of securing new stem in place results in the use of a multitude of screws, clamps, and metal wires in order to replace the sections of removed bone around the new implant. An x-ray of a revised femoral implant can resemble mangled barbed wire surrounding the bone. A patient's recovery from stem revision surgery is prolonged and painful.

24. Further, depending on the mode of failure for a hip prosthesis, the patient's natural anatomy may be so damaged that subsequent revision hip implants will be more likely to fail prematurely.

HIP IMPLANT DESIGN

25. Modern techniques for performing THA and for designing and manufacturing hip replacement components are based on a design introduced by Sir John Charnley in 1962. The design he created and used to perform THA consisted of three components: a one-piece stainless-steel femoral stem and head; an acetabular cup made of Ultra High Molecular Weight Polyethylene (a very strong plastic); and acrylic bone cement. A picture is found below for reference:

 [1]

26. Long-term studies of patients undergoing a Charnley THA in the 1960s and early 1970s show excellent results. These studies found that between 85% and 96% of patients still had a well-functioning Charnley hip 25 years after implant. Another study found that 78% of patients still didn't need to have their original Charnley hip replaced even after 35 years.

27. However, the Charnley hip was not without its weaknesses. The one piece design of the femoral stem and head did not allow surgeons to adjust the implant for any leg-length discrepancies due to surgery.

28. Over time, varying designs and various compounds of plastic, ceramic, and metal have been implemented for the stem, femoral head (or ball) and the acetabular cup in an effort to improve upon the Charnley design.

29. Most modern acetabular cups now implement some form of porous coating on the backside where the cup affixes to the hip socket. This allows for bone to naturally grow into the pores so that the surgeon does not need to use screws or bone cement to affix the cup to the bone.

[1] Charnley Hip Implant. Available at http://whichorthopaedicimplant.com/wp-content/uploads/2011/06/classic-charnley.jpg. Accessed on Feb. 25, 2014.

30. Unlike Charnley's original one-piece stem design, the ball atop almost all modern stems is not fused to the stem. Instead, the ball is a separate component that attaches to the top of the stem, or "neck."

31. These modern designs have resulted in highly successful implants intended to last and capable of lasting 20+ years in a patient.

THE FDA'S 510(k) CLEARANCE PROCESS

32. Prior to the sale and implant of Plaintiff's ProFemur components, DEFENDANTS were required to first gain permission from the U.S. Food and Drug Administration (hereafter "FDA") to market the ProFemur in the USA.

33. Typically, medical devices must be approved for safety and effectiveness by the FDA through what is called a "Pre-Market Approval" process (hereafter PMA).

34. The FDA's PMA process to approve medical devices for sale is intensive, time-consuming, and expensive. It requires *laboratory* (*in-vitro*) testing regarding safety and effectiveness to be confirmed by extensive *clinical* (*in-vivo*) testing prior to approval.

35. However, DEFENDANTS did not gain access to the USA market for Plaintiff's product through the FDA's PMA process. In an effort to sidestep the lengthy PMA requirements to prove the safety and efficacy of their device, DEFENDANTS chose to gain access to the USA market for their product through a backdoor method: Section 510(k) of the Medical Device Amendments of 1976 (hereafter "MDA") of the Federal Food, Drug, and Cosmetic Act (hereafter "510(k)").

36. Originally, the 510(k) process was meant to grandfather clearance for devices that were "substantially equivalent" to those that were approved for sale prior to when the MDA was first enacted in 1976. However, subsequent amendments to the MDA allowed for 510(k)

clearance for devices deemed "substantially equivalent" to any device previously cleared under the MDA 510(k) process, not just those that had been approved for sale prior to the MDA.

37. Importantly, *clearance* for sale under the 510(k) process does not equate to FDA *approval* of the cleared device.

38. In 2012, at the request of the FDA, the National Institute of Health (hereafter "NIH") conducted a thorough review of the 510(k) process, coming to the following major conclusions

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

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

40. By choosing to take advantage of this loophole, DEFENDANTS knowingly and willfully neglected to perform extensive clinical testing which would have allowed the actual, real-world risks inherent with the use of the product to be known by the FDA and the medical community.

DEFENDANTS' PROFEMUR SYSTEM

41. DEFENDANTS design and manufacture various medical devices and implants.

42. DEFENDANTS designed, manufactured, marketed and sold all of the ProFemur components implanted in Plaintiff.

43. DEFENDANTS' ProFemur System is a "modular" hip stem system.

44. A "modular" device is one that is made of multiple components.

45. Modular stems, such as the one implanted in Plaintiff, have a separate neck component that attaches to the top of the stem. The femoral ball, in turn, attaches to the modular neck. DEFENDANTS' ProFemur Plasma Z stem and titanium-alloy neck (which are the particular ProFemur components at issue in this case) are pictured below:

46. The advertised purpose of this modularity is to provide a surgeon more flexibility during surgery in order to cater to the individual anatomy of his or her patient.

47. The ProFemur Plasma Z stem is made of a titanium alloy containing vanadium. The bottom (distal) portion of the stem is purportedly grit-blasted. The top (proximal) portion is purportedly plasma sprayed.

48. The ProFemur Z modular neck has a polished surface and is purportedly made from a Ti6Al4V titanium alloy.

49. DEFENDANTS proclaimed, "No existing hip implant is better suited to address . . . the historical challenges of total hip arthroplasty." [2]

50. DEFENDANTS' marketing stated:

> [T]he clinical effectiveness and dependability of the modular necks has been consistently demonstrated throughout the PROFEMUR® Hip clinical history. *Utilized in both primary and revision applications, the current neck design has been successfully employed to improve surgical outcomes with no reported failures.*[3]

51. Further, DEFENDANTS touted the strength of the coupling between the neck and stem:

> Modular neck clinical experience and extensive laboratory tests have proven the coupling between the modular neck and femoral implant provides:
>
> - Structural reliability
> - Absence of significant micromovement
> - Absence of fretting corrosion
>
> These excellent characteristics are obtained due to the patented geometry of the coupling. The necks are made from titanium alloy (Ti6Al4V) which is proven to afford suitable mechanical properties, ideal biocompatibility, and excellent resistance to corrosion.[4]

52. The reference above to a patent refers to Patent Number 4,957,510, which is dated September 18, 1990. The abstract for the patent states:

> This prosthesis essentially comprises a given size stem at the top portion thereto there is provided an oval crosssection seat for firmly coupling one oval end of a coupling bar, the other frustum of cone shaped end of which bears a spherical head to be coupled to a hip acetabulum, the coupling bar having a variable length and a longitudinal axis of any given angle of inclination.

PROBLEMS WITH DEFENDANTS' PROFEMUR PLASMA Z HIP STEM SYSTEM

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[2] As archived on June 24, 2004. Available at http://web.archive.org/web/20040624040110/http://www.wmt.com/physicians/products/hips/profemurZhipStems.asp

[3] Emphasis in original. 2004 WMT Technical Monograph – ProFemur Modular Neck, at page 4.

[4] *Id*. at 6.

53. Patent Number 4, 957,510 does not discuss the clinical safety or effectiveness of the ProFemur Plasma Z stem system.

54. Patent Number 4, 957,510 does not discuss a plasma sprayed hip stem system.

55. Upon information and belief, at the time of Plaintiff's implant, the 510(k) clearance under which Plaintiff's implant was purportedly cleared for sale does not reference the "ProFemur" system.

56. Upon information and belief, at the time of Plaintiff's implant, the 510(k) clearance under which Plaintiff's implant was purportedly cleared for sale does not reference a plasma-sprayed hip stem system.

57. DEFENDANTS did not clinically test the ProFemur Plasma Z system for safety prior to its release.

58. Despite DEFENDANTS' claims of the advantages of the ProFemur Plasma Z system, the product is and always was deeply flawed and defective.

59. The testing done on the product prior to launch was woefully inadequate and not representative of real-world, clinical situations.

60. DEFENDANTS marketed their ProFemur Plasma Z device as having a clinical history of being safe on account of the clinical history of predicate devices, not the device being marketed.

61. At the time the ProFemur Plasma Z was introduced to the United States market, DEFENDANTS knew that there was no *clinical* evidence to support the contention that its device was safe or effective.

62. The modular neck of the ProFemur Plasma Z, made of a titanium alloy, was prone to fretting and corrosion as the titanium alloy reacted to the environmental fluids inside the body.

This reaction significantly weakens the modular neck's ability to tolerate weight and stress under normal conditions.

63. As a result of this fretting and corrosion, cracks develop in the weakened modular neck. These cracks expand over time. As the cracks expand, they reach across nearly the entire width of the neck until one final motion—which may be as simple as sitting down or standing up—puts enough stress to extend the crack completely across the width of the neck and effectuate a complete "neck fracture."

64. In some occasions, the progression of the crack into a complete neck fracture occurs much more quickly—sometimes instantaneously—depending on how seriously the neck juncture has been weakened and the nature of the stress put upon the juncture.

65. Where a modular neck fracture occurs, a patient will no longer have any skeletal connection remaining between the hip and the affected leg. The patient will be in agonizing pain, unable to bear any weight on the affected leg. Immediate emergency medical care is required.

66. The titanium alloy modular neck of DEFENDANTS' ProFemur System was so prone to fretting, corrosion, and fracture that in 2009 DEFENDANTS changed the design of the modular necks from a titanium alloy to a cobalt-chrome alloy in order to increase its safety and efficacy.

67. In the absence of severe trauma or a loose implant, a stem or neck fracture indicates a defect in the product.

68. DEFENDANTS took no corrective action in the form of a recall or any warning to doctors or patients having previously received a titanium modular neck.

69. All patients who received a ProFemur titanium-alloy modular neck prior to DEFENDANTS' redesign in 2009 are at a much greater risk of harm than reasonably

anticipated.

70. Further, recent clinical research indicates that modular stems do not provide any clear benefit on restoration of hip geometry. Accordingly, the theoretical, *in-vitro* advantages of a modular stem touted by DEFENDANTS are now countered by clinical, *in-vivo* experience.

71. Upon information and belief, prior to Plaintiff's implant and revision surgeries, DEFENDANTS were aware of defects and unreasonably high rates of problems with the ProFemur Plasma Z, including, but not limited to fretting, corrosion, and fracture near the juncture between the stem and titanium-alloy modular neck.

72. Prior to marketing and selling the ProFemur Plasma Z, DEFENDANTS knew or should have known that the ProFemur Plasma Z stem system was not a clinically safe prosthesis.

73. Despite knowing, or being in a position where they should have known of the unreasonable risks associated with the ProFemur System, DEFENDANTS still marketed and sold the ProFemur System utilizing an FDA mechanism that did not require any testing for safety and/or efficacy.

74. Since its inception and especially until 2009, the ProFemur System experienced an unreasonably high rate of failures worldwide.

75. DEFENDANTS received a high number of reports and warnings from surgeons and others regarding failed ProFemur System components.

76. DEFENDANTS did not take proper action in response to surgeon reports and warnings.

77. The ProFemur Plasma Z stem system, with its titanium-alloy modular neck, was more dangerous than an ordinary consumer would reasonably expect, and the risks associated with it were more dangerous than the risks associated with other hip replacement devices that

were available to treat Plaintiff's condition.

78. As a result of the rising concerns regarding the risks of ProFemur modular necks, on August 3, 2012, DEFENDANTS received a subpoena from the U.S. Attorney's Office requesting records and documentation relating to the ProFemur series of hip replacement devices. The subpoena covers the period from January 1, 2000 to August 2, 2012.

PLAINTIFF'S IMPLANT AND REVISION

79. Plaintiff experienced a history of pain and disease in his hips that caused him to be treated by Eric Hume M.D.

80. Dr. Hume determined that Plaintiff's osteoarthritis and pain were unresponsive to medical management and that surgical intervention was proper.

81. On May 3, 2004, Dr. Hume performed a THA on Plaintiff's right hip at Cooper University Hospital in Camden, New Jersey.

82. During this THA, Dr. Hume implanted Plaintiff with DEFENDANTS' Lineage Ceramic-on-Ceramic ball and socket system as well as ProFemur Plasma Z Stem with a titanium alloy modular neck.

83. In preparation for the May 3, 2004 surgery, Dr. Hume or someone at his direction contacted DEFENDANTS, or an agent and/or employee of DEFENDANTS, to notify them of the need for DEFENDANTS' hip system components, including the ProFemur components at issue.

84. DEFENDANTS selected and provided the specific components for use in Plaintiff and delivered them to the operating room.

85. Prior to Plaintiff's THA surgery, DEFENDANTS' sales representatives provided information to Plaintiff's orthopedic surgeon, including but not limited to advantages of the

ProFemur System compared to its competitors, design rationale, surgical techniques, and components that can best be mated with the ProFemur System.

86. DEFENDANTS' sales representative agents were responsible for answering any questions or concerns Plaintiff's orthopedic surgeon had regarding the product at issue.

87. The above information was provided to Plaintiff's orthopedic surgeon with the intended purpose of convincing and inducing Plaintiff's orthopedic surgeon to use the ProFemur System instead of one of the competing femoral hip arthroplasty products.

88. At all times relevant to this Complaint, Plaintiff's orthopedic surgeon, nurses and hospital staff relied on information and assistance from DEFENDANTS and their sales representative agents.

89. While walking his dogs on September 18, 2013, Plaintiff felt a sudden pop in his right hip. Plaintiff experienced intense and agonizing pain. He fell, unable to bear any weight on the affected leg.

90. What Plaintiff experienced was a catastrophic failure of his femoral implant. The titanium modular neck of Plaintiff's ProFemur System inexplicably fractured.

91. Plaintiff was immediately transported and admitted to Virtua Memorial Hospital in Mount Holly, New Jersey. Physicians at Virtua Memorial Hospital felt that Plaintiff would receive better treatment for his condition at Penn Presbyterian Medical Center (hereafter "PPMC"), in Philadelphia, Pennsylvania. Plaintiff was subsequently transferred to PPMC, where he stayed until being discharged on September 27, 2013.

92. On September 23, 2013, Plaintiff underwent revision surgery on his right hip performed by Dr. Gwo-Chin Lee at PPMC.

93. Dr. Chin's preoperative and postoperative diagnosis was: "Failed right total hip arthroplasty, broken stem. Indication is to relieve pain and improve function." His surgical notes state, "The Patient had broken stem with severing of the modular neck with engaged piece inside the stem."

PLAINTIFF'S INJURIES

94. Plaintiff suffered injuries including, but not limited to, significant pain, loss of balance, loss of enjoyment of life and limitation of daily activities as a result of the negligent design, manufacture, marketing and distribution of Plaintiff's ProFemur System and component parts. Plaintiff expects such injuries to continue in the future.

95. As a direct and proximate result of the failed ProFemur System, Plaintiff was caused to incur medical expenses, and expects to incur additional medical expenses in the future.

96. Upon undergoing the highly traumatic revision of his ProFemur System, Plaintiff underwent lengthy and protracted rehabilitation preventing him from performing activities of daily living, suffered scar tissue in his hips, and has hip components that have decreased longevity.

97. As a direct and proximate result of the failed ProFemur System, Plaintiff experienced emotional trauma and distress, and is likely to experience emotional trauma and distress in the future.

COUNT ONE
VIOLATION OF NEW JERSEY PRODUCTS LIABILITY ACT - FAILURE TO WARN

98. Plaintiff re-alleges and incorporates by reference paragraphs 1-97 above as if fully stated herein.

99. At the time that DEFENDANTS designed, manufactured, promoted, marketed, sold, supplied, distributed and serviced the ProFemur System components implanted in Plaintiff, such components contained defects that made them unreasonably dangerous beyond the expectations of the ordinary consumer, and were unfit for their intended use.

100. The hip replacement components reached Plaintiff without substantial change in the condition in which they were sold.

101. At the time and on the occasions in question, the components were being properly used for the purpose for which they were intended, and such components were in fact defective, unsafe and unreasonably dangerous.

102. The foreseeable risk of harm from the defects in the components could have been reduced or avoided by providing adequate instructions or warnings.

103. In violation of N.J. Stat § 2A:58C-1 et. al., DEFENDANTS did not provide adequate instructions or warnings regarding the defects ProFemur System which were known by DEFENDANTS or should have been known by DEFENDANTS.

104. As a direct and proximate result of the lack of reasonable and adequate instructions or warnings regarding the defects in the ProFemur System, Plaintiff suffered injuries as described specifically in paragraphs 94-97.

WHEREFORE, Plaintiff respectfully demands judgment against DEFENDANTS for compensatory damages and any other relief the Court deems just and proper.

COUNT TWO
VIOLATION OF NEW JERSEY PRODUCTS LIABILITY ACT –
MANUFACTURING AND DESIGN DEFECT

105. Plaintiff re-alleges and incorporates by reference paragraphs 1-97 above as if fully stated herein.

106. At the time that DEFENDANTS designed, manufactured, promoted, marketed, sold, supplied, distributed and serviced the ProFemur System's components implanted in Plaintiff, such components contained defects that made them unreasonably dangerous beyond the expectations of the ordinary consumer, and were unfit for their intended use.

107. The hip replacement components reached Plaintiff without substantial change in the condition in which they were sold.

108. At the time and on the occasions in question, the components were being properly used for the purpose for which they were intended, and were in fact defective, unsafe and unreasonably dangerous.

109. In violation of N.J. Stat § 2A:58C-1 et. al., the hip replacement components, for the reasons stated herein, were defective and unreasonably dangerous in design and manufacture.

110. As a direct and proximate result of the defects in the ProFemur System, Plaintiff suffered injuries as described specifically in paragraphs 94-97.

WHEREFORE, Plaintiff respectfully demands judgment against DEFENDANTS for compensatory damages and any other relief the Court deems just and proper.

COUNT THREE – BREACH OF EXPRESS WARRANTY

111. Plaintiff re-alleges and incorporates by reference paragraphs 1-97 above as if fully stated herein.

112. DEFENDANTS made affirmations, promises, and descriptions about the ProFemur System, and specifically Plaintiff's ProFemur Plasma Z Stem and titanium-alloy modular neck. The following list is a non-exhaustive list of such affirmations, promises, and descriptions:

- Clinical history of safety and efficacy;
- Structural reliability;
- No reported failures;
- Absence of significant micromovement; and
- Absence of fretting corrosion.

113. Such affirmations, promises, and descriptions were more than mere puffery.

114. DEFENDANTS' affirmations, promises, and descriptions were part of the basis of the bargain for the product with Plaintiff and Plaintiff's surgeon agent.

115. In breach of these express warranties, the ProFemur System ultimately did not conform to the aforementioned affirmations, promises, and descriptions.

116. As a result of the breach, Plaintiff suffered injuries as described specifically in paragraphs 94-97.

WHEREFORE, Plaintiff respectfully demands judgment against DEFENDANTS for compensatory damages and any other relief the Court deems just and proper.

COUNT FOUR – BREACH OF THE NEW JERSEY CONSUMER FRAUD ACT

117. Plaintiff re-alleges and incorporates by reference paragraphs 1-94 above as if fully stated herein.

118. The ProFemur components at issue in this lawsuit are "merchandise" which were "advertised" and "sold" by "persons" within the scope of the Consumer Fraud Act, N.J.S.A. § 56:8-1.

119. The following is a non-exhaustive list of qualities advertised by DEFENDANTS as reasons the ProFemur stem system was safe, effective, and should be purchased:

- Clinical history of safety and efficacy;
- Structural reliability;
- No reported failures;
- Absence of significant micromovement; and
- Absence of fretting corrosion.

120. DEFENDANTS knew that these advertised qualities were unproven and untrue in a clinical setting.

121. Plaintiff's ProFemur components were not safe, effective, or structurally reliable, as evidenced by the catastrophic failure of Plaintiff's components.

122. DEFENDANTS were aware of reported failures but failed to share such information with Plaintiff, Plaintiff's medical providers, the medical community, or the public.

123. DEFENDANTS were aware that the design of the ProFemur modular stem system left its components susceptible to significant micromovement.

124. DEFENDANTS were aware that the titanium alloy used is the design and production of the ProFemur modular neck left it susceptible to fretting corrosion.

125. DEFENDANTS affirmatively misrepresented the safety and efficacy of the ProFemur System.

126. DEFENDANTS knowingly omitted material facts from Plaintiff, Plaintiff's medical care providers, the medical community, and the public regarding the safety and efficacy of the ProFemur System.

127. As a result of the affirmative misrepresentations or knowing omissions by DEFENDANTS, Plaintiff's ProFemur components were worthless for their intended purpose.

128. When the Product failed, Plaintiff expended a substantial sum of money he otherwise would not have expended to purchase a replacement for the product and undergo surgery to implant the replacement product, in addition to the loss of income and other economic harm Plaintiff suffered due to DEFENDANTS' violation of the Consumer Fraud Act.

129. Such expenditure is an ascertainable loss of money or other property.

WHEREFORE, Plaintiff respectfully demands judgment against DEFENDANTS for compensatory damages, treble damages, attorney fees and any other relief the Court deems just and proper.

COUNT FIVE – BREACH OF WRITTEN WARANTY UNDER THE MAGNUSON-MOSS WARRANTY ACT

130. Plaintiff re-alleges and incorporates by reference paragraphs 1-97 above as if fully stated herein.

131. The ProFemur components at issue in this lawsuit are "consumer products" which

were sold to a "consumer" by "warrantors" making "written warranties" within the scope of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301, et seq.

132. DEFENDANTS made affirmations, promises, and descriptions about the ProFemur System, and specifically Plaintiff's ProFemur Plasma Z Stem and titanium-alloy modular neck. The following list is a non-exhaustive list of such affirmations, promises, and descriptions:

- Clinical history of safety and efficacy;
- Structural reliability;
- No reported failures;
- Absence of significant micromovement; and
- Absence of fretting corrosion.

133. Such affirmations, promises, and descriptions were more than mere puffery, and formed written warranties.

134. DEFENDANTS' affirmations, promises, and descriptions were part of the basis of the bargain for the product with Plaintiff and Plaintiff's surgeon agent.

135. In breach of these written warranties, the ProFemur System ultimately did not conform to the aforementioned affirmations, promises, and descriptions.

136. As a result of the breach, Plaintiff suffered injuries as described above specifically in paragraphs 94-97.

137. When the Product failed, Plaintiff expended a substantial sum of money he otherwise would not have expended to purchase a replacement for the product and undergo surgery to implant the replacement product, in addition to the loss of income and other economic harm Plaintiff suffered due to DEFENDANTS' violation of the Magnuson-Moss Warranty Act.

WHEREFORE, Plaintiff respectfully demands judgment against DEFENDANTS for compensatory damages, costs, attorney fees and any other relief the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff respectfully requests that a jury be impaneled to hear this cause of action and to award such damages as the jury finds to be fair and reasonable under the circumstances.

Dated this 4th day of April, 2014.

\s\ Michael A. Katz, Esquire
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