UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

[redacted] and [redacted], Plaintiffs, v. EXACTECH, INC. and EXACTECH US, INC. Defendants.	**Civil Docket No.: 1:22-cv-7633** **COMPLAINT AND JURY DEMAND**

COMES NOW, the plaintiffs, [redacted] and [redacted], by and through undersigned counsel and submits this Complaint and Jury Demand against EXACTECH, INC. ("Exactech") and EXACTECH US, INC. ("Exactech US") for compensatory and punitive damages, equitable relief, and such other relief deemed just and proper arising from the injuries to plaintiffs [redacted] and [redacted], suffered as a direct and proximate result of Defendants' designing, testing, assembling, selecting, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting, and/or selling the Defective GXL Device sold under the name Connexion GXL Liner (also referred to herein as "Subject Defective GXL Device"), a polyethylene component part of the Novation Crown Cup total hip replacement system. In support, Plaintiffs allege the following:

NATURE OF THE ACTION

1. This case involves claims of strict product liability, failure to warn, negligence, fraudulent concealment, breach of warranties, deceptive trade practices, among others, in the designing, testing, assembling, selecting, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting, and/or selling of a Defective GXL hip liner sold

under the name Connexion GXL Liner, by the Defendants directly or through their agents, apparent agents, servants, and/or employees.

2. The Defendants touted their Novation Crown Cup total hip replacement system and the Defective GXL Liner as being first-class and comprised primarily of proprietary polyethylene materials, thus being a quality product with a long device lifetime.

3. On June 20, 2018, the Novation Crown Cup and its component parts, including the defective polyethylene Connexion GXL Liner (also referred to herein as the "Defective Implant"), was implanted into Plaintiff [redacted]'s right hip during a total hip arthroplasty procedure in which Plaintiff's natural hip was replaced with the prosthetic device. The expected lifetime for her hip implant was approximately twenty years. However, the device prematurely failed in less than four years. On February 23, 2022, x-rays of her pelvis and hips revealed evidence of polyethylene wear and osteolysis at the lateral aspect of the right femoral component shoulder. An MRI performed on June 17, 2022 confirmed osseous resorption along the right implant components and synovial expansion. Ms. [redacted] had the Defective Implant removed and replaced on October 26, 2022 due to "failure of the recalled hardware of the right total hip arthroplasty".

4. Upon information and belief, the polyethylene GXL liner implanted into the Plaintiff was defective and not reasonably fit for its intended and foreseeable purpose and use. Specifically, the polyethylene liner was defective, unreasonably dangerous, packaged in non-conforming bags and of an inferior quality than that of which the Defendants represented their product to be.

5. Prior to Plaintiff [redacted] being implanted with the hip replacement device, the EXACTECH DEFENDANTS knew or should have known, based on anecdotal,

clinical and scientific research, studies and evidence, that the Defective GXL Liner, was subject to high failure and revision rates and had the propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision and/or full replacement surgery in patients.

6. The EXACTECH DEFENDANTS concealed, failed to disclose, misstated, downplayed and understated the risks associated with the use of the defective hip implant devices and their component parts, including the Connexion GXL Liner. Defendants intentionally continued to market and sell the devices to consumers and physicians as safe, long-lasting, top-of-the-line, innovative and high performing devices with a low failure rate.

7. On June 29, 2021, the EXACTECH DEFENDANTS issued a Class II recall of the subject hip device's polyethylene acetabular Connexion GXL Liner due to excessive edge loading and premature wear of the polyethylene material.

8. On August 11, 2022, the EXACTECH DEFENDANTS expanded the recall due to the defective liners' risk of premature wear and failure as a result of the liners being packaged in out-of-specification, non-conforming vacuum bags which exposed the liners to increased oxidation. Over time, the increased oxidation degrades the polyethylene and subjects the liners to accelerated wear and bone loss, component fatigue, cracking and fracture, and the need for corrective revision and/or replacement surgery.

9. As a direct and proximate result of the EXACTECH DEFENDANTS' defective polyethylene Connexion GXL Liner being surgically implanted into her body, Plaintiff [redacted] suffered and will continue to suffer serious personal injuries, including a painful hip replacement revision surgery, continued rehabilitation, medical care, medical expenses, loss of

enjoyment of life, psychological and emotional distress, and other medical and non-medical sequelae. Her husband, [redacted], has likewise suffered injury including the loss of consortium, society and services of his wife as a result of her injuries from the Defective Implant.

10. Plaintiffs bring this action for personal injuries suffered as a proximate result of [redacted] being implanted with the Defective Implant. Plaintiffs accordingly seek compensatory and punitive damages, monetary restitution, and all other available remedies provided to Plaintiffs under equity and law as a result of injuries [redacted] and [redacted] sustained due to the EXACTECH DEFENDANTS' conduct.

PARTIES

11. At all times relevant hereto, Plaintiff [redacted] was and is a resident and citizen of New York, New York, County of Suffolk, located in this District.

12. At all times relevant hereto, Plaintiff [redacted] was and is a resident and citizen of New York, New York, County of Suffolk, located in this District.

13. Plaintiffs [redacted] and [redacted] have been legally married since August 14, 1988 and have continuously resided together since that time.

14. Defendant EXACTECH, INC. is a for-profit Florida corporation with its principal place of business located at 2320 NW 66th Court, Gainesville, Florida 32653.

15. Defendant EXACTECH, INC. develops, manufactures, markets and sells orthopedic implant devices and related surgical instrumentation throughout the United States, including in and throughout the State of New York and within the Eastern District of New York.

16. Defendant EXACTECH, INC. derives substantial revenue from goods and products used in the State of New York and within the Eastern District of New York.

17. Defendant EXACTECH, INC. is registered to do business in the State of New York with a registered agent at Corporation Service Company, 80 State Street, Albany, NY 12207.

18. Defendant EXACTECH US, INC., a wholly owned subsidiary of Defendant Exactech, Inc., is a for-profit Florida corporation with its principal place of business located at 2320 NW 66th Court, Gainesville, Florida 32653.

19. According to public filings, Defendant EXACTECH US, INC. conducts Defendants' U.S. sales and distribution activities.

20. EXACTECH US, INC. is engaged in the business of designing, developing, testing, assembling, selecting, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting, selling, and introducing Defendants' products, including the Defective Implant, into commerce throughout the United States and the District.

21. EXACTECH US, INC. is thus also an agent, representative, joint venturer, partner and/or alter ego of Defendant Exactech, Inc.

22. Collectively, Exactech, Inc. and Exactech US, Inc. are referred to in this pleading as "EXACTECH DEFENDANTS" or "Defendants."

JURISDICTION AND VENUE

23. 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. Defendants have significant contacts with this District by virtue of doing substantial business within the State of New York and within the District, the Plaintiffs reside in the District and a substantial part of the facts giving rise to this action, including Plaintiffs' injuries and continued medical care and treatment, occurred within the District.

24. The Court has supplemental jurisdiction over the remaining common law and state law claims pursuant to 28 U.S.C. § 1367.

25. The Court maintains personal jurisdiction over Defendants as they purposely engaged in the business of designing, developing, selecting, testing, assembling, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting, selling, and introducing into interstate commerce, their products, including the Defective Implant, within the State of New York and specifically the District, with a reasonable expectation that the products would be used within this District.

26. Further, Defendants also engaged in making false representations and statements to health care professionals and consumers in the State of New York and within the District, specifically about the nature, durability and quality of the materials used in their implants.

27. Defendants derived substantial revenue and benefit from their business activities within the State of New York and the District. These activities included the promotion, sale and use of the Defective Connexion GXL Liner, including the Defective Implant.

28. Therefore, this Court has both specific and general personal jurisdiction over all named defendants.

29. Venue is proper within this district pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the acts and/or omissions giving rise to these claims occurred within this District.

FACTUAL BACKGROUND

a. THE DEFECTIVE HIP IMPLANT

30. A total hip arthroplasty (also referred to herein as "THA") is a hip replacement surgery during which the patient's natural hip anatomy is totally replaced with synthetic components.

31. The synthetic hip is comprised of four main component parts: 1) Acetabular shell; 2) Acetabular liner; 3) Femoral head; and 4) Femoral Stem.

32. The majority of hip replacements available on the market utilize a metal acetabular cap, a polyethylene plastic acetabular liner, a metal or ceramic femoral head, and a metal femoral stem.

33. At all times material hereto, Defendants designed, developed, tested, assembled, selected, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, warranted, and/or sold the Novation Crown total hip replacement system with the defective Connexion GXL acetabular liner, including the defective liner implanted into the Plaintiff [redacted].

34. The Novation Crown total hip replacement system features a mix of polyethylene and metal-based components, including the plastic Defective GXL Liner.

35. The subject Exactech Connexion GXL acetabular liner was first released into the market for broad commercialization in 2005.

36. Starting in 2005, Defendants utilized the Connexion GXL Liners in their AcuMatch A-Series hip implant. Subsequently, in 2007, Defendants began marketing their Novation Crown Cup with the Defective GXL Liners, claiming the Novation Crown Cup featured "enhanced" GXL liners.

37. The Connexion GXL Liners are composed of moderately cross-linked Ultra High Molecular Weight Polyethylene.

38. Defendants claimed that these purportedly "enhanced" GXL liners were "developed to create a robust arthroplasty respecting the need for lower wear, sufficient fracture toughness, and oxidation behavior to provide a lifelong implant for patients."

39. In a publication dated March 14, 2017, Exactech co-founder Gary Miller, Ph.D., stated that Exactech manufactured the subject liners with sheet molded UHMPE, a process which "provides a 59% reduction in gravimetric abrasive wear over the clinically successful standard Exactech."

40. Defendants explicitly claimed that "Connexion GXL enhanced polyethylene acetabular liners provide a low wear rate."

41. Defendants explicitly claimed that the GXL "provides a 59% wear reduction" over what it deemed was their "clinically successful" standard polyethylene liners.

42. Defendants told sales representatives that, "Connexion GXL acetabular liners were developed to create a polyethylene articular couple that creates a robust arthroplasty respective the need for lower wear, sufficient fracture toughness, and oxidation behavior to provide a lifelong implant for patients."

43. However, among their failures and omissions, Defendants did not utilize appropriate sterilization processes to prevent the defective Connexion GXL Liners from becoming susceptible to on-the-shelf and/or in-vivo premature oxidation and failure after implantation, despite alternative, feasible designs and processes being available to them at the time they put the liners into the stream of commerce.

44. In addition, Defendants failed to package the defective Connexion GXL Liners in vacuum bags with a secondary barrier layer containing ethylene vinyl alcohol (EVOH) that further strengthens the liners' oxygen resistance. Consequently, the liners were packaged in out-of-specification and non-conforming bags that significantly increased the liners risk of premature oxidation, wear and failure.

45. In or around February 2007, Defendants submitted a §510(k) premarket notification and obtained marketing approval for the Connexion GXL Liners from the FDA under Section 510(k) of the Act. See U.S.C. §360 et seq.

46. In or around March 2007, Defendants obtained fast tracked 510(k) clearance from the Food and Drug Administration ("FDA") for the Connexion GXL Liners, in a process that took less than 30 days.

47. Under the §510(k) approval process, the FDA determined that Defendants' Connexion GXL Liners were "substantially equivalent" to devices that have been reclassified in accordance with the provisions of the Act and did not require FDA approval of a pre-market approval application (PMA).

48. The Exactech Defendants identified its AcuMatch A-Series as the substantially equivalent predicate device.

49. Defendants performed no clinical testing for safety, efficacy, performance and/or longevity of the Connexion GXL Liners prior to releasing them into the marketplace.

50. Similarly, Defendants did not test the safety, efficacy, performance and/or longevity of the Connexion GXL Liners in the in-vivo setting, meaning when it was implanted inside the body.

51. Defendants failed to perform proper and adequate clinical testing of the safety, efficacy, performance and/or longevity of the Connexion GXL Liners in combination with the other component parts of the Novation Crown Cup hip implant system, including the Cluster Hole Shell and Biolex Delta Femoral Head.

52. Despite publicly representing that the Defective GXL Liners were safe and of the highest-grade materials, for many years prior to Plaintiff [redacted] receiving the

Defective Implant, and, at all relevant times, Defendants were aware that the Defective GXL Liners, and the polyethylene material they were made of, had higher than anticipated revision rates when compared to its competitors, and required Patients to undergo revision surgeries to remove, replace, and/or revise the Defective GXL Devices.

53. Academic studies found catastrophic early polyethylene wear of the Connexion GXL Liners in some Patients after a short period of time.

54. Had Defendants conducted clinical trials of the Connexion GXL Liner before the device was first released on the market, they would have discovered the device's propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision and/or full replacement surgery in patients.

b. *RECALL*

55. On or about June 28, 2021, Exactech posted an "Urgent Dear Healthcare Professional Communication" ("June 28 DHCP Letter") on their website. The purpose of the letter was to inform the medical community that they had observed "that in a small percentage of patients (.118%) who are between 3-6 years from index total hip arthroplasty, the Connexion GXL liner exhibits early linear and volumetric wear" and "[i]n some of these patients, wear has led to proximal femoral and acetabular osteolysis" (emphasis added).

56. Defendants recommended that surgeons consider revising failing GXL liners and replacing them with their newer XLE liners.

57. Defendants waited approximately two years from the time the GXL was replaced by the XLE hip implant to first inform the medical community regarding their observations of premature wear with the Defective GXL Liners.

58. On June 29, 2021, Defendants initiated a Class II recall of the Connexion GXL acetabular polyethylene liners due to excessive, premature prosthesis wear. However, at the time that Defendants posted the June 28 Dear Doctor Letter, they did not inform the public that they were, in fact, instituting a recall of the products.

59. On July 22, 2021, the FDA posted the June 29, 2021 recall notice, stating that the devices were being recalled due to the risk of edge-loading and premature prosthesis wear in a specific subset of patients with certain implant configurations and surgical implant positioning. The recall implicated 89,050 liners in circulation within the United States.

60. Defendants' delay in informing the public of problems with their GXL until a marketable alternative was available displays a conscious disregard for the safety of the public in favor of profit.

61. Defendants' pretext of blaming the recall on physician technique and patient activity level also served to undermine the significance and urgency of the recall.

62. Subsequently, on August 11, 2022, Exactech expanded the recall after determining that the Defective GXL Liners were subject to premature plastic deterioration which can lead to accelerated wear and bone loss, and/or component fatigue cracking/fracture and the need for revision or replacement surgery.

63. Specifically, in an Urgent Medical Device Correction letter defendants described, "an additional risk factor for premature wear that was not known at the time of the prior DHCP communication. GXL liners manufactured since 2004 were packaged in out-of-specification (referred to hereafter as "non-conforming") vacuum bags that are oxygen resistant but do not contain a secondary oxygen barrier layer known as ethylene vinyl alcohol (EVOH), which further augments oxygen resistance. The use of these non-conforming bags may enable increased oxygen

diffusion to the polyethylene insert resulting in increased oxidation of the material relative to inserts packaged with the specified additional oxygen barrier layer. Over time, oxidation can severely degrade the mechanical properties of the Connexion GXL polyethylene, which, in conjunction with other surgical factors, can lead to both accelerated wear and bone loss, and/or component fatigue cracking/fracture, all leading to corrective revision surgery."

64. At all times relevant to this action, Defendants were aware of the problems with the Defective GXL Liners design and their propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision and/or full replacement surgery in patients. Nonetheless, Defendants still did not adequately warn patients, the medical community, or the public about these risks, and continued to promote, market, sell, distribute and defend the defective GXL devices without limitation until August 11, 2022.

65. Despite Defendants' knowledge of early onset failures of the defective GXL devices, including the devices and components implanted in Plaintiff [redacted], Defendants continued to manufacture, package, promote, and distribute the devices and their defective component parts without alerting surgeons of the potential increased risks of early onset failures of the devices.

66. Despite Defendants' knowledge of early onset failures of the defective GXL devices, including the devices and components implanted in Plaintiff [redacted], Defendants continued to manufacture, package, promote, and distribute the devices and their defective component parts without changing, modifying, or improving the device or its packaging to address the increased risk of early failure.

67. Despite Defendants' knowledge of early onset failures of the defective GXL devices, including the devices and components implanted in Plaintiff [redacted], Defendants did not change the labeling, marketing materials or product inserts to adequately and accurately warn patients or physicians of the associated increased risks, longevity, and alternative product options manufactured by Defendants or other companies with lesser risks and rates of early failure.

68. Despite knowledge that the defective GXL devices, including the devices and components implanted in Plaintiff [redacted], were defective and resulted in premature failures and accompanying complications, Defendants continued to aggressively market and sell the devices and their defective component parts, all the while maintaining that they were safe and effective for use in total hip replacements and concealing the true safety information related to these devices.

69. Despite Defendants' knowledge of early onset failures of the defective GXL devices, including the devices and components implanted in Plaintiff [redacted], Defendants did not partially alert the FDA of the known increased risks until June 29, 2021, and did not more fully alert the FDA until August 11, 2022.

70. Defendants concealed their knowledge of the defective GXL devices', including the devices and components implanted in Plaintiff [redacted], unreasonably dangerous risks, including an increased risk of early failure, from Plaintiff, Plaintiff's medical providers, other consumers, and the medical community at large.

c. *PLAINTIFF [redacted] IS INJURED BY THE DEFECTIVE IMPLANT*

71. Plaintiff, [redacted], is a 66-year-old citizen and resident of New York.

72. Plaintiff [redacted] is of a healthy weight for a woman of her age and height.

73. Plaintiff, [redacted], does not suffer from or have a family history of any bone disorders or diseases.

74. On April 20, 2018, Plaintiff [redacted] underwent a right total hip arthroplasty, anterior approach, during which the EXACTECH Novation Crown Cup (Lot Number 4982981) and defective Connexion GXL Liner (Lot Number 5342070) was implanted into the Plaintiff's right hip cavity (hereinafter the "Defective Implant").

75. The April 20, 2018 right hip replacement was done correctly and did not deviate from accepted medical custom and practice with regards to the implantation of a prosthetic hip, and namely the Novation Crown Cup hip replacement system and GXL Liner.

76. On or around February 23, 2022, x-rays performed at HSS showed views of the right hip which demonstrated evidence of polyethylene wear. The radiographic imaging identified new, enlarged lucency at the lateral aspect of the femoral component shoulder.

77. In or around June 6, 2022, Plaintiff [redacted] complained of pain, discomfort and stiffening in her right hip.

78. On or around June 17, 2022, HSS performed an MRI of her right hip due to clinical concern for polyethylene wear in a patient with a recalled hip prosthesis. The MRI of the right hip demonstrated areas of cystic resorption and fibrous membrane formation along the superior aspect of the acetabular component proximal portion of the femoral component as well as synovial expansion.

79. In or around October 26, 2022, [redacted] underwent a total hip revision surgery to remove and replace the defective EXACTECH hip implant. The clinical indication for

the procedure was "periprosthetic osteolysis of the right hip joint" and "failure of recalled hardware of right total hip arthroplasty."

80. Gross inspection of the explanted hardware showed yellow discoloration of the surface and backside. The specimens were submitted to the HSS biomechanics department for further analysis and preservation.

81. Plaintiff [redacted] required and continues to require medical treatment, care and follow-up, including extensive physical therapy, after the October 26, 2022 revision and replacement procedure.

82. As a result of her exposure to the Defective Implant and the need for a revision and replacement surgery, Plaintiff [redacted] has suffered and will continue to suffer pain, stiffness and discomfort requiring medical treatment, physical therapy, monitoring and care.

83. Upon information and belief, the Defective Implant failed prematurely, especially in light of the Plaintiff's body mass index and lifestyle.

84. The Defective Implant contained a polyethylene plastic GXL liner insert that is subject to the August 11, 2022 recall initiated by the Defendants.

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

86. Upon information and belief, the polyethylene substance used in the Defective Implant was defectively made and/or designed, of an inferior quality, improperly selected and/or improperly packaged.

87. Upon information and belief, the Defective Implant contained polyethylene plastic components, namely the Connexion GXL Liner, that is unfit for use and/or unreasonably dangerous.

88. Upon information and belief, the defective polyethylene substance used in the Defective Implant caused and/or contributed to its premature failure, less than four years after it was implanted into Plaintiff's right hip, causing injury to Plaintiff, [redacted].

89. Upon information and belief, the Defective Implant was defective in design, manufacturing and materials at the time it left the Defendants' hands and was delivered into the stream of commerce in its defective condition.

90. It was foreseeable, expected and intended by the Defendants for the Defective Implant to be used in a total hip arthroplasty, such as Plaintiff [redacted]'s.

91. Defendants allowed the Defective Implant to be implanted during Plaintiff's total hip arthroplasty in said defective condition.

92. Defendants failed with respect to the selection, processes, testing, quality audits, supervision for their hip implant devices and component parts, including the Defective GXL Liner Implant.

93. As a direct and proximate result of the deficiencies in the Defective Implant and the Defendants' failures, the Plaintiff has suffered and continues to suffer injuries and damages, including without limit was caused to undergo a painful revision and replacement surgery, has required and will continue to require additional medical care and treatment, pain management, physical therapy and surgery, and has experienced and will continue to experience prolonged and lasting pain and suffering and loss of enjoyment of life.

d. DEFENDANTS VIOLATED FEDERAL REQUIREMENTS

94. Upon information and belief, Defendants' violated federal and state laws and regulations regarding the design, selection, testing, manufacturing, packaging, storage, selling, and/or distribution of medical hip implant devices, including without limit the following: 21

U.S.C. § 351, *et seq*. and 21 C.F.R. § 820 *et seq*. regarding federal regulations for medical devices and Current Good Manufacturing Practices; as well as 15 U.S.C. § 2051, *et seq*. and 16 C.F.R. § 1101, *et seq*. regarding the Consumer Product Safety Act. Moreover, upon information and belief, the EXACTECH DEFENDANTS violated one or more of the following federal laws and regulations.

95. Pursuant to federal law, a 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. 95.

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

97. 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. See 21 U.S.C. §360(i). 97.

98. Pursuant to federal law, manufacturers must keep records and make reports of any medical device that may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury. See 21 U.S.C. §360(i). 97.

99. Federal law mandates that the FDA establish regulations requiring a manufacturer of a medical device to report promptly to FDA any correction or removal of a device undertaken

to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. See 21 U.S.C. §360(i).

100. Pursuant to federal law, the Secretary of Health and Human Services may prescribe regulations requiring that the methods used in, and that facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device), 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 and effective and otherwise in compliance with federal law. See 21. U.S.C. §360j(f).

101. Pursuant to FDA regulation, adverse events associated with a medical device must be reported to the FDA within 30 days after the manufacturer becomes aware that a device may have caused or contributed to death or serious injury, or that a device has malfunctioned and would be likely to cause or contribute to death or serious injury if the malfunction was to recur. Such reports must contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. In addition, manufacturers are responsible for conducting an investigation of each adverse event and must evaluate the cause of the adverse event. See 21 CFR §803.50.

102. Pursuant to federal regulation, manufacturers of medical devices must also describe every individual adverse event report whether remedial action was taken in regard to the adverse event, and whether the remedial action was reported to FDA as a removal or correction of the device. See 21 CFR §803.52.

103. Pursuant to federal regulation, manufacturers must report to FDA within five (5) business days after becoming aware of any reportable MDR event or events, including a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. See 21 CFR §803.53. 101.

104. Pursuant to federal regulation, device manufacturers must report promptly to FDA any device corrections and removals and maintain records of device corrections and removals. FDA regulations require submission of a written report within ten (10) working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, or to remedy a violation of the Act caused by the device, which may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported and the corrective or removal actions taken, and any illness or injuries that have occurred with the use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal and provide a copy of all communications regarding the correction or removal. See 21 CFR §806. 102.

105. Pursuant to federal regulation, manufacturers must comply with specific quality system requirements promulgated by FDA. These regulations require manufacturers to meet design control requirements, including but not limited to conducting design validation to ensure that devices conform to define user needs and intended uses. Manufacturers must also meet quality standards in manufacture and production. Manufacturers must establish and maintain procedures for implementing corrective actions and preventive actions and investigate the cause of nonconforming products and take corrective action to prevent recurrence. Manufacturers are also required to review and evaluate all complaints and determine whether an investigation is

necessary. Manufacturers are also required to use statistical techniques where necessary to evaluate product performance. See 21 CFR §820.

106. The regulations requiring conformance to good manufacturing practices are set forth in 21 CFR §820 et seq. As explained in the Federal Register, because the Current Good Manufacturing Practice (CGMP) regulations must apply to a variety of medical devices, the regulations do not prescribe the details for how a manufacturer must produce a device. 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 processes 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.

107. Pursuant to 21 CFR §820.1 (c), the failure to comply with any applicable provision in Part 820 renders a device adulterated under section 501(h) of the Federal Food Drug & Cosmetic Act ("the Act") (21 U.S.C. § 351). 105. 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 organizations structure, responsibilities, procedures, processes and resources for implementing quality management. See 21 CFR §820.3(v).

108. 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.

109. Pursuant to 21 CFR §820.30(a), each manufacturer shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met. 108. Pursuant to 21 CFR §820.30(d), 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.

110. 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.

111. 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.

112. 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, or batches, or their equivalents. Design validations shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions.

113. 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.

114. 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.

115. 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. Such process controls shall include: a)

Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production; b) Monitoring and control of process parameters and component and device characteristics during production; c) Compliance with specified reference standards or codes; d) The approval of processes and process equipment; and e) Criteria for workmanship which shall be expressed in documented standards or by other equivalent means.

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

117. 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 system(s) to verify that the system, including necessary equipment, is adequate and functioning properly.

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

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

120. 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 to ensure that it is removed or limited to an amount that does not adversely affect the device's quality.

121. 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 shall validate computer software for its intended use according to an established protocol.

122. 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 shall establish and maintain procedure to ensure that equipment is routinely calibrated, inspected, checked and maintained.

123. Pursuant to 21 CFR §820.75(a), where the results of a process cannot be fully verified by subsequent inspection and test, 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. See 21 CFR §820.3(z)(1).

124. Pursuant to 21 CFR §820.75(b), each manufacturer shall establish and maintain procedures for monitoring and 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 qualified individuals.

125. Pursuant to 21 CFR §820.90, each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements.

126. Pursuant to 21 CFR §820.100, each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

a) Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problem; b) Investigating the cause of nonconformities relating to product, processes and the quality system;

c) Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

d) Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device;

e) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

f) Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and

g) Submitting relevant information on identified quality problems, as well as corrective and preventative actions, for management review.

127. Upon information and belief, Defendants' Subject Defective GXL Devices also violated the FDA 510(k) approval process. See U.S.C. §360 et seq.

128. Under the §510(k) approval process, the FDA determined that Defendants' hip implant devices and Connexion GXL Liners were "substantially equivalent" to devices that have been reclassified in accordance with the provisions of the Act and did not require FDA approval of a pre-market approval application (PMA).

129. Upon information and belief, Defendants' Subject Defective GXL Devices are adulterated pursuant to 21 U.S.C. §351 because, among other things, they failed to meet established performance standards, and/or the methods, facilities, or controls used for their manufacture, packing, storage or installation are not in conformity with federal requirements. See 21 U.S.C. §351. 129.

130. Upon information and belief, Defendants' Subject Defective GXL 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.

131. Upon information and belief, Defendants' Subject Defective GXL Devices are adulterated pursuant to 21 U.S.C. §351 because Defendants failed to establish and maintain CGMP for their devices in accordance with 21 CFR §820 et seq., as set forth above.

132. Upon information and belief, Defendants failed to establish and maintain CGMP with respect to the quality audits, quality testing and process validation for their Subject Defective GXL Devices, including the Defective Implant.

133. As a result of Defendants' failure to establish and maintain CGMP as set forth above, Defendants' Defective hip implant devices and liners were defective and failed, resulting in injuries to the Plaintiff.

TOLLING OF STATUTE OF LIMITATIONS

a. FRAUDULENT CONCEALMENT

134. The EXACTECH DEFENDANTS, through their affirmative misrepresentations and omissions actively concealed from Plaintiff and Plaintiff's healthcare providers the true and

significant risks associated with the Subject Defective GXL Devices claiming any failures were due to surgical technique, positioning or patient characteristics. [1]

135. At the time of implantation the defective hip implant device, Plaintiff and Plaintiff's healthcare providers relied on Defendants' continued representations that the Subject Defective GXL Devices had excellent long-term clinical outcomes.

136. The EXACTECH DEFENDANTS made these representations with knowledge of their falsity given their knowledge of reports and studies of high failure rates.

137. Although clinical evidence demonstrated that the Subject Defective GXL Devices were failing at a rate higher than promoted, Defendants failed to initiate a recall earlier or issue any communications to healthcare providers that patients should not have these devices implanted, should be monitored, and/or should have replacements done with alternative devices.

138. Earlier disclosure of the Subject Defective GXL Devices true failure rates could have impacted the sale of the company to private equity investors.

139. Had Defendants not actively concealed evidence of growing reports of premature device failures, Plaintiff would have opted to have a different device implanted and/or would have obtained radiological intervention at an earlier time that would have led to an earlier diagnosis of bone loss and earlier removal of the Defective Implant, thereby reducing damage to bone and tissue.

140. As a result of Defendants' actions, Plaintiff and Plaintiff's healthcare providers were unaware, and could not have reasonably known or have learned through reasonable diligence,

[1] Hereinafter, the term "Subject Defective GXL Devices" refers generally to the Exactech Connexion GXL Liners, including the defective implant utilized in Plaintiff's April 20, 2018 surgery.

that Plaintiff had been exposed to the risks identified herein, and that those risks were the result of defects in the product due to Defendants' acts, omissions, and misrepresentations.

141. Accordingly, no limitations period ought to accrue until such time as Plaintiff knew or reasonably should have known of some causal connection between Plaintiff being implanted with the Defective Implant, and the resulting harm later suffered by Plaintiff as a result of Defendants' fraudulent concealment.

142. Additionally, Defendants are equitably estopped from asserting any limitations defense by virtue of their fraudulent concealment and other misconduct as described herein.

143. Further, the limitations period ought to be tolled under principles of equitable tolling.

a. CPLR 214-c (2) and (4)

144. To the extent it is claimed that Plaintiff suffered symptoms prior to undergoing revision surgery, the statute of limitations is tolled under NY CPLR § 214-C(2) because development of osteolysis and bone loss are latent conditions caused by years of exposure to the unknown, toxic properties of polyethylene that could not be appreciated until the time of revision surgery or after.

145. Moreover, pursuant to NY CPLR § 214-C(4), Plaintiff exhibited due diligence but did not possess technical, scientific or medical knowledge and information sufficient to ascertain the cause of her injuries until after Defendants initiated a recall process of the Defective GXL Liner, and Plaintiff was first informed that the recalled implant was the cause of the osteolysis seen on radiographic imaging and of the need for revision surgery in or around June 2022.

CAUSES OF ACTION

COUNT I
STRICT LIABILITY: MANUFACTURING DEFECT
AGAINST ALL DEFENDANTS

146. Plaintiffs repeat and reallege the allegations of the paragraphs above as if fully stated herein.

147. The EXACTECH DEFENDANTS had a duty to manufacture the Subject Defective GXL Devices in a manner that prevents unreasonable risk of harm or injury to users and patients, including Plaintiff [redacted].[2]

148. The EXACTECH DEFENDANTS had a duty to distribute, market, and/or sell the Subject Defective GXL Devices without manufacturing defects to prevent an unreasonable risk of harm or injury to users and patients, including Plaintiff [redacted].

149. The Subject Defective GXL Devices manufactured by the EXACTECH DEFENDANTS were not reasonably safe for their expected, intended, and/or foreseeable uses, functions and purposes.

150. The Subject Defective GXL Devices were not reasonably safe as manufactured, distributed, marketed and/or sold by the EXACTECH DEFENDANTS.

151. The Subject Defective GXL Devices were defectively manufactured for a multitude of reasons, including but not limited to the following:

a) The polyethylene substance used within the devices was of an inferior grade or quality than that advertised and promoted by the EXACTECH DEFENDANTS;

[2] Plaintiffs' reference to the Subject Defective Devices includes the Defective Implant that Plaintiff [redacted] received on April 20, 2018 and which was surgically removed on October 26, 2022. See Paragraph No. 74, *supra*.

b) Defendants packaged the Subject Defective GXL Devices in out-of-specification or non-conforming vacuum bags that did not contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) that further prevents oxidation and/or promotes oxygen resistance;

c) Defendants' method of sterilizing the defective polyethylene inserts increased the risk of users and patients suffering from pain, discomfort, injury and the need for revision surgery;

d) Defendants' use of the gamma-inert sterilization method rendered the polyethylene plastic components in the Subject Defective GXL Devices, susceptible to oxidation either while in the packaging and/or following implantation in the patient;

e) Defendants utilized and/or selected barrier packaging which was not sufficient to prevent the polyethylene plastic components in the Subject Defective GXL Devices from being exposed to oxidation while on the shelf;

f) Defendants manufactured a product with polyethylene plastic components that created highly-reactive macroradicals in the UHMWPE material, which attempt to bond to oxygen atoms and degrade the Subject Defective GXL Devices' polyethylene plastic components;

g) Defendants failed to package polyethylene plastic components in barrier packaging with sufficient layers to prevent oxidation of the Subject Defective GXL Devices' polyethylene plastic components while on the shelf;

h) The sterilization method used by Defendants did not utilize feasible alternative sterilization methods, such as EtO and/or GP sterilization, and, thereby, failed

to eliminate the creation and/or substantial risk of the creation of highly reactive macroradicals that caused oxidation and degradation of the Subject Defective GXL Devices polyethylene plastic components;

i) The sterilization method used by Defendants did not utilize feasible alternative sterilization methods, such as EtO and/or GP sterilization, and, thereby, failed to substantially reduce and/or eliminate the risk of oxidation;

j) The EXACTECH DEFENDANTS failed to exercise sufficient quality control to ensure the polyethylene inserts were safe for implantation in users and patients and would not degrade abnormally under average and regular use;

k) The polyethylene substance within the Subject Defective GXL Devices did not comply with the required specifications for the polyethylene inserts that should be used in the devices;

l) The EXACTECH DEFENDANTS failed to perform quality control or other such testing on the polyethylene inserts used in the Subject Defective GXL Devices to ensure they complied with required specifications;

m) The EXACTECH DEFENDANTS violated applicable state and federal laws and regulations;

n) and in all other ways.

152. The Exactech Defendants knew or should have known and been aware that the Subject Defective GXL Devices were defectively manufactured.

153. The Subject Defective GXL Devices were defective in their manufacturing and materials at the time they left the Defendants' hands and were delivered into the stream of commerce in their defective condition.

154. The Subject Defective GXL Devices should not have been distributed, marketed, and/or sold by Defendants in a defectively manufactured condition.

155. It was foreseeable, expected and intended by the Defendants for the Subject Defective GXL Devices to be used in a hip arthroplasty patient, such as Plaintiff [redacted].

156. The manufacturing defects of the Subject Defective GXL Devices presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff [redacted], when they were used and operated for the purposes intended by Defendants.

157. The manufacturing defects of the Subject Defective GXL Devices presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff [redacted], when they were used and operated in a manner that was foreseeable to Defendants.

158. The EXACTECH DEFENDANTS breached their duty to manufacture the Subject Defective GXL Devices in a manner that eliminated or prevented an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff [redacted].

159. The EXACTECH DEFENDANTS breached their duty to distribute, market, and/or sell the Subject Defective GXL Devices without manufacturing defects to eliminate or prevent an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff [redacted].

160. Plaintiff [redacted] was seriously injured as a direct and proximate result of the manufacturing defects in the Defective Implant, caused by Defendants.

161. The EXACTECH DEFENDANTS are strictly liable for the defective manufacture of the Subject Defective GXL Devices, including the Defective Implant; the distribution,

marketing, and/or sale of the defectively manufactured Subject Defective GXL Devices; and the injuries sustained by Plaintiff [redacted].

162. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff [redacted] was caused to sustain and will continue to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

163. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff [redacted] was caused to sustain and will continue to sustain serious personal injuries, conscious pain and suffering, and physical disability that will require continued and additional medical treatment.

164. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff [redacted] was caused to sustain and will continue to sustain disabilities in activities of daily living.

165. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff [redacted] has sustained and will sustain medical expenses and related economic losses.

166. The injuries, damages, harm, and losses sustained by Plaintiff [redacted] were caused solely and wholly by virtue of the foregoing acts, omissions, and conduct of Defendants and were in no way caused and/or contributed to by [redacted].

167. By reason of the foregoing, [redacted] is entitled to monetary damages from the EXACTECH DEFENDANTS for her past, present and future non-economic and economic injuries, harm and losses in an amount that exceeds the jurisdictional minimum.

168. Defendants acted intentionally, recklessly and wantonly without regard for Plaintiff's rights beyond all standards of decency, entitling Plaintiff to recover punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT II
STRICT LIABILITY: DESIGN DEFECT
AGAINST ALL DEFENDANTS

169. Plaintiffs repeat and reallege the allegations of the paragraphs above as if fully stated herein.

170. Exactech had a duty to design the Subject Defective GXL Devices in a manner that did not present an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff [redacted].

171. The EXACTECH DEFENDANTS each had a duty to distribute, market, and/or sell the Subject Defective GXL Devices with a design that did not present an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff [redacted].

172. The design of the Subject Defective GXL Devices, and specifically the use of the Connexion GXL Liner, is defective and not reasonably safe.

173. The Subject Defective GXL Devices are not reasonably safe as designed, distributed, marketed, delivered and/or sold by Defendants.

174. The Subject Defective GXL Devices are defectively designed for a multitude of reasons, including but not limited to the following:

a) Defendants' method of sterilizing the polyethylene plastic insert pursuant to their design increased the risk of users and patients suffering from pain, discomfort, injury and the need for revision and/or full replacement surgery;

b) Defendants' design of the defective polyethylene plastic components caused them to have the propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision and/or full replacement surgery in patients;

c) Defendants' use of the gamma-inert sterilization method pursuant to their design rendered the Subject Defective GXL Devices' polyethylene plastic components susceptible to in-vivo oxidation either while in the packaging and/or following implantation in the patient;

d) Defendants utilized barrier packaging pursuant to their design which was not sufficient to prevent the polyethylene plastic components from being exposed to oxidation while on the shelf;

e) Defendants designed a product with polyethylene plastic that created highly-reactive macroradicals in the UHMWPE material, which attempt to bond to oxygen atoms and degrade the polyethylene plastic components;

f) Defendants failed to utilize a design that required sufficient layers in the barrier packaging to prevent oxidation of the polyethylene plastic components while on the shelf;

g) Defendants packaged the polyethylene plastic components in improperly designed vacuum bags that did not contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) to prevent oxidation;

h) The sterilization method used by Defendants pursuant to their design did not utilize feasible alternative sterilization methods, such as EtO and/or GP sterilization, and, thereby, failed to eliminate the creation and/or substantial risk of the creation of highly reactive macroradicals that caused oxidation and degradation of the polyethylene plastic components;

i) The sterilization method used by Defendants pursuant to their design did not utilize feasible alternative sterilization methods, such as EtO and/or GP sterilization, and, thereby, failed to substantially reduce and/or eliminate the risk of oxidation;

j) Defendants failed to perform adequate quality assurance testing and validation before and after sterilization;

k) The Subject Defective GXL Devices as designed had a propensity to sustain substantial early polyethylene wear component, loosening and/or other failures causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision and/or full replacement surgery in patients;

l) The polyethylene material used in the Subject Defective GXL Devices caused and/or contributed to the device having a higher failure rate than other similar devices available at the time the devices were put on the market;

m) The polyethylene material caused and/or contributed to the device having a shorter effective lifetime than other similar devices available at the time the Subject Defective GXL Devices were put on the market;

n) The Defendants' method of forming the polyethylene insert increased the risk of users and patients suffering from pain, discomfort, injury and the need for revision surgery;

o) Defendants failed to conduct adequate mechanical testing, including wear or other testing, on components, subassemblies and/or the finished Subject Defective GXL Devices, including the Defective Implant;

p) Defendants failed to test an adequate number of samples of Subject Defective GXL Devices and/or their component parts on an ongoing basis;

q) Defendants failed to take adequate steps to specifically identify failure modes with clarity and to suggest methods to monitor, avoid, and/or prevent further failures;

r) Defendants failed to identify and/or note the significance of any testing that resulted in failure of the Subject Defective GXL Devices;

s) Defendants failed to perform adequate testing in an environment that adequately simulated in vivo conditions;

t) Defendants failed to perform adequate testing of the Defective Implant, including their components and subassemblies, to ensure that the Subject Defective GXL Devices functioned properly during and after implantation;

u) Defendants failed to properly record in-field failures and maintain an adequate feedback loop in order to identify and correct failure modes;

v) The EXACTECH DEFENDANTS violated applicable state and federal laws and regulations;

w) and in all other ways.

175. The EXACTECH DEFENDANTS knew or reasonably should have known and been aware that the Subject Defective GXL Devices were defectively designed.

176. The Subject Defective GXL Devices were defective in their design at the time they left the Defendants' hands, and they were delivered into the stream of commerce in their defective condition.

177. The Subject Defective GXL Devices should not have been sold, marketed, distributed, and/or delivered by Defendants in a defectively designed condition.

178. It was foreseeable, expected and intended by the Defendants for the Subject Defective GXL Devices to be used in a hip arthroplasty patient, such as Plaintiff [redacted].

179. The design defects of the Subject Defective GXL Devices present an unreasonable risk of harm when they are used and operated for purposes expected and intended by Defendants.

180. The design defects of the Subject Defective GXL Devices present an unreasonable risk of harm when they are used in a manner that was or should have been foreseeable to Defendants.

181. Pre-existing feasible safer alternative designs providing the same functional purpose were available to the Defendants at the time the Subject Defective GXL Devices were designed and offered for sale in the market.

182. The EXACTECH DEFENDANTS failed to balance the feasibility of safer alternative designs for the Subject Defective GXL Devices against existing risks of injury.

183. The EXACTECH DEFENDANTS failed to use pre-existing feasible safer alternative designs providing the same functional purpose.

184. The EXACTECH DEFENDANTS failed to use their own pre-existing feasible safer alternative designs providing the same functional purpose.

185. The EXACTECH DEFENDANTS failed to take into account the reasonable cost of feasible safer alternative designs.

186. The EXACTECH DEFENDANTS failed to balance the risks of injury against the utility and costs of feasible safer alternative designs.

187. The EXACTECH DEFENDANTS failed to develop feasible safer alternative designs providing the same functional purpose with reasonable price adjustments.

188. The EXACTECH DEFENDANTS failed to take into account improvements related to safety and injury prevention presented by feasible safer alternative designs.

189. Defendants failed to consider foreseeable safety hazards and serious injury risks arising from designs using conventional polyethylene.

190. Defendants breached their duty to design the Subject Defective GXL Devices in a manner that eliminates or prevents an unreasonable risk of harm or injury.

191. Defendants breached their duty to distribute, market, and/or sell the Subject Defective GXL Devices with a design that eliminated or prevented an unreasonable risk of harm or injury.

192. Plaintiff [redacted] was seriously injured as a direct and proximate result of the design defects in the Subject Defective GXL Devices caused by Defendants.

193. The EXACTECH DEFENDANTS are strictly liable for the defective design of the Subject Defective GXL Devices, including the Defective Implant; the distribution, marketing,

and/or sale of the defectively designed Subject Defective GXL Devices; and the injuries sustained by Plaintiff [redacted] as a result thereof.

194. By reason of the foregoing acts, omissions, and conduct committed by the EXACTECH DEFENDANTS, Plaintiff [redacted] was caused to sustain and will continue to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

195. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff [redacted] was caused to sustain and will continue to sustain serious personal injuries, conscious pain and suffering, and physical disability that will require continued and additional medical treatment.

196. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff [redacted] was caused to sustain and will continue to sustain disabilities in activities of daily living.

197. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff [redacted] has sustained and will sustain medical expenses and related economic losses.

198. The injuries, damages, harm, and losses sustained by Plaintiff [redacted] were caused solely and wholly by virtue of the foregoing acts, omissions, and conduct of Defendants and were in no way caused and/or contributed to by [redacted].

199. By reason of the foregoing, Plaintiff [redacted] is entitled to monetary damages from Defendants for her past, present, and future non-economic and economic injuries, harm, and losses in an amount that exceeds the jurisdictional minimum.

200. Defendants acted intentionally, recklessly and wantonly without regard for Plaintiff's rights beyond all standards of decency, entitling Plaintiff to recover punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT III
STRICT LIABILITY: FAILURE TO WARN
AGAINST ALL DEFENDANTS

201. Plaintiffs repeat and reallege the allegations of the paragraphs above as if fully stated herein.

202. The EXACTECH DEFENDANTS had a duty to provide proper and adequate safety warnings to doctors, users and patients concerning the Subject Defective GXL Devices, including to Plaintiff [redacted].

203. The EXACTECH DEFENDANTS had a duty to provide proper and adequate safety warnings to ensure that doctors, users and patients possessed detailed, unequivocal and unambiguous information about the Subject Defective GXL Devices' health and safety risks so that doctors, users and patients could make informed decisions about whether to use the Subject Defective GXL Devices, including the Defective Implant.

204. The EXACTECH DEFENDANTS had a duty to provide proper and adequate safety warnings about potential safety hazards, dangers and serious health risks presented by the Subject Defective GXL Devices' expected, intended and foreseeable uses.

205. The EXACTECH DEFENDANTS breached their duty and failed to exercise ordinary care in the labeling of the defective Connexion GXL Liner and failed to issue adequate pre-marketing or post-marketing warnings to doctors and the general public, including Plaintiff

[redacted], regarding the risk of serious injury, including premature polyethylene wear and risk of early revision surgery.

206. The EXACTECH DEFENDANTS knew or should have known that Plaintiff could suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

207. Despite the fact that the EXACTECH DEFENDANTS knew or should have known that the Subject Defective GXL Devices posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market the Subject Defective GXL Devices for implantation into consumers without appropriate and adequate labels and warnings.

208. Defendants failed to exercise due care under the circumstances, and their negligence and recklessness includes the following acts and omissions:

a) Designing, manufacturing, marketing, advertising, distributing, and selling the Subject Defective GXL Devices to consumers, including Plaintiff [redacted], without an adequate warning of the dangerous risks of the devices;

b) Negligently failing to notify and warn the public including Plaintiff [redacted] and her doctors of reported incidents involving injury and the negative health effects attendant to the use of the Subject Defective GXL Devices;

c) Negligently failing to notify and warn the public including Plaintiff [redacted] and her doctors of the risk of oxidation of the polyethylene plastic components in the Subject Defective GXL Devices;

d) Negligently failing to notify and warn the public including Plaintiff

[redacted] and her doctors that they were using a sterilization method for the polyethylene plastic components which created highly-reactive macroradicals which can cause the plastic components to oxidize and age when exposed to oxygen atoms, thereby, causing device fatigue and failure;

e) Negligently failing to notify and warn the public including Plaintiff [redacted] and her doctors that they were not using alternative state-of-the art sterilization methods, including EtO and/or GP sterilization, which were available during the relevant time period, and would not create highly reactive macroradicals that cause oxidation and degradation of the polyethylene plastic components in the Subject Defective GXL Devices, including the Defective Implant;

f) Negligently failing to notify and warn the public including Plaintiff [redacted] and her doctors that the polyethylene plastic components were packaged in non-conforming barrier packaging;

g) Negligently misrepresenting the safety of the Subject Defective GXL Devices, including the Defective Implant;

h) Negligently failing to provide warnings, instructions or other information that accurately reflected the risks of early failure of the Subject Defective GXL Devices, including the Defective Implant;

i) Negligently failing to provide warnings, instructions or other information that accurately reflected the risks of early degradation of the polyethylene substance in the Subject Defective GXL Devices,

including the Defective Implant;

j) Negligently failing to provide warnings, instructions or other information to the public including Plaintiff [redacted] and her doctors of adequate precautions that could be taken to avoid fatigue and failure of the Subject Defective GXL Devices, including the Defective Implant;

k) Negligently failing to exercise due care in the advertisement and promotion of the Subject Defective GXL Devices, including the Defective Implant;

l) Negligently disseminating 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 Subject Defective GXL Devices, including the Defective Implant;

m) Aggressively promoting the Defective Implant without proper warnings of the risk of early failure or material degradation in the average user;

n) Aggressively promoting the Subject Defective GXL Devices even after Defendants knew or should have known of the unreasonable risks from implantation;

o) Negligently diminishing or hiding the risks associated with the implantation of the Subject Defective GXL Devices;

p) Negligently failing to provide warnings in accordance with

applicable state and federal laws and regulations;

q) and in all other ways.

209. The EXACTECH DEFENDANTS knew or reasonably should have known that they failed to provide proper and adequate safety warnings to consumers, users, doctors and patients that were sufficient for users to make informed decisions about implantation.

210. The EXACTECH DEFENDANTS knew or reasonably should have known that they failed to provide proper and adequate safety warnings to consumers, users, doctors and patients that were sufficient for the Subject Defective GXL Devices' expected, intended and foreseeable uses.

211. The Subject Defective GXL Devices should not have been designed, manufactured, distributed, marketed, and/or sold by Defendants without proper and adequate safety warnings to consumers, users, doctors and patients about the potential health and safety risks of the product.

212. The EXACTECH DEFENDANTS breached their duty to provide proper and adequate safety warnings to consumers, users, doctors and patients to make informed decisions about implantation and product use.

213. The EXACTECH DEFENDANTS breached their duty to design, manufacture, distribute, market, and/or sell the Subject Defective GXL Devices with proper and adequate safety warnings to consumers, users, doctors and patients to make informed decisions about implantation and product use.

214. Plaintiff [redacted] was seriously injured by Defendants' failure to provide proper and adequate safety warnings to consumers, users, doctors and patients.

215. As a direct and proximate result of Defendants' acts and omissions, including their failure to provide proper and adequate safety warnings to consumers, users, doctors and patients

regarding the Defective Opterak Devices, Plaintiff [redacted] was implanted with the Defective Implant.

216. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff [redacted] was caused to sustain and will continue to sustain serious personal injuries, conscious pain and suffering, mental anguish, emotional distress, fear, loss of enjoyment of life and physical disability that will require continued and additional medical treatment.

217. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff [redacted] was caused to sustain and will continue to sustain disabilities in activities of daily living.

218. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff [redacted] has sustained and will sustain medical expenses and related economic losses.

219. The injuries, damages, harm, and losses sustained by Plaintiff [redacted] were caused solely and wholly by virtue of the foregoing acts, omissions, and conduct of Defendants and were in no way caused and/or contributed to by [redacted].

220. By reason of the foregoing, Plaintiff [redacted] is entitled to monetary damages from Defendants for her past, present, and future non-economic and economic injuries, harm, and losses in an amount that exceeds the jurisdictional minimum.

221. Defendants acted intentionally, recklessly and wantonly without regard for Plaintiff's rights beyond all standards of decency, entitling Plaintiff to recover punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief

as the Court deems proper.

COUNT IV
NEGLIGENCE
AGAINST ALL DEFENDANTS

222. Plaintiffs repeat and reallege the allegations of the paragraphs above as if fully stated herein.

223. The EXACTECH DEFENDANTS had a duty to exercise reasonable care in the design, development, selection, formulation, testing, manufacture, marketing, sale and distribution of the Subject Defective GXL Devices into the stream of commerce, including a duty to assure that their products did not pose a significantly increased risk of physical bodily harm and adverse events to users and patients.

224. The EXACTECH DEFENDANTS had an obligation to follow the law in the manufacture, design, selecting, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, post market surveillance, preparing for use and otherwise distributing the Subject Defective GXL Devices, including the Defective Implant.

225. The EXACTECH DEFENDANTS had a duty to warn Plaintiff [redacted] and other consumers of the risks and dangers associated with the Subject Defective GXL Devices that were known or should have been known to Defendants at the time of the sale to the Plaintiff.

226. The EXACTECH DEFENDANTS' acts and omissions constitute a breach of duty, subjecting Defendants to civil liability for all damages arising therefrom.

227. The EXACTECH DEFENDANTS owed Plaintiff [redacted] a duty to exercise reasonable care when designing, manufacturing, selecting marketing, advertising, distributing, and selling the Subject Defective GXL Devices, including the duty to take all

reasonable steps necessary to ensure the product was not unreasonably dangerous to their consumers and users.

228. At all times material hereto, the EXACTECH 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 Subject Defective GXL Devices, including the Defective Implant.

229. The EXACTECH DEFENDANTS breached their duty and failed to exercise ordinary care and/or were negligent, reckless and/or wanton in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotion and distribution of the Subject Defective GXL Devices into interstate commerce because Defendants knew or should have known that these products would cause significant bodily harm and were not safe for use by consumers.

230. The EXACTECH DEFENDANTS knew or should have known that Plaintiff could suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

231. Despite the fact that the EXACTECH DEFENDANTS knew or should have known that the Subject Defective GXL Devices posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market the Subject Defective GXL Devices for implantation into consumers, such as the Plaintiff.

232. The EXACTECH DEFENDANTS failed to exercise due care under the circumstances, and their negligence and recklessness includes the following acts and omissions:

a) Negligently failing to properly and thoroughly select the material that would be used in the Subject Defective GXL Devices, including the Defective Implant;

b) Negligently failing to properly and adequately test the Subject Defective GXL Devices before releasing the devices to market;

c) Negligently failing to properly and adequately package the polyethylene plastic components used in the Subject Defective GXL Devices in packaging with sufficient barrier layers and/or a second barrier layer containing EVOH;

d) Negligently failing to properly and adequately test the barrier packaging used to package the Subject Defective GXL Devices' polyethylene plastic;

e) Negligently failing to properly manage, supervise and monitor the production of the polyethylene plastic components used in the Subject Defective GXL Devices;

f) Negligently failing to conduct sufficient post-market testing and surveillance of the Subject Defective GXL Devices;

g) Negligently utilizing an outdated, improper and/or ineffective sterilization method for the Subject Defective GXL Devices' polyethylene plastic components when other feasible, alternative methods were available and could prevent and/or substantially reduce the risk of the plastic oxidizing, breaking down, fatiguing and/or failing;

h) Negligently failed to utilize feasible, economical alternatives to gamma inert sterilization which would have prevented and/or substantially reduced the risk of oxidation, fatigue and premature failure of the Subject Defective GXL Devices;

i) Negligently failing to stay apprised of the scientific research and advances of the time which dictated that there were feasible, economical alternatives to

gamma inert sterilization and would have prevented and/or substantially reduced the risk of oxidation, fatigue and premature failure of the Subject Defective GXL Devices;

j) Negligently failing to identify, investigate and/or respond to reports by the Public, Patients and/or surgeons, including Plaintiff [redacted], regarding fatigue and failure of the polyethylene plastic found in the Subject Defective GXL Devices;

k) Negligently failing to establish a proper, appropriate and effective feedback loop mechanism in order to identify, investigate and/or respond to reports by the Public, Patients and/or surgeons, including Plaintiff [redacted], regarding fatigue and failure of the polyethylene plastic components found in the Subject Defective GXL Devices so that such reported defects could be remedied;

l) Negligently failing to adequately prevent, identify, mitigate, and fix defective designs and hazards associated with the Subject Defective GXL Devices in accordance with good practices;

m) Negligently manufacturing, designing, selecting, testing, assembling, inspecting, labeling, packaging, supplying, marketing, selling, advertising, and surveilling the Subject Defective GXL Devices;

n) Continuing to negligently manufacture, and distribute the Subject Defective GXL Devices after the Defendants knew or should have known of their adverse effects and/or the increased early onset failure rates;

o) Negligently failing to select appropriate third-parties to produce the polyethylene used in the Subject Defective GXL Devices;

p) Negligently failing to properly supervise and monitor the production of the polyethylene plastic used in the Subject Defective GXL Devices;

q) Negligently failing to select appropriate third-parties to produce the barrier packaging used to package the Subject Defective GXL Devices and/or their polyethylene plastic;

r) Negligently failing to properly supervise and monitor the production of the barrier packaging used to package the Subject Defective GXL Devices and/or their polyethylene plastic;

s) Negligently violating applicable state and federal laws and regulations;

t) and in all other ways.

233. 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 Subject Defective GXL Devices, and otherwise distributing the Subject Defective GXL Devices.

234. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of the Subject Defective GXL Devices, Plaintiff [redacted] was implanted with the Defective Implant and was caused to sustain and will continue to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

235. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff [redacted] was caused to sustain and will continue to sustain serious personal injuries, conscious pain and suffering, mental anguish, emotional distress, fear, loss of enjoyment of life and physical disability that will require continued and additional medical treatment.

236. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff [redacted] was caused to sustain and will continue to sustain disabilities in activities of daily living.

237. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff [redacted] has sustained and will sustain medical expenses and related economic losses.

238. The injuries, damages, harm, and losses sustained by Plaintiff [redacted] were caused solely and wholly by virtue of the foregoing acts, omissions, and conduct of Defendants and were in no way caused and/or contributed to by [redacted].

239. By reason of the foregoing, Plaintiff [redacted] is entitled to monetary damages from Defendants for her past, present, and future non-economic and economic injuries, harm, and losses in an amount that exceeds the jurisdictional minimum.

240. Defendants acted intentionally, recklessly and wantonly without regard for Plaintiff's rights beyond all standards of decency, entitling Plaintiff to recover punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT V
NEGLIGENT MISREPRESENTATION
AGAINST ALL DEFENDANTS

241. Plaintiffs repeat and reallege the allegations of the paragraphs above as if fully stated herein.

242. The EXACTECH DEFENDANTS owed a duty in all of their undertakings, including the dissemination of information concerning the Subject Defective GXL Devices to exercise reasonable care to ensure they did not create unreasonable risks of personal injury to others.

243. The EXACTECH DEFENDANTS disseminated to health care professionals and consumers, through published labels, marketing materials, direct communications, and otherwise, information that misrepresented the quality and longevity of the Subject Defective GXL Devices with the intention that health care professionals and consumers would rely upon that information in their decisions concerning whether to implant the Subject Defective GXL Devices.

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

245. The EXACTECH DEFENDANTS failed to exercise reasonable care to ensure that the information they disseminated to health care professionals and consumers concerning the quality and longevity of the Subject Defective GXL Devices was accurate, complete, and not misleading. As a result, Defendants disseminated information to health care professionals and

consumers that was materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Plaintiff.

246. The EXACTECH DEFENDANTS, as designers, manufacturers, sellers, promoters, and/or distributors of the Subject Defective GXL Devices, knew or reasonably should have known that surgeons would implant the Subject Defective GXL Devices in reliance on the information disseminated by Defendants, and that the patients implanted with the Subject Defective GXL Devices would suffer early failure and require revision and/or full replacement surgery because the information disseminated by Defendants and relied upon by health care professionals and consumers, including Plaintiff [redacted], was materially inaccurate, misleading, or otherwise false.

247. The EXACTECH DEFENDANTS made material misrepresentations to Plaintiff, Plaintiff's health care professionals, the healthcare community, and the general public, about the Subject Defective GXL Devices including without limit:

a) Negligently misrepresenting the Subject Defective GXL Devices' safety risks, including risk of dangerous early failure; polyethylene degradation, fatigue and failure; and increased rate of wear;

b) Negligently representing that their polyethylene plastic components were top-quality or of superior quality than competitors' polyethylene inserts;

c) Negligently representing that the Subject Defective GXL Devices have lower wear propensities than comparable products;

d) Negligently representing that the Subject Defective GXL Devices have greater longevity than comparable products;

e) Negligently failing to disclose that the Subject Defective GXL Devices were failing at a high rate, despite knowledge of same;

f) Negligently failing to disclose that recipients of the Subject Defective GXL Devices were experiencing problems including osteolysis, loosening of the components, deterioration of the polyethylene, and significant swelling, stiffness and pain, and failing to disclose same;

g) Negligently representing that the Subject Defective GXL Devices were safe to be used for their intended purposes;

h) Negligently representing that the polyethylene selected for the Subject Defective GXL Devices was of the same quality as that described in promotion and marketing materials and brochures;

i) Negligently representing that the Subject Defective GXL Devices had been adequately tested;

j) Negligently representing that the polyethylene selected for the Subject Defective GXL Devices was developed from the same processes as that described in promotion and marketing materials and brochures;

k) Overstating and/or mispresenting the success rate of the Subject Defective GXL Devices;

l) Negligently failing to comply with applicable state and federal laws and regulations regarding the promotion and advertisement of orthopedic devices;

m) and in all other ways.

248. These representations were made directly by Defendants, their sales representatives, and other authorized agents, and in publications and other written materials

directed to health care professionals, medical patients, and the public, including Plaintiff [redacted] and Plaintiff's physicians.

249. Defendants made these representations with the intent to induce reliance thereon, and to encourage purchase and implantation of the Subject Defective GXL Devices.

250. Defendants made these representations without any reasonable ground for believing them to be true.

251. Defendants had a duty to accurately and truthfully represent to medical professionals and consumers, including Plaintiff [redacted] the truth regarding Defendants' claims that the Subject Defective GXL Devices contained parts and materials that were of the quality and grade that the Defendants represented they were.

252. Defendants had a duty to accurately and truthfully represent to medical professionals and consumers, including Plaintiff [redacted] the truth regarding Defendants' claims that the Subject Defective GXL Devices contained parts and materials that had been adequately tested and approved by the Defendants.

253. The misrepresentations made by Defendants, in fact were false and known by Defendants to be false at the time the misrepresentations were made.

254. Defendants failed to exercise ordinary care in making their representations concerning the Subject Defective GXL Devices and, in the manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce of the Subject Defective GXL Devices.

255. Defendants engaged in a nationwide marketing campaign, over-promoting the Subject Defective GXL Devices in written marketing literature, in written product packaging, and in direct-to-consumer advertising via print and internet advertisements and television commercial

ads. Defendants' over-promotion was undertaken by touting the safety, quality and longevity of the Subject Defective GXL Devices while concealing, misrepresenting, and actively downplaying the serious, severe, and life-threatening risks of harm to patients implanted with the Subject Defective GXL Devices, when compared to comparable alternative implant options.

256. Defendants negligently misrepresented the Subject Defective GXL Devices' safety, quality and longevity.

257. As a direct and proximate result of Defendants' acts and omissions, including their failure to provide proper and adequate safety warnings to consumers, users, doctors and patients regarding the Subject Defective GXL Devices, Plaintiff [redacted] was implanted with the Defective Implant and was caused to sustain and will continue to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

258. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff [redacted] was caused to sustain and will continue to sustain serious personal injuries, conscious pain and suffering, mental anguish, emotional distress, fear, loss of enjoyment of life and physical disability that will require continued and additional medical treatment.

259. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff [redacted] was caused to sustain and will continue to sustain disabilities in activities of daily living.

260. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff [redacted] has sustained and will sustain medical expenses and related economic losses.

261. The injuries, damages, harm, and losses sustained by Plaintiff [redacted] were caused solely and wholly by virtue of the foregoing acts, omissions, and conduct of Defendants and were in no way caused and/or contributed to by [redacted].

262. By reason of the foregoing, Plaintiff [redacted] is entitled to monetary damages from Defendants for her past, present, and future non-economic and economic injuries, harm, and losses in an amount that exceeds the jurisdictional minimum.

263. Defendants acted intentionally, recklessly and wantonly without regard for Plaintiff's rights beyond all standards of decency, entitling Plaintiff to recover punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VI
FRAUDULENT INDUCEMENT
AGAINST ALL DEFENDANTS

264. Plaintiffs repeat and reallege the allegations of the paragraphs above as if fully stated herein.

265. The EXACTECH DEFENDANTS having undertaken to test, study, research, design, formulate, manufacture, inspect, label, package, promote, advertise, market, distribute and sell the Subject Defective GXL Devices owed a duty to provide accurate and complete information to Plaintiff, her orthopedic surgeon, and the public regarding the safety and efficacy of the devices and their component parts.

266. The EXACTECH DEFENDANTS misled Plaintiff [redacted], her medical providers and the public into believing that the Subject Defective GXL Devices were safe and effective for use in total hip replacement surgeries and engaged in deceptive, misleading and

unconscionable promotional, marketing and sales tactics to convince orthopedic surgeons and patients to use the Subject Defective GXL Devices even though Defendants knew or should have known that the devices were unreasonably dangerous as alleged herein.

267. The EXACTECH DEFENDANTS failed to warn orthopedic surgeons and the public about the serious risks associated with the use of the Subject Defective GXL Devices, including their high failure and revision rates and their propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision and/or full replacement surgery in patients.

268. The EXACTECH DEFENDANTS' advertising campaigns, marketing materials and promotional items, by containing affirmative misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the Subject Defective GXL Devices was safe for human use, had no unacceptable risks and was equivalent to or superior to other similar orthopedic devices on the market.

269. The EXACTECH DEFENDANTS purposefully concealed, failed to disclose, misstated, downplayed and understated the risks associated with the use of the Subject Defective GXL Devices.

270. The EXACTECH DEFENDANTS, through sales representatives, advertisements, and other marketing and promotional practices and communications as well as through the publication of medical literature including non-peer reviewed studies, deceived orthopedic surgeons, Plaintiff, other patients, and the public about the true risks of the Subject Defective GXL Devices.

271. The EXACTECH DEFENDANTS falsely and deceptively kept relevant information from orthopedic surgeons, the FDA and the public, including Plaintiff, regarding the safety of the Subject Defective GXL Devices.

272. The EXACTECH DEFENDANTS expressly denied that the Subject Defective GXL Devices created an increased risk of injury and took affirmative steps to prevent the discovery and dissemination of any evidence regarding the increased likelihood of injury from the Subject Defective GXL Devices including but not limited to the device's high failure and revision rates and propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision and/or full replacement surgery in patients.

273. The EXACTECH DEFENDANTS did not accurately report the results of adverse events by fraudulently and intentionally withholding from the FDA, orthopedic surgeons, Plaintiff, and the public, the truth regarding Subject Defective GXL Devices' failures for years, all the while undertaking sales, marketing and promotional campaigns to sell the Subject Defective GXL Devices.

274. The EXACTECH DEFENDANTS received reports of defects in their Subject Defective GXL Devices from various sources, including those alleged herein, and intentionally withheld this information from the FDA, orthopedic surgeons, Plaintiff, and the public, while continuing to sell the Subject Defective GXL Devices for implantation in patients such as Plaintiff.

275. The EXACTECH DEFENDANTS provided disclosures which were inadequate, incomplete, and/or misleading regarding the Subject Defective GXL Devices' defects.

276. Through the EXACTECH DEFENDANTS' wrongful conduct, Defendants effectively deceived and misled the scientific and medical communities regarding the risks and benefits of the Subject Defective GXL Devices.

277. The EXACTECH DEFENDANTS failed to fully inform orthopedic surgeons, Plaintiff, other patients, and the public of the true risks associated with the Subject Defective GXL Devices, which were known to Defendants, and continued to assure orthopedic surgeons and patients that the Subject Defective GXL Devices were safe and effective device for the purpose of continuing to derive substantial profits from their sale.

278. Through the EXACTECH DEFENDANTS' advertising campaigns, sales and marketing materials and promotional items, Defendants falsely and deceptively misrepresented and omitted numerous material facts regarding the Subject Defective GXL Devices, including but not limited to the device's high failure and revision rates and propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision and/or full replacement surgery in patients.

279. The EXACTECH DEFENDANTS continued to market the Subject Defective GXL Devices by providing false and misleading information about the device's safety and efficacy to Plaintiff and Plaintiff's orthopedic surgeon, despite the fact that possessed reports, clinical information and scientific studies and evidence demonstrating the devices caused serious injuries.

280. Among the EXACTECH DEFENDANTS' numerous misrepresentations and misleading omissions to Plaintiff, Plaintiff's orthopedic surgeon, and the public were Defendants' assurances that the Subject Defective GXL Devices were a safe device, had a low failure rate; were

long-lasting, top-of-the-line, innovative and high performing; and performed as well or better than other similar devices on the market

281. The EXACTECH DEFENDANTS concealed from Plaintiff and Plaintiff's healthcare providers the true and significant risks associated with the Subject Defective GXL Devices and claimed claiming any failures were due to surgical technique, positioning or patient characteristics, such as body mass index.

282. The EXACTECH DEFENDANTS did not reveal, and in fact concealed, their knowledge of numerous and serious complications and other bad data during their meetings with orthopedic surgeons.

283. Despite their knowledge of the risks with the Subject Defective GXL Devices, the EXACTECH DEFENDANTS, instructed their sales representatives to continue marketing the Devices for profit.

284. The EXACTECH DEFENDANTS distributed medical literature including non-peer reviewed studies and other communications to orthopedic surgeons which did not adequately convey the risks of the devices in an effort to mislead them and the public about the serious risks associated with their use.

285. The EXACTECH DEFENDANTS engaged in all the acts and omissions alleged herein with the intent that Plaintiff and Plaintiff's orthopedic surgeon would rely on the misrepresentations, deceptions and concealments in deciding to implant and use the Defective Implant rather than another of product.

286. In addition, the EXACTECH DEFENDANTS engaged in all the acts and omissions alleged herein so that these failure rates would not impact the sale of the company to private equity.

287. Plaintiff and Plaintiff's orthopedic surgeon justifiably relied to their detriment on the Exactech Defendant's intentional and fraudulent misrepresentations in their decision to buy and utilize the Defective Implant and this reliance proximately caused Plaintiff's injuries and damages as alleged herein.

288. Had the EXACTECH DEFENDANTS disclosed accurate, complete and truthful information about the device's high failure and revision rates and propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision and/or full replacement surgery in patients, Plaintiff would not have allowed her orthopedic surgeon to implant the Defective Implant into her body.

289. As a direct and proximate result of Defendants' wrongful conduct described herein, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

290. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff [redacted] was caused to sustain and will continue to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses that will require continued and additional medical treatment.

291. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff [redacted] was caused to sustain and will continue to sustain disabilities in activities of daily living.

292. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff [redacted] has sustained and will sustain medical expenses and related economic losses.

293. The injuries, damages, harm, and losses sustained by Plaintiff [redacted] were caused solely and wholly by virtue of the foregoing acts, omissions, and conduct of Defendants and were in no way caused and/or contributed to by [redacted].

294. By reason of the foregoing, Plaintiff [redacted] is entitled to monetary damages from Defendants for her past, present, and future non-economic and economic injuries, harm, and losses in an amount that exceeds the jurisdictional minimum.

295. Defendants acted intentionally, recklessly and wantonly without regard for Plaintiff's rights beyond all standards of decency, entitling Plaintiff to recover punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VII
FRAUDULENT CONCEALMENT
AGAINST ALL DEFENDANTS

296. Plaintiffs repeat and reallege the allegations of the paragraphs above as if fully stated herein.

297. At all times during the course of dealing between the Defendants, Plaintiff, Plaintiff's healthcare providers, and/or the FDA, the Defendants misrepresented the safety of the Subject Defective GXL Devices for their intended use.

298. In representations to the public, Plaintiff [redacted], Plaintiff's healthcare providers, and/or the FDA, the Defendants fraudulently concealed and intentionally omitted material information, including but not limited to the fact that:

a) the subject product was not as safe as other similar devices indicated for hip arthroplasty;

b) that the subject product was manufactured and/or packaged negligently;

c) that the subject product was manufactured and/or packaged defectively;

d) that the subject product was manufactured and/or packaged improperly;

e) that the subject product and/or product packaging was designed negligently;

f) that the subject product and/or product packaging was designed defectively;

g) that the subject product and/or product packaging was designed improperly;

h) that the subject product was packaged in insufficient and/or improper barrier packaging;

i) that the Defendants did not utilize state-of-the-art technology in their design and manufacturing of the Subject Defective GXL Devices, despite Defendants' representations as to same;

j) that the subject product was defective, and that it caused dangerous side effects, including but not limited to the risks of developing serious and dangerous medical and orthopedic conditions, including but not limited to component loosening, component mal-alignment, substantial early polyethylene wear, pain, irritation and discomfort, as well as the need for additional procedures to remove and replace the device, notwithstanding the Defendants' knowledge of

an increased risk of these injuries and side effects over other hip arthroplasty devices; and

k) in all other ways.

299. Defendants knew or were reckless in not knowing that their representations were false.

300. Defendants were under a duty to disclose to the public, Plaintiff [redacted], Plaintiff's healthcare providers, and/or the FDA the defective nature of the subject product, including but not limited to the risk of the device's propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries, as well as the need for revision and/or full replacement surgery in patients.

301. Defendants had sole access to material facts concerning the defective nature of the subject product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used the Subject Defective GXL Devices, including the Plaintiff [redacted].

302. Defendants' concealment and omissions of material facts concerning, *inter alia*, the safety of the Subject Defective GXL Devices were made purposefully, willfully, wantonly, and/or recklessly, to mislead the public, Plaintiff [redacted] and Plaintiff's physicians, hospitals and healthcare providers into reliance on the use of the devices, and to cause them to purchase, prescribe, dispense and/or use the subject product.

303. Defendants knew that the public, Plaintiff [redacted], Plaintiff's healthcare providers, and/or the FDA had no way to determine the truth behind the Defendants' concealment and omissions, as set forth herein.

304. Plaintiff, as well as Plaintiff's doctors, healthcare providers, and/or hospitals, reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by the Defendants.

305. As a direct and proximate result of Defendants' fraudulent misrepresentations and omissions and/or their failure to disclose their violations of federal requirements applicable to their Subject Defective GXL Devices, Plaintiff used the Defective Implant, and the Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

306. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff [redacted] was caused to sustain and will continue to sustain serious personal injuries, conscious pain and suffering, mental anguish, emotional distress, fear, loss of enjoyment of life and physical disability that will require continued and additional medical treatment.

307. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff [redacted] was caused to sustain and will continue to sustain disabilities in activities of daily living.

308. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff [redacted] has sustained and will sustain medical expenses and related economic losses.

309. The injuries, damages, harm, and losses sustained by Plaintiff [redacted] were caused solely and wholly by virtue of the foregoing acts, omissions, and conduct of Defendants and were in no way caused and/or contributed to by [redacted].

310. By reason of the foregoing, Plaintiff [redacted] is entitled to monetary damages from Defendants for her past, present, and future non-economic and economic injuries, harm, and losses in an amount that exceeds the jurisdictional minimum.

311. Defendants acted intentionally, recklessly and wantonly without regard for Plaintiff's rights beyond all standards of decency, entitling Plaintiff to recover punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VIII
CONSUMER FRAUD AND DECEPTIVE TRADE PRACTICES
VIOLATIONS OF GBL §§ 349 AND 350
AGAINST ALL DEFENDANTS

312. Plaintiffs repeat and reallege the allegations of the paragraphs above as if fully stated herein.

313. The allegations contained in previous paragraphs set forth specific representations the EXACTECH DEFENDANTS have made to consumers, physicians, and other healthcare providers through their public statements, advertising and promotional materials (some of which are stated above). These representations were made by the EXACTECH DEFENDANTS on an ongoing and repeated basis, and, as specifically relevant here, at various points prior to 2018.

314. The representations made by the EXACTECH DEFENDANTS were materially deceptive in that they asserted that their defective hip implants were equivalent or superior to other similar devices on the market, utilized innovative technologies which resulted in improved outcomes for patients and longevity of the implants, when in fact, the devices had a high failure and revision rates and caused patients to experience substantial early polyethylene wear,

component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery.

315. In such representations, the EXACTECH DEFENDANTS willfully ignored or avoided the reports, scientific data and studies concluding that their defective hip implants had high failure and revision rates so that it could continue to sell the Subject Defective GXL Devices and profit from their sales.

316. The EXACTECH DEFENDANTS willfully failed to take protective measures, such as changing their products, packaging, guidelines, instructions, and/or warnings, which would have prevented Patients such as [redacted] from being implanted with the Defective GXL Devices and thereafter developing and suffering long-term medical problems as a result, including early polyethylene wear, component loosening and/or other failure, tissue damage, osteolysis, pain, inflammation, stiffness, and other injuries as well as the need for revision and/or full replacement surgery or surgeries.

317. The acts, omissions, and practices of Defendant ABBOTT alleged herein constitute deceptive trade practices within the meaning of N.Y.GEN.BUS.LAW § 349 and § 350.

318. Plaintiffs have standing to bring these claims because they have been injured in that they suffered and lost money as a result of the EXACTECH DEFENDANTS' deceptive trade practices.

319. The EXACTECH DEFENDANTS engaged in deceptive trade practices by and through the following without limit:

a) Developed a systematic, pervasive, effective, and manipulative marketing scheme designed to make Patients, including Plaintiff, and healthcare providers believe that their Subject Defective GXL Devices were safe; had a low failure rate; were long-

lasting, top-of-the-line, innovative and high performing; and performed as well or better than other similar devices on the market;

b) Acted, used and employed unconscionable commercial practices, deception, fraud, false pretenses, false promises and misrepresentations;

c) Knowingly concealed, suppressed and omitted material facts with the intent that consumers, including the Plaintiff herein and her physicians and medical providers, rely upon such concealment, suppression and omission, in connection with the sale, advertisement and promotion of Subject Defective GXL Devices;

d) Representing that the Subject Defective GXL Devices had characteristics, uses or benefits that they did not have;

e) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding;

f) Making monetary contributions to endear itself to the medical profession and win its favor; and

g) In all other ways.

320. The EXACTECH DEFENDANTS intended for Patients like [redacted] and healthcare providers to rely on their representations and advertisements regarding the Subject Defective GXL Devices, so that the EXACTECH DEFENDANTS would profit from their sale.

321. The Defendants' deceptive conduct was directed at physicians, healthcare providers, Patients, including Plaintiff, and the public in order to create demand and sell the Subject Defective GXL Devices.

322. Each aspect of the EXACTECH DEFENDANTS' conduct combined to artificially create sales of their Subject Defective GXL Devices and to deceive the public at large and Plaintiff, [redacted], in particular.

323. As a result of the deceptive trade practices engaged in by the EXACTECH DEFENDANTS, patients such as Plaintiff paid and will continue to pay large sums of money to care for and treat their injuries, including past and future medical costs and expenses.

324. The EXACTECH DEFENDANTS' intentional, deceptive, unconscionable, immoral, and fraudulent representations and material omissions to Plaintiff [redacted], physicians, and consumers constitute deceptive trade practices.

325. Under New York law, the EXACTECH DEFENDANTS are under a duty to not act deceptively in design, labeling, development, manufacture, promotion, and sale of their consumer products including the Subject Defective GXL Devices.

326. Had the EXACTECH DEFENDANTS not engaged in the deceptive conduct described above, [redacted] would not have been implanted with the defective and dangerous product and would not have incurred related injuries and damages.

327. The EXACTECH DEFENDANTS had actual knowledge of the defective and dangerous condition of the Subject Defective GXL Devices, including their defective polyethylene GXL devices, and failed to take any action to cure such defective and dangerous conditions.

328. Plaintiff [redacted] and healthcare providers relied upon the EXACTECH DEFENDANTS misrepresentations and omissions in deciding to purchase and use the Subject Defective GXL Devices, costs which were passed off to Plaintiff as a patient and consumer.

329. Plaintiff [redacted] and healthcare providers were misled into not objecting to the use of the Subject Defective GXL Devices as a direct and proximate result of the

EXACTECH DEFENDANTS misrepresentations, omissions, and deceptive marketing campaigns.

330. As a direct and proximate result foregoing acts, omissions, and conduct committed by the EXACTECH DEFENDANTS, Plaintiff [redacted] was implanted with the Defective Implant and was caused to sustain and will continue to sustain serious personal injuries, conscious pain and suffering, mental anguish, emotional distress, fear, loss of enjoyment of life and physical disability that will require continued and additional medical treatment.

331. By reason of the foregoing acts, omissions, and conduct committed by the EXACTECH DEFENDANTS, Plaintiff [redacted] was caused to sustain mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses, in the past and continuing into the future.

332. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff [redacted] was caused to sustain disabilities in activities of daily living, in the past and continuing into the future.

333. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff [redacted] has sustained and will sustain medical expenses and related economic losses.

334. The injuries, damages, harm, and losses sustained by Plaintiff [redacted] were caused solely and wholly by virtue of the foregoing acts, omissions, and conduct of Defendants and were in no way caused and/or contributed to by [redacted].

335. By reason of the foregoing, Plaintiff [redacted] is entitled to monetary damages from Defendants for her past, present, and future non-economic and economic injuries, harm, and losses in an amount that exceeds the jurisdictional minimum.

336. Defendants acted intentionally, recklessly and wantonly without regard for Plaintiff's rights beyond all standards of decency, entitling Plaintiff to recover punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT IX
BREACH OF EXPRESS WARRANTY
AGAINST ALL DEFENDANTS

337. Plaintiffs repeat and reallege the allegations of the paragraphs above as if fully stated herein.

338. At all times herein mentioned, the Defendants manufactured, packaged, distributed, recommended, merchandized, advertised, promoted, and sold the Subject Defective GXL Devices, including the Defective Implant.

339. Defendants expressly represented and warranted that the Subject Defective GXL Devices were safe and effective devices for those patients requiring a hip replacement.

340. The Subject Defective GXL Devices manufactured, packaged, and sold by Defendants did not conform to these express representations and warranties because they caused serious injury to the Plaintiff when used as recommended and directed.

341. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue.

342. The Subject Defective GXL Devices were placed into the stream of commerce by Defendants in a defective, unsafe, and inherently dangerous condition, and the product's materials

were expected to and did reach users, handlers, and persons encountering said products without substantial change in the condition in which they were sold.

343. Plaintiff [redacted] and Plaintiff's surgeon relied on Defendants' express representations and warranties about the safety and efficacy of the Subject Defective GXL Devices, including the Defective Implant. Plaintiff and Plaintiff's surgeon reasonably relied upon the skill and judgment of Defendant as to whether the Defective Implant were of merchantable quality and safe and fit for their intended use.

344. The Defendant breached the aforesaid express warranties as the Subject Defective GXL Devices were not fit for their intended purposes and uses.

345. As a direct and proximate result of Defendants' breach of warranty, Plaintiff [redacted] was implanted with the Defective Implant and was caused to sustain and will continue to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

346. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff [redacted] was caused to sustain and will continue to sustain serious personal injuries, conscious pain and suffering, mental anguish, emotional distress, fear, loss of enjoyment of life and physical disability that will require continued and additional medical treatment.

347. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff [redacted] was caused to sustain and will continue to sustain disabilities in activities of daily living.

348. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff [redacted] has sustained and will sustain medical expenses and related economic losses.

349. The injuries, damages, harm, and losses sustained by Plaintiff [redacted] were caused solely and wholly by virtue of the foregoing acts, omissions, and conduct of Defendants and were in no way caused and/or contributed to by [redacted].

350. By reason of the foregoing, Plaintiff [redacted] is entitled to monetary damages from Defendants for her past, present, and future non-economic and economic injuries, harm, and losses in an amount that exceeds the jurisdictional minimum.

351. Defendants acted intentionally, recklessly and wantonly without regard for Plaintiff's rights beyond all standards of decency, entitling Plaintiff to recover punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT X
BREACH OF IMPLIED WARRANTY
AGAINST ALL DEFENDANTS

352. Plaintiffs repeat and reallege the allegations of the paragraphs above as if fully stated herein.

353. Prior to Plaintiff [redacted]'S 2018 surgery, and at all relevant times in this action, the EXACTECH DEFENDANTS tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Subject Defective GXL Devices for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

354. EXACTECH DEFENDANTS impliedly warranted, through their marketing, advertising, distributors and sales representatives, that the Subject Defective GXL Devices were of merchantable quality and fit for the ordinary purposes and uses for which they were sold.

355. The Subject Defective GXL Devices were not of merchantable quality nor fit for the ordinary purposes and uses for which they were sold and did not meet the expectations of consumers.

356. The Subject Defective GXL Devices manufactured and supplied by the EXACTECH DEFENDANTS were not of merchantable quality and were not fit for the ordinary and/or particular purpose for which they were intended as physicians and patients would expect the components to be properly manufactured, treated to prevent oxidation, and packaged and stored as to avoid premature degradation of component materials.

357. Plaintiff [redacted] and/or Plaintiff's physician reasonably relied upon the skill and judgment of the EXACTECH DEFENDANTS as to whether the Subject Defective GXL Devices were of merchantable quality and safe for their intended and particular use and purpose.

358. Contrary to such implied warranties, the Subject Defective GXL Devices were not of merchantable quality or safe for their intended and particular use and purpose, because the EXACTECH DEFENDANTS failed to prevent the components from undergoing increased oxidation and causing patients to experience substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery.

359. As a direct and proximate result of the EXACTECH DEFENDANTS' acts and omissions, including breach of implied warranties, Plaintiff was implanted with a Device and was

caused to sustain and will continue to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

360. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff [redacted] was caused to sustain and will continue to sustain serious personal injuries, conscious pain and suffering, mental anguish, emotional distress, fear, loss of enjoyment of life and physical disability that will require continued and additional medical treatment.

361. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff [redacted] was caused to sustain and will continue to sustain disabilities in activities of daily living.

362. By reason of the foregoing acts, omissions and conduct committed by the EXACTECH DEFENDANTS, Plaintiff [redacted] has sustained and will sustain medical expenses and related economic losses.

363. The injuries, damages, harm, and losses sustained by Plaintiff [redacted] were caused solely and wholly by virtue of the foregoing acts, omissions, and conduct of Defendants and were in no way caused and/or contributed to by [redacted].

364. By reason of the foregoing, Plaintiff [redacted] is entitled to monetary damages from Defendants for her past, present, and future non-economic and economic injuries, harm, and losses in an amount that exceeds the jurisdictional minimum.

365. Defendants acted intentionally, recklessly and wantonly without regard for Plaintiff's rights beyond all standards of decency, entitling Plaintiff to recover punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble

and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT XI
LOSS OF CONSORTIUM AND SERVICES
BY PLAINTIFF JONATHAN SCHROTT, INDIVIDUALLY,
AGAINST ALL DEFENDANTS

366. Plaintiffs repeat and reallege the allegations of the paragraphs above as if fully stated herein.

367. At all relevant times, Plaintiff [redacted] was and is the lawfully wedded spouse of Plaintiff [redacted] since 1987 and resided continuously with her, and as such, was and is entitled to the services, consortium and society of [redacted].

368. As a result of the foregoing acts by the EXACTECH DEFENDANTS, Plaintiff [redacted] was and continues to be deprived of the services, consortium and society of [redacted].

369. As a result of the foregoing acts by the EXACTECH DEFENDANTS, Plaintiff [redacted] is entitled to monetary damages for his losses.

370. As a result of the foregoing, Plaintiff [redacted] is entitled to monetary damages for his non-economic and economic injuries.

371. As a result of the foregoing, Plaintiff [redacted] demands judgment in an amount that exceeds the jurisdictional minimum.

DEMAND FOR JURY TRIAL

Plaintiffs demand trial by jury pursuant to Rule 38 of the Federal Rules of Civil Procedure and the Seventh Amendment of the U.S. Constitution.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, and severally, as follows:

a) For general damages in a sum in excess of $75,000, the jurisdictional minimum of this Court;

b) For medical, incidental and hospital expenses according to proof;

c) For pre-judgment and post-judgment interest as provided by law;

d) For consequential damages in excess of the jurisdictional minimum of this Court;

e) For compensatory damages in excess of the jurisdictional minimum of this Court;

f) For punitive damages on Counts I, II, III, IV, V, VI, VII, VIII, IX, and X in an amount in excess of any jurisdictional minimum of this Court and in an amount sufficient to deter similar conduct in the future and punish the Defendants for the conduct described herein;

g) For attorneys' fees, expenses and costs of this action; and

h) For such further and other relief as this Court deems necessary, just and proper.

Dated: December 15, 2022

Respectfully submitted,

[redacted]