IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

JOSEPH PANDOLFO, Plaintiff, v. EXACTECH, INC., and **Serve:** NATIONAL REGISTERED AGENTS, INC., 120 South Central Avenue, Clayton, MO 63105 EXACTECH US, INC.., **Serve:** NATIONAL REGISTERED AGENTS, INC., 120 South Central Avenue, Clayton, MO 63105 Defendants.	)	Cause No. Division No. **JURY TRIAL DEMANDED**

COMPLAINT

COMES NOW Plaintiff, Joseph Pandolfo, by and through his undersigned counsel, and for his Complaint against Exactech, Inc. ("Exactech") and Exactech US, Inc. ("Exactech US") (collectively "Defendants") states as follows:

ALLEGATIONS APPLICABLE TO ALL COUNTS

1. At all times relevant hereto, Plaintiff Joseph Pandolfo was a resident and citizen of St. Louis County, Missouri.

2. On May 5, 2014, Plaintiff underwent a left total knee replacement surgery in which an Exactech Optetrak System was implanted to treat left knee degenerative joint disease. The Exactech Optetrack System, (hereinafter, "Defective Device") consisted of the following components: "Optetrak Tibial Tray Trapezoid, Cemented," "Optetrak Asymmetric Femoral Posterior Stabilized, Cemented," "Optetrak 3 Peg Patella Cemented," "Posterior Stabilized Tibial

Insert" and "Simplex Bone Cement."

3. Defendant Exactech, Inc. is a for-profit Florida corporation with its principal place of business at 2320 NW 66th CT, Gainesville, Florida, 32653. Exactech's stated business purpose is to "develop, manufacture, market, distribute and sell orthopedic implant devices, related surgical instrumentation and biologic services to hospitals and physicians in the United States and internationally" and to introduce its products, including the Defective Device, into interstate commerce, either directly or indirectly through third parties or related entities.

4. Exactech US, Inc., a wholly owned subsidiary of Defendant Exactech, Inc., is a for-profit Florida corporation with its principal place of business at 2320 NW 66th CT, Gainesville, Florida, 32653. Defendant Exactech Inc.'s U.S. sales and distribution activities are conducted by [its] wholly owned subsidiary Exactech US, Inc. and Exactech U.S., Inc. is engaged in the business of designing, developing, testing, assembling, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting, selling, and introducing its products, including the Defective Device, into interstate commerce, either directly or indirectly through third parties or related entities. Collectively, Exactech, Inc. and Exactech US, Inc. are referred to in this pleading as "Exactech" or "Defendants."

5. Defendants, directly or through their agents, servants, and/or employees designed, developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, warranted and/or sold the Defective Device for the use as a total knee replacement.

6. After implantation of the Defective Device, Plaintiff experienced pain and other symptoms and was ultimately diagnosed in 2019 with failed left total knee arthroplasty.

7. On March 12, 2019, and as a direct and proximate result of the Defendants' actions and inaction, Plaintiff required left total knee revision surgery to remove the failed

Defective Device and replace it with a new total knee replacement system. The Optetrak knee replacement implant was defective, unreasonably dangerous, and caused permanent injury and damages to Plaintiff.

8. The Defective Device failed and was defective because of aseptic loosening of the femoral and tibial components, substantial and defective polyethylene wear including particulate debris of the plastic polyethylene insert found throughout the knee area, polyethylene wear resulting in loosening of the device around the worn polyethylene insert area, and other failures of the Device.

9. As a result of the defective nature of the Optetrak knee replacement system, persons who were implanted with a Defective Device, including Plaintiff, have suffered, and may continue to suffer, severe and permanent personal injuries, including polyethylene wear and device failure, disbursement of the polyethylene into bone and other body structures, painful knee revision surgery to remove or revise the Defective Device, continued rehabilitation, medical care, and possible additional surgeries.

10. Defendants concealed, and continue to conceal, their knowledge of the Defective Device's unreasonably dangerous risks, including an increased risk of early failure**,** from Plaintiff, Plaintiff's medical providers, other consumers, and the medical community at large.

11. Plaintiff brings this action for personal injuries suffered as a proximate result of being implanted with the Defective Device. Plaintiff accordingly seeks compensatory and punitive damages, monetary restitution, and all other available remedies provided to Plaintiff

12. This Court has jurisdiction over Defendants in this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiff and Defendants and because the amount in controversy exceeds $75,000 exclusive of interest and costs, and because,

among other reasons, Defendants have significant contacts with this district by virtue of doing business within this judicial district.

13. At all times relevant to this action, Defendants engaged, either directly or indirectly, in the business of designing, developing, testing, assembling, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting, selling, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the Defective Device, within the State of Missouri with a reasonable expectation that the products would be used or consumed in this state, and thus regularly solicited or transacted business in this state.

14. At all times relevant to this action, Defendants were engaged in disseminating inaccurate, false, and/or misleading information about the Defective Device to health care professionals in the State of Missouri, including Plaintiff's health care professionals, with a reasonable expectation that such information would be used and relied upon by health care professionals throughout the State of Missouri.

15. Defendants engaged in substantial business activities in the State of Missouri. At all relevant times, Defendants transacted, solicited, and conducted business in Missouri through their employees, agents, and/or sales representatives and derived substantial revenue from such business in Missouri. Said activities including for the promotion, sale, and use of the Defective Device.

16. Further, Defendants committed torts in whole or in part against Plaintiff in the State of Missouri. As such, this Court has personal jurisdiction over all named Defendants.

17. Venue is proper within this district pursuant to 28 U.S.C. § 1391 because Plaintiff resides in this district and because a substantial part of the acts and/or omissions giving rise to

these claims occurred within this district

18. At all times material hereto, Defendants designed, developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, warranted and/or sold the Defective Device under various versions of the name "Optetrak."

19. Upon information and belief, the first Optetrak knee device was implanted in 1994.

20. Since 1994, Defendants have obtained 510(k) clearance for various Optetrak devices and tibal inserts including the Optetrak total knee replacement system as referenced above and the Defective Device.

21. A typical knee replacement surgery, referred to as a total knee arthroplasty ("TKA"), is performed under general anesthesia. The primary indication for TKA is to relieve severe pain associated with arthritis and may also be used to correct knee trauma or minor knee deformities.

22. During the TKA procedure, the surgeon removes any diseased bone, places a femoral implant onto the distal femur using surgical cement, implants the tibial tray using surgical cement, and implants a polyethylene product between the femoral implant and tibial tray.

23. Defendants promoted their Optetrak devices as a system with nearly three decades of clinical success and proven outcomes for patients around the world because of an improved articular design resulting in low polyethylene stresses.

24. Defendants became aware of a high rate of early failures with the Optetrak products which required recipients of the Optetrak knee implant to undergo revision surgeries to remove the defective device.

25. Despite actual knowledge of the increased risk of failure related to the defective nature of the Optetrak knee implant design, Defendants made the decision not to recall, stop selling, or otherwise change the warnings for the affected devices until there was a suitable replacement approved for the U.S. market.

26. Despite Defendants' knowledge of early onset failures of the Optetrak knee implants, Defendants continued to manufacture, promote, and distribute the Optetrak knee implants without alerting surgeons of potential increased risks of early onset failures of the Optetrak knee implants.

27. Despite Defendants' knowledge of early onset failures of the Optetrak knee implants, Defendants continued to manufacture, promote, and distribute the Optetrak knee implants without changing, modifying or improving the Defective Device to address the increased risk of early failure.

28. Despite Defendants knowledge of early onset failures of the Optetrak knee implants, Defendants never changed the labeling, marketing materials or product inserts to warn patients or physicians of the associated increased risks.

29. Despite Defendants knowledge of early onset failures of the Optetrak knee implants, Defendants never alerted the FDA of the known increased risks.

30. By 2012, Defendants had further clinical evidence that Optetrak knee implants were failing at a rate higher than promoted. Reports in the Manufacturer and User Facility Device Experience (MAUDE) indicate instances of revision due to "loose tibial component", "aseptic loosening", "pain and visible loosening", and "pain, limited mobility, knee swelling and sensitivity" due to "loose" joint. These early onset failure mode reports are representative of the increased rate of incidents of which Defendants had become internally aware.

31. In 2013, complaints continued to be reported. Some examples include revision for "tibial loosening" just two years postoperatively, "revision due to tibial loosening", "during revision, the tibial component was found to be loose and easily removed", "revision of knee component due to loosening", "revision due to pain and loosening."

32. The complaints of early onset failures continued in 2014. Some examples include "revision due to tibial loosening", "tibial loosening", "revision of optetrak knee components due to tibial loosening", "revision due to pain and loosening", "revision of optetrak knee components due to aseptic loosening", several reports described as "revision of knee components due to tibial loosening", and "revision of optetrak knee components reportedly due [to] aseptic loosening"

33. Upon information and belief, instead of warning consumers and the medical community about the increased failure rates with its Optetrak devices, including but not limited to the Defective Device, Defendants engaged in a "silent recall" campaign where it slowly replaced all tibial trays with a new, more substantial design. Concurrent with this strategy of product replacement, Defendants also engaged in a campaign of misinformation where any incidents of early onset failure were blamed on surgeon specific factors instead of admitting to any issues with the finned product itself.

34. In the year 2015, Defendants did over $241 million in sales across all product lines. Defendants state in the 2015 Form 10-K, "to better meet the demand for revision surgeries, we began the initial launch of a new revision knee system in 2015."

35. Of the more than $241 million in sales, knee device sales accounted for over $70 million in sales, or 29.3% of all Defendants' sales in 2015.

36. In 2016, Defendants' revenue increased by 7%, up to $257.6 million with knee device sales increasing 4%. Knee device sales for the fourth quarter of 2016 was accounted for

$19.8 million of this amount.

37. According to Exactech CEO and President David Petty, the increases in knee device revenue "reflect excellent surgeon acceptance of Exactech innovations, including our three new revision systems." Mr. Petty further stated that he anticipates the "revision knee rollout in the fourth quarter" of 2016 will "carry momentum into 2017."

38. A new knee implant, Truliant, is anticipated for release in the second half of 2017. Truliant received FDA 510(k) clearance, K170240, on February 23, 2017.

39. Despite Defendants' claims in its promotional materials of over 30 years of successful outcomes with knee devices, Defendants knew of an unacceptably high early failure rate of its Optetrak knee implants.

FEDERAL REQUIREMENTS

40. Pursuant to federal law, a medical device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. See 21 U.S.C. § 351.

41. Pursuant to federal law, a device is deemed misbranded if, among other things, its labeling is false or misleading in any particular way, or if it is dangerous to health if used in the manner prescribed, recommended or suggested in the labeling thereof. See 21 U.S.C. § 352.

42. Pursuant to federal law, manufacturers are required to comply with FDA regulation of medical devices, including FDA requirements for records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any medical device may have caused or contributed to a death or serious injury,

or if the device has malfunctioned in a manner likely to cause or contribute to a death or serious injury. Federal law also requires the FDA to establish regulations requiring a manufacturer of a medical device to promptly report to the FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation federal law which may present a risk to health. See 21 U.S.C. § 360i.

43. Pursuant to federal law, the Secretary of Health and Human Services may prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation, packaging, storage, and installation of a device conform to current good manufacturing practice, as prescribed in such regulations, to assure that the device will be safe, effective and otherwise in compliance with federal law. *See* 21 U.S.C. §360j(f).

44. The regulations requiring conformance to good manufacturing practices are set forth in 21 CFR § 820 et seq. The Federal Register explains that the Current Good Manufacturing Practice (CGMP) regulations do not prescribe the details of how a manufacturer must produce a device because the regulations must apply to a variety of medical devices. Rather, the quality system regulations provide a framework of basic requirements for each manufacturer to use in establishing a quality system appropriate to the devices designed and manufactured, and the manufacturing process employed. Manufacturers must adopt current and effective methods and procedures for each device they design and manufacture to comply with and implement the basic requirements set forth in the quality system regulations.

45. Pursuant to 21 CFR § 820.1(c), the failure to comply with any applicable provisions in section 820 renders a device adulterated under section 501(h) of the Act. *See* 21 U.S.C. § 351.

46. Pursuant to 21 CFR § 820.5, each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device designed or manufactured. "Quality system" means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management. See 21 CFR § 820.3(v).

47. Pursuant to 21 CFR § 820.22, each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system.

48. Pursuant to 21 CFR § 820.30(a), each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements.

49. Pursuant to 21 CFR § 820.30(e), each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development.

50. Pursuant to 21 CFR § 820.30(f), each manufacturer shall establish and maintain procedures for verifying the device design to confirm that the device design output meets the design input requirements.

51. Pursuant to 21 CFR § 820.30(g), each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, batches, or their equivalents. Design validations shall ensure that the devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions.

52. Pursuant to 21 CFR § 820.30(h), each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

53. Pursuant to 21 CFR § 820.30(i), each manufacturer shall establish and maintain procedures for the identification, documentation, validation or, where appropriate, verification, review, and approval of design changes before their implementation.

54. Pursuant to 21 CFR § 820.70(a), each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications.

55. Pursuant to 21 CFR § 820.70(b), each manufacturer shall establish and maintain procedures for changes to a specification method, process, or procedure.

56. Pursuant to 21 CFR § 820.70(c), each manufacturer shall establish and maintain procedures to adequately control environmental conditions that could reasonably be expected to have an adverse effect on product quality, including periodic inspection of environmental control systems to verify that the system, including necessary equipment, is adequate and functioning properly.

57. Pursuant to 21 CFR § 820.70(e), each manufacturer shall establish and maintain procedures to prevent contamination of equipment or products by substances that could reasonably be expected to have an adverse impact on quality.

58. Pursuant to 21 CFR § 820.70(g), each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirements and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning and use.

59. Pursuant to 21 CFR § 820.70(h), each manufacturer shall establish and maintain

procedures for the use and removal of manufacturing material which could reasonably be expected to have an adverse effect on product quality in order to ensure that it is removed or limited to an amount that does not adversely affect the device's quality.

60. Pursuant to 21 CFR § 820.70(i), when computers or automated data processing systems are used as part of production or the quality system, the manufacturer is required to validate computer software for its intended use according to an established protocol.

61. Pursuant to 21 CFR § 820.72, each manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer must establish and maintain procedures to ensure that equipment is calibrated, inspected, checked, and maintained.

62. Pursuant to 21 CFR § 820.75(a), where the results of a process cannot be fully verified by subsequent inspections and testing, the process shall be validated with a high degree of assurance and approved according to established procedures. "Process validation" means establishing, by objective evidence, that a process consistently produces a result or product meeting its predetermined specifications. 21 CFR § 820.3(z)(1).

63. Pursuant to 21 CFR § 820.75(b), each manufacturer shall establish and maintain procedures for monitoring internal processes and establish control of process parameters for validated processes to ensure that the specified requirements continue to be met. Each manufacturer shall ensure that validated processes are performed by qualifies persons.

64. Pursuant to 21 CFR § 820.90, each manufacturer also must establish and maintain procedures to control products that do not conform to specified requirements.

65. Pursuant to 21 CFR § 820.100, each manufacturer shall establish and maintain

procedures for implementing corrective and preventative actions.

66. Based on information and belief, Defendants' knee implant devices are adulterated pursuant to 21 U.S.C. § 351 because, among other things, they failed to meet established performance standards, and/or methods, facilities, or controls used for their manufacture, packaging, storage or installation and are not in conformity with federal requirements. See 21 U.S.C. § 351.

67. Based on information and belief, Defendants' knee implant devices are misbranded because, among other things, they are dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. See 21 U.S.C. § 352.

68. Based on information and belief, Defendants' knee implant devices are adulterated pursuant to 21 U.S.C. § 351 because Defendants failed to establish and maintain CGMP for its knee implant devices in accordance with 21 CFR § 820 et seq., as set forth above.

69. Based on information and belief, Defendants failed to establish and maintain CGMP with respect to quality audits, quality testing and process validation for its knee implant devices.

70. As a result of Defendants' failure to establish and maintain CGMP as set forth above, Defendants' knee implant devices were defective and failed, resulting in injuries to Plaintiff.

71. If Defendants had complied with the federal requirements regarding CGMP, Defendants' knee implant devices would have been manufactured properly and would not have resulted in injuries to Plaintiffs.

COUNT 1
NEGLIGENCE

COMES NOW Plaintiff Pandolfo, by and through his undersigned counsel, and for Count

I of his cause of action states as follows:

72. Plaintiff restate, adopts and incorporates by reference the above allegations as if fully set forth herein.

73. Defendants designed, developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, warranted and/or sold the Defective Device.

74. Defendants owed to the general public, including Plaintiff, the duty to exercise ordinary care in the design, manufacture, sale and/or distribution of the Defective Device into the stream of commerce, including a duty to ensure that their products did not pose a significantly increased risk of bodily harm and adverse events as well as a duty to comply with federal requirements.

75. Defendants had an obligation to follow the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers of the Defective Device, and otherwise distributing the Defective Device.

76. The Defendants had a duty to exercise ordinary care when designing, manufacturing, marketing, advertising, distributing, and selling the Defective Device, including the duty to take all reasonable steps necessary to ensure the product was not unreasonably dangerous to its consumers and users, and to warn Plaintiff and other consumers of the dangers associated with the Defective Device.

77. Plaintiff, as a purchaser of the Defective Device, is within the class of persons that the statutes and regulations previously described herein are designed to protect, and Plaintiff's injuries are the type of harm these statutes and regulations are designed to prevent.

78. The above-described Defective Device was used by physicians and consumers,

including Plaintiff, for the purpose for which it was reasonably and foreseeably intended.

79. The Defective Devise was defective and unreasonably dangerous when put to a reasonably expected use by Plaintiff because of its unsafe design, defective manufacture, and propensity for early failure requiring revision surgery.

80. The above described defects and dangerous conditions existed when Defendants distributed the Defective Device.

81. Defendants' acts and omissions constitute an adulteration, misbranding, or both, as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C §§ 331(a) and 333(a)(2), and constitute a breach of duty, subjecting Defendants to civil liability for all damages arising therefrom.

82. Missouri's negligent product's liability common law cause of action is congruent to 21 U.S.C §§ 331(a) and 333(a)(2).

83. At all times material hereto, Defendants had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers of the Defective Device.

84. Despite the fact that Defendants knew or should have known that the Defective Device caused serious injuries, including early failure requiring revision, they failed to exercise reasonable care to warn of the severity of the dangerous risks associated with its implantation. The dangerous propensities of the Defective Device, as referenced above, were known to the Defendants, or scientifically knowable to them, through appropriate research and testing by known methods, at the time they designed, distributed, supplied, or sold the Defective Device. Such information was not known to ordinary physicians who would be expected to implant the Defective Device.

85. The Defendants failed to exercise ordinary care and/or were negligent and/or wanton in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotion and distribution of the Defective Device into interstate commerce because Defendants knew or should have known that these products caused significant bodily harm and were not safe for use by consumers.

86. Despite the fact that Defendants knew or should have known that the Defective Device posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market the Defective Device for implantation into consumers and/or continued to fail to comply with federal requirements.

87. The Defendants failed to exercise ordinary care and were negligent in one or more of the following respects:

a. Negligently designing and manufacturing the Defective Device;

b. Negligently distributing the Defective Device;

c. Failing to properly and thoroughly test the Defective Device before releasing the Defective Device to market;

d. Failing to properly and thoroughly analyze the data resulting from the premarketing tests of the Defective Device;

e. Failing to conduct sufficient post-market testing and surveillance of the Defective Device;

f. Designing, manufacturing, marketing, advertising, distributing, and selling the Defective Device to physicians and consumers, including Plaintiff, without an adequate warning of the dangerous risks of the Defective Device;

g. Failing to provide warnings, instructions or other information that accurately reflected the risks of early failure of the Defective Device;

h. Failing to disclose known problems and defects with the Defective Device;

i. Failing to exercise due care when advertising and promoting Defective Device; and

j. Negligently continuing to manufacture, market, advertise, and distribute the Defective Device after the Defendants knew or should have known of its adverse effects and/or the increased early onset failure rates.

88. As a direct and proximate result of Defendants' negligence, Plaintiff was injured and damaged and required and underwent left total knee replacement revision surgery and rehabilitation. Plaintiff incurred medical bills for reasonable and necessary medical treatment, and will incur additional medical expenses in the future. He has been caused to suffer, and will continue to suffer, physical pain and mental anguish. Plaintiff has incurred lost wages.

89. Defendants knew and/or should have known that it was foreseeable that consumers such as Plaintiff would suffer injuries as a result of Defendants' failure to exercise ordinary care in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers of the Defective Device, and otherwise distributing the Defective Device.

90. Plaintiff contends that the conduct of the Defendants as described above, including, but not limited to, their failure to adequately design and manufacture, as well as their continued marketing and distribution of the Defective Device when they knew or should have known of the serious health risks the device created and/or the failure to comply with federal

requirements, is attended by circumstances of oppression, fraud, malice, willfulness, wantonness, and constitutes a conscious, reckless and flagrant disregard for human life, which warrants the imposition of punitive damages.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT II
VIOLATION OF THE MISSOURI MERCHANDISING PRACTICES ACT

COMES NOW Plaintiff Pandolfo, by and through his undersigned counsel, and for Count II of his cause of action states as follows:

91. Plaintiff states, adopts and incorporates by reference the above allegations as though fully set forth herein.

92. The Missouri Merchandising Practice Act ("MMPA") RSMo. § 407.020 provides in part as follows:

> The act, use, or employment of any person of any deception, fraud, false pretense, false promise, false misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce … in or from the state of Missouri, is declared to be an unlawful practice … Any act, use or employment declared unlawful by this subsection violations this subsection whether committed before, during, or after the sale, advertisement, or solicitation.

93. Missouri's Merchandising Practices Act is congruent to 21 U.S.C §§ 331(a) and 333(a)(2).

94. Defendants are merchants, who study, test, design, develop, manufacture, inspect, produce, market, promote, advertise, distribute and/or sell medical devices, including the Defective Device.

95 Defendants researched, developed, designed, tested, manufactured, inspected,

labeled, distributed, marketed, promoted, sold, and otherwise released the Defective Device into the stream of commerce. In the course of same, Defendants directly advertised, marketed, and promoted the Defective Device to the FDA, health care professionals, Plaintiff, and other consumers.

96. The Defective Device, as manufactured and/or supplied by Defendants, was defective due to its high early failure rate leading to painful revision surgery. Defendants knew that the product created significant risks of serious bodily harm to consumers.

97. Defendants employed and used deception, fraud, false pretense, false promise, false misrepresentations, unfair practice and concealment, suppression, and omission of material facts in connection with the sale and advertisement of the Defective Device in trade or commerce in the State of Missouri.

98. Defendants knew or should have known through post market surveillance and other methods that the Defective Device was inadequate and resulted in a high risk of early failure, but they failed to communicate adequate information on the dangers and safe use of its product, taking into account the characteristics of and the ordinary knowledge common to physicians who would be expected to implant the Defective Device.

99. At all times relevant herein, Defendant knowingly and indirectly represented to consumers, physicians, and Plaintiff that its medical devices, including the Defective Device:

a) Were a safe and effective knee implant device;

b) Could be used as directed by Defendants and physicians without unreasonable risk of harm.

100. Defendants communicated to health care professionals information that failed to contain relevant notice of high early failure rates that would enable health care professionals to

implant safe and effective knee implant devices. Defendants fraudulently and intentionally suppressed information about the severity of the risks of injuries associated with implantation of the Defective Device from physicians and Plaintiffs, including Plaintiff and Plaintiff's surgeon, used sales and marketing documents that contained information contrary to Defendants' internally held knowledge regarding the aforesaid risks and injuries, and overstated the efficacy, safety and longevity of the Defective Device. In particular, Defendants:

a) Disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the high early failure rate associated with the implantation of the Defective Device;

b) Continued to aggressively promote the Defective Device even after Defendants knew or should have known of the unreasonable risks from implantation;

c) Downplayed, or otherwise suppressed, through aggressive marketing and promotion the risks associated with the implantation of the Defective Device

d) The Defective Device was not as safe and effective as other TKA implants given its intended purpose;

e) The risks of early failure associated with the implantation of the Defective Device was greater than the risks of early failure associated with other TKA implants;

f) The risk of early failure with the Defective Device was not adequately tested and was known by Defendants, but Defendants knowingly failed to adequately test the product;

g) Defendants intentionally and knowingly failed to disclose and concealed the

early failure rate discovered in any clinical studies and trial results;

h) The Defective Device was defective, and had an unreasonably high risk of early failure and associated injuries, including the specific injuries described herein.

101. At all relevant times herein, Defendants knowingly misrepresented and/or concealed to consumers, physicians and Plaintiff that the knee replacements, including the Defective Device, when used as intended caused a significantly increased risk of injuries, including early failure and painful knee revision surgery.

102. At all relevant times herein, Defendants knowingly concealed and failed to inform the FDA, consumers, physicians, and Plaintiff of their knowledge concerning the dangers posed to Plaintiff.

103. At all relevant times herein, Defendants failed to give adequate warnings regarding the use and potential complications with the Defective Device.

104. The Defendants' Defective Device was purchased and used in treating Plaintiff.

105. The purchase and use of Defendants' Defective Device was for personal (non-commercial) purposes.

106. Had Defendants properly disclosed and disseminated the risks associated with early failure of the Defective Device, Plaintiff and Plaintiff's surgeon would have avoided the risk of implantation of the Defective Device and/or medically monitored Plaintiff differently after the Defective Device was implanted in order to minimize and/or mitigate the damages which would result from the Defective Device.

107. As a direct and proximate result of Defendants' deceptive practices, Plaintiff was injured and damaged and required and underwent left total knee replacement revision surgery

and rehabilitation. Plaintiff incurred medical bills for reasonable and necessary medical treatment, and will incur future medical expenses. He has been caused to suffer, and will continue to suffer, physical pain and mental anguish. Plaintiff has incurred lost wages.

108. Plaintiff is entitled to recover his actual damages, attorney's fees, and other equitable relief, pursuant to Missouri law, including RSMo. § 407.025.

109. Defendant's conduct as set forth in this Complaint caused a significantly increased risk of injury, showed a complete indifference to or a conscious disregard for the safety of Plaintiff, was and is wanton, willful, outrageous, and manifests a reckless disregard for the consequences of their actions and for the rights of Plaintiff. Defendants' conduct warrants an award of punitive damages to deter Defendants and others in similar circumstances from committing such actions in the future.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT III
STRICT PRODUCT LIABILITY – PRODUCT DEFECT

COMES NOW Plaintiff Pandolfo, by and through his undersigned counsel, and for Count III of his cause of action states as follows:

110. Plaintiff restates, adopts and incorporates by reference the above allegations as though fully set forth herein.

111. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released the Defective Device into the stream of commerce in the course of Defendants' business.

112. Defendants did so knowing that its defective devices would reach implanting

orthopedic surgeons, health care professionals and consumers, including Plaintiff and Plaintiff's health care professionals in Missouri, without substantial change in the condition in which they were sold and distributed, and that, at the time the defective devices left Defendants' control, they were defective, unreasonably dangerous, and unreasonably endangering to health when put to a reasonably anticipated use.

113. The Defective Device was in a defective condition and unreasonably dangerous when Plaintiff put it to a reasonably expected use due to its high rate of component loosening, substantial early wear of the polyethylene insert causing particulate debris, and overall early system failure necessitating revision surgery.

114. The dangerous propensities of the Defective Device, as referenced above, were known to the Defendants, or scientifically knowable to them, through appropriate research and testing by known methods, at the time they designed, distributed, supplied or sold the Defective Device. Such information was not known to ordinary physicians who would be expected to implant the Defective Device or consumers, including Plaintiff, who were implanted with the Defective Device.

115. Defendants designed, manufactured and distributed into the stream of commerce health endangering medical devices, including the Defective Device. Defendants' acts and omissions constitute an adulteration, misbranding, or both, as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C §§ 331(a) and 333(a)(2), and constitute a breach of duty, subjecting Defendants to civil liability for all damages arising therefrom.

116. Missouri's strict product's liability common law cause of action is congruent to 21 U.S.C §§ 331(a) and 333(a)(2).

117. The above described defects and dangerous, health endangering condition of the Defective Device existed when Defendant sold and distributed the Defective Device.

118. The Defective Device was defective and unreasonably dangerous when used by Plaintiff in a manner reasonably anticipated;

119. The use of the Defective Device according to the product's intended use caused serious injury to Plaintiff necessitating total left knee replacement revision surgery, which was also reasonably foreseeable.

120. As a direct and proximate result of the defective and unreasonably dangerous condition of Defendants' Defective Device as it existed when it was sold and distributed, Plaintiff was injured and damaged and required total left knee replacement revision surgery and rehabilitation. Plaintiff incurred medical bills for reasonable and necessary medical treatment, and will incur additional medical expenses in the future. He has been caused to suffer, and will continue to suffer, physical pain and mental anguish. Plaintiff has incurred lost wages.

121. Defendant's conduct as set forth in this Complaint caused a significantly increased risk of injury, showed a complete indifference to or a conscious disregard for the safety of Plaintiff, was and is wanton, willful, outrageous, and manifests a reckless disregard for the consequences of their actions and for the rights of Plaintiff. Defendants' conduct warrants an award of punitive damages to deter Defendants and others in similar circumstances from committing such actions in the future.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT IV
STRICT PRODUCTS LIABILITY – FAILURE TO WARN

COMES NOW Plaintiff Pandolfo, by and through his undersigned counsel, and for Count IV of his cause of action states as follows:

122. Plaintiff restates, adopts and incorporates by reference the above allegations as though fully set forth herein.

123. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released the Defective Device into the stream of commerce in the course of Defendants' business.

124. In the course of same, Defendants directly advertised, marketed, and promoted the Defective Device to the FDA, health care professionals, Plaintiff, and other consumers, and therefore had a duty to warn of the risks of high early failure rates associated with the implantation of the Defective Device.

125. Defendants expected the Defective Device to reach, and it did in fact reach, implanting orthopedic surgeons, health care professionals and consumers, including Plaintiff and Plaintiff's health care professionals, without any substantial change in the condition of the product from when it was initially distributed by Defendants.

126. The Defective Device, as manufactured and/or supplied by Defendants, was defective due to its high rate of component loosening, substantial early wear of the polyethylene insert causing particulate debris, and overall early system failure necessitating revision surgery.

127. The Defective Device was then unreasonably dangerous when it was put to a reasonably anticipated use without knowledge of its characteristics.

128. The Defective Device was defective and unsafe when it left Defendants' possession and control, was distributed by Defendants, and implanted by Plaintiff's surgeon.

129. The Defective Device design created an unreasonable risk of early failure and

resulting painful revision surgery.

130. The dangerous propensities of the Defective Device, as referenced above, were known to the Defendants, or scientifically knowable to them, through appropriate research and testing by known methods, at the time they designed, distributed, supplied or sold the Defective Device. Such information was not known to ordinary physicians who would be expected to implant the Defective Device.

131. Defendants failed to give adequate warning of the danger to physicians and consumers, including Plaintiff, of the dangerous risks associated with the Defective Device, including the risk of early failure requiring revision surgery.

132. Defendants had a continuing duty to warn Plaintiff of the dangers associated with the early failure of the Defective Device.

133. Defendants knew or should have known through post market surveillance and other methods that the Defective Device was inadequate and resulted in a high risk of early failure, but they failed to communicate adequate information on the dangers and safe use of its product, taking into account the characteristics of and the ordinary knowledge common to physicians who would be expected to implant the Defective Device.

134. Plaintiff could not have discovered any defects in the Defective Device through the exercise of reasonable care and relied upon the skill, superior knowledge, and judgment of Defendants.

135. Had Defendants properly disclosed and disseminated the risks associated with early failure of the Defective Device, Plaintiff and Plaintiff's surgeon would have avoided the risk of implantation of the Defective Device and/or medically monitored Plaintiff differently after the Defective Device was implanted in order to minimize and/or mitigate the damages

which would result from the Defective Device.

136. The Defective Device caused serious injury to Plaintiff, who used the Defective Device for its intended purposes and in a reasonably anticipated manner.

137. Defendants design, manufacture and distribution of the Defective Device into the stream of commerce without adequate warning constitutes an adulteration, misbranding, or both, as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C §§ 331(a) and 333(a)(2), and constitute a breach of duty, subjecting Defendants to civil liability for all damages arising therefrom.

138. Missouri's strict product's liability common law cause of action for failure to warn is congruent to 21 U.S.C §§ 331(a) and 333(a)(2).

139. As a direct and proximate result of the Defective Device being sold without an adequate warning, Plaintiff was injured and damaged and required and underwent total left knee replacement revision surgery and rehabilitation. Plaintiff incurred medical bills for reasonable and necessary medical treatment, and will incur additional medical expenses in the future. He has been caused to suffer, and will continue to suffer, physical pain and mental anguish. Plaintiff has incurred lost wages.

140. Defendants' conduct as set forth in this Complaint caused a significantly increased risk of injury, showed a complete indifference to or a conscious disregard for the safety of Plaintiff, was and is wanton, willful, outrageous, and manifests a reckless disregard for the consequences of their actions and for the rights of Plaintiff. Defendants' conduct warrants an award of punitive damages to deter Defendants and others in similar circumstances from committing such actions in the future.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's

favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT V
FRAUDULENT MISREPRESENTATION

COMES NOW Plaintiff Pandolfo, by and through his undersigned counsel, and for Count V of his cause of action states as follows:

141. Plaintiff restates, adopts and incorporates by reference all of the above allegations as though fully set forth herein.

142. From the time the Defective Device was first tested, studied, researched, evaluated, endorsed, manufactured, marketed, and distributed, and up to the present, Defendants failed to disclose material facts regarding the safety, efficacy, and longevity of the Defective Device. Defendants made material misrepresentations to Plaintiff, Plaintiff's health care professionals, the healthcare community, and the general public.

143. Defendants engaged in a nationwide marketing campaign, over-promoting the Defective Device in written marketing literature, in written product packaging, and in direct-to-consumer advertising via written and internet advertisements and television commercial ads. Defendants' over-promotion was undertaken by touting the safety and efficacy of Defective Device while concealing, misrepresenting, and actively downplaying the serious, severe, and life-threatening risks of harm to patients implanted with the Defective Device, when compared to comparable or superior alternative TKA implant options. Defendants fraudulently misrepresented the Defective Device's safety, efficacy, and longevity.

144. At all times relevant herein, Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions to Plaintiff and to Plaintiff's physician that its products,

including the Defective Device:

a) had been tested and found to be safe and effective for use in TKA,

b) Upon information and belief, Defendants represented that the Defective Device was safer than other alternative medical devices;

c) Failed to disseminate information and concealed information on known high early failure rates of the Defective Device;

d) Misrepresented the efficacy and longevity of the Defective Device

145. The representations were made by the Defendants with the intent that doctors and patients, including Plaintiff and Plaintiff's physicians, rely upon them in purchasing and using the Defective Device.

146. Defendants' representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, Plaintiff's physicians, and the medical community to induce and encourage the sale of the Defective Device.

147. Defendants' representations were false.

148. Defendants knew that their representations were false at the time they were made, yet they willfully, wantonly, and recklessly disregarded their obligation to provide truthful representations regarding the safety and risks associated with implantation of the Defective Device to Plaintiff, other consumers, Plaintiff's physicians, and the medical community.

149. Defendants' representations were material to Plaintiff and Plaintiff's physician's decision to purchase and use the Defective Device.

150. Plaintiff and his physician relied on Defendants' representations when purchasing the Defective Device and such reliance was reasonable under the circumstances.

151. Had Defendants not misrepresented the safety of the Defective Device, Plaintiff

and Plaintiff's surgeon would have avoided purchase and use of the Defective Device.

152. Defendants misrepresentations regarding the Defective Device constitutes an adulteration, misbranding, or both, as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C §§ 331(a) and 333(a)(2), and constitute a breach of duty, subjecting Defendants to civil liability for all damages arising therefrom.

153. Missouri's common law cause of action for fraudulent misrepresentation is congruent to 21 U.S.C §§ 331(a) and 333(a)(2).

154. As a direct and proximate result of Defendants' misrepresentations, Plaintiff was injured and damaged and required and underwent total left knee replacement revision surgery and rehabilitation. Plaintiff incurred medical bills for reasonable and necessary medical treatment, and will incur additional medical expenses in the future. He has been caused to suffer, and will continue to suffer, physical pain and mental anguish. Plaintiff has incurred lost wages.

155. Defendants risked the lives of consumers and users of the Defective Device, including Plaintiff. Defendants had knowledge of the safety problems and suppressed this knowledge from the general public. Defendants made conscious decisions for years not to redesign, re-label, adequately warn, or inform the unsuspecting public. Defendants' conduct as set forth in this Complaint caused a significantly increased risk of injury, showed a complete indifference to or a conscious disregard for the safety of Plaintiff, was and is wanton, willful, outrageous, and manifests a reckless disregard for the consequences of their actions and for the rights of Plaintiff. Defendants' conduct warrants an award of punitive damages to deter Defendants and others in similar circumstances from committing such actions in the future

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred,

attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT VI
NEGLIGENT MISREPRESENTATION

COMES NOW Plaintiff Pandolfo, by and through his undersigned counsel, and for Count VI of his cause of action states as follows:

156. Plaintiff restates, adopts, and incorporates by reference all of the above allegations as though fully set forth herein.

157. At all times relevant herein, Defendants, in the course of their business, represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions to Plaintiff and to Plaintiff's physician that its products, including the Defective Device:

a) had been tested and found to be safe and effective for use in TKA,

b) Upon information and belief, Defendants represented that the Defective Device was safer than other alternative medical devices;

c) Failed to disseminate information on known high early failure rates of the Defective Device;

d) Misrepresented the efficacy and longevity of the Defective Device

158. In supplying the information immediately above, Defendants failed to exercise reasonable care to ensure the accuracy of said representations.

159. The representations were made by Defendants with the intent that doctors, consumers and patients, including Plaintiff, rely upon them in purchasing and using the Defective Device.

160. Defendants' representations were material to Plaintiff and Plaintiff's physician's decision to purchase and use the Defective Device.

161. Defendants' representations were false.

162. Defendants, as the designers, manufacturers, sellers, promoters, and/or distributors of the Defective Device, knew or reasonably should have known that health care professionals and consumers of the Defective Device would rely on information disseminated and marketed to them regarding the product when weighing the potential benefits and potential risks of implanting Defective Device.

163. Defendants failed to exercise ordinary care to ensure that the information and representations they disseminated to health care professionals and consumers concerning the efficacy and longevity of the Defective Device was accurate, complete, and not misleading. As a result, Defendants disseminated information to health care professionals and consumers that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Plaintiff.

164. Plaintiff and his physician relied on Defendants' representations when purchasing the Defective Device and such reliance was reasonable under the circumstances.

165. Had Defendants not misrepresented the safety of the Defective Device, Plaintiff and Plaintiff's surgeon would have avoided purchase and use of the Defective Device.

166. Defendants misrepresentations regarding the Defective Device constitutes an adulteration, misbranding, or both, as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C §§ 331(a) and 333(a)(2), and constitute a breach of duty, subjecting Defendants to civil liability for all damages arising therefrom.

167. Missouri's common law cause of action for negligent misrepresentation is congruent to 21 U.S.C §§ 331(a) and 333(a)(2).

168. As a direct and proximate result of Defendants' misrepresentations, Plaintiff was

injured and damaged and required and underwent total left knee replacement revision surgery and rehabilitation. Plaintiff incurred medical bills for reasonable and necessary medical treatment, and will incur additional medical expenses in the future. He has been caused to suffer, and will continue to suffer, physical pain and mental anguish. Plaintiff has incurred lost wages.

169. Defendants risked the lives of consumers and users of the Defective Device, including Plaintiff. Defendants had knowledge of the safety problems and suppressed this knowledge from the general public. Defendants made conscious decisions for years not to redesign, re-label, adequately warn, or inform the unsuspecting public. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of the Defective Device, including Plaintiff. Defendants had knowledge of the safety problems and suppressed this knowledge from the general public. Defendants made conscious decisions for years not to redesign, re-label, adequately warn, or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT VII
BREACH OF EXPRESS WARRANTY

COMES NOW Plaintiff Pandolfo, by and through his undersigned counsel, and for Count VII of his cause of action states as follows:

170. Plaintiff restates, adopts and incorporates by reference all of the above allegations as though fully set forth herein.

171. At all times material hereto, Defendants sold and Plaintiff or his physician purchased the Defective Device.

172. Defendants expressly represented to Plaintiff, other consumers, Plaintiff's physicians, and the medical community, by and through statements made and written materials disseminated by Defendants or their authorized agents or sales representatives, that the Defective Device:

a) was safe and fit for its intended purposes;

b) was of merchantable quality; and

c) had been adequately tested and found to be safe and effective for implantation in TKA.

173. These express representations include incomplete marketing materials and labeling that purports, but fails, to include the true risks associated with high early failure rates of the Defective Device. Defendants knew or should have known of the high early failure rates associated with implantation of the Defective. Despite this, Defendants expressly warranted the Defective Device as safe and effective for implantation in TKA.

174. Defendants advertised, labeled, marketed, and promoted the Defective Device, representing the quality to health care professionals, Plaintiff, and the public in such a way as to induce the Defective Device's purchase or implantation, thereby making an express warranty that the Defective Device would conform to the representations. More specifically, the marketing materials and labeling of the Defective Device did not and does not contain adequate information about the true risks of high early failure rate and the injuries complained of herein.

175. Despite this, Defendants expressly represented that the Defective Device was safe and effective, that it was safe and effective for use by individuals such as Plaintiff, and/or that it was safe and effective for implantation in TKA.

176. The representations about the Defective Device contained or constituted

affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

177. The Defective Device does not conform to Defendants' express representations because it is not safe, effective, or have the implantation life warranted by Defendants. Therefore, Defendants breached the aforementioned warranties.

178. At all times relevant, the Defective Device did not perform as safely and as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner.

179. Neither Plaintiff nor Plaintiff's surgeon had knowledge of the falsity or incompleteness of the Defendants' statements and representations concerning the Defective Device.

180. Plaintiff, other consumers, Plaintiff's physicians, and the medical community justifiably and detrimentally relied upon Defendants' express warranties when recommending and implanting the Defective Device.

181. Had the marketing and labeling information for the Defective Device accurately set forth the true risks associated with the high early failure rate and increased risk of failure of the Defective Device and potential injuries, including Plaintiff's injuries, rather than expressly excluding such information and warranting that the product was safe for its intended purpose, Plaintiff could have avoided the injuries complained of herein.

182. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff was injured and damaged and required and underwent total left knee replacement revision surgery and rehabilitation. Plaintiff incurred medical bills for reasonable and necessary medical treatment, and will incur additional medical

expenses in the future. He has been caused to suffer, and will continue to suffer, physical pain and mental anguish. Plaintiff has incurred lost wages.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT VIII
BREACH OF IMPLIED WARRANTY

COMES NOW Plaintiff Pandolfo, by and through his undersigned counsel, and for Count VIII of his cause of action states as follows

183. Plaintiff restates, adopts and incorporates by reference all of the above allegations as though fully set forth herein.

184. Defendants manufactured, distributed, advertised, promoted, and sold the Defective Device.

185. At all relevant times, Defendants knew of the purpose for which the Defective Device was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

186. Defendants were aware that consumers, including Plaintiff, would be implanted with the Defective Device during TKA.

187 The Defective Device was neither safe for its intended purpose nor of merchantable quality, as impliedly warranted by Defendants, in that the Defective Device has dangerous propensities when used as intended and can cause serious injuries, including early failure resulting in additional painful revision surgeries and the risks associated with additional surgery.

188. At all relevant times, Defendants intended that the Defective Device be used in

the manner used by Plaintiff, and Defendants impliedly warranted it to be of merchantable quality, safe, and fit for such purpose, despite the fact that the Defective Device was not adequately tested.

189. Defendants were aware that consumers, including Plaintiff, would be implanted with the Defective Device as marketed by Defendants. As such, Plaintiff was a foreseeable user of the Defective Device.

190. Upon information and belief, Plaintiff and/or Plaintiff's health care professionals were at all relevant times in privity with Defendants.

191. The Defective Device was dangerous and defective when Defendants placed it into the stream of commerce because of its propensity to cause Plaintiff's injuries.

192. Plaintiff and the medical community reasonably relied upon the judgment and sensibility of Defendants to sell the Defective Device only if it was indeed of merchantable quality and safe and fit for its intended purpose.

193. Defendants breached their implied warranty to consumers, including Plaintiff. The Defective Device was not of merchantable quality, nor was it safe and fit for its intended purpose.

194. Plaintiff and Plaintiff's physicians reasonably relied upon Defendants' implied warranty for the Defective Device when recommending and implanting the Defective Device.

195. Plaintiff's use of the Defective Device was as intended and in a foreseeable manner as intended, recommended, promoted, and marketed by Defendants.

196. The Defective Device was expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendants.

197. Defendants breached the warranties of merchantability and fitness for its particular purpose because the Defective Device was unduly dangerous and caused undue injuries, including Plaintiff's injuries.

198. The harm caused by the Defective Device far outweighed its alleged benefit, rendering the Defective Device more dangerous than an ordinary consumer or health care professional would expect and more dangerous than alternative products.

199. Neither Plaintiff nor Plaintiff's health care professionals reasonably could have discovered or known of the risk of early failure associated with the Defective Device.

200. Defendants' breach of these implied warranties caused Plaintiff's injuries.

223. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff was injured and damaged and required and underwent total left knee replacement revision surgery and rehabilitation. Plaintiff incurred medical bills for reasonable and necessary medical treatment, and will incur additional medical expenses in the future. He has been caused to suffer, and will continue to suffer, physical pain and mental anguish. Plaintiff has incurred lost wages.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper.

Respectfully Submitted,

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