UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
(BROOKLYN)

IN RE: EXACTECH POLYETHYLENE ORTHOPEDIC PRODUCTS LIABILITY LITIGAITON	**MDL No.: 3044** **Case No.: 22-MD-3044 (NGG) (MMH)**
BRENDAN LEDDY and PATRICIA LEDDY, **Plaintiffs,** **v.** **EXACTECH, INC., EXACTECH US, INC., TPG, INC., TPG PARTNERS VII, L.P., TPG GENPAR VII, L.P., TPG GENPAR VII ADVISORS, LLC, OSTEON HOLDINGS, INC., OSTEON MERGER SUB, INC., OSTEON HOLDINGS, L.P., AND OSTEON INTERMEDIATE HOLDINGS II, INC.,** **Defendants.**	**Docket No.:** 1:23-cv-00929 **DIRECT FILED COMPLAINT PURSUANT TO PRACTICE AND PROCEDURE ORDER NO. 2**

COMES NOW, the plaintiffs, BRENDAN LEDDY and PATRICIA LEDDY, by and through undersigned counsel and submits this Complaint and Jury Demand against Defendants **EXACTECH, INC., EXACTECH US, INC., TPG, INC., TPG PARTNERS VII, L.P., TPG GENPAR VII, L.P., TPG GENPAR VII ADVISORS, LLC, OSTEON HOLDINGS, INC., OSTEON MERGER SUB, INC., OSTEON HOLDINGS, L.P., AND OSTEON INTERMEDIATE HOLDINGS II, INC.,** for compensatory and punitive damages, equitable relief, and such other relief deemed just and proper arising from the injuries to plaintiffs BRENDAN LEDDY and PATRICIA LEDDY, 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 device sold under the name "Optetrak Logic" Total Knee System and its component parts. In support,

Plaintiffs allege the following:[1]

INTRODUCTION

1. Exactech, Inc. and Exactech U.S., Inc. (collectively "Exactech" or "Exactech Defendants") failed patients and operating surgeons by designing, manufacturing, and selling defective and unreasonably dangerous hip, knee, and ankle joint replacement systems. Exactech cut corners, utilized inferior manufacturing practices, sold defective medical devices, distributed improperly packaged (and therefore compromised) devices that were never validated or properly tested, sequestered important adverse event information, only disclosed information or took corrective action if contacted by regulatory authorities, misled doctors and the medical community, and worst of all, left patients catastrophically injured, in great pain, and in need of revision/corrective surgery. Wherefore, these severely injured patients bring to this Court in this Multidistrict Litigation their product liability actions seeking monetary damages for their injuries caused by Defendants' tortious acts and omissions and the failure of Exactech's defective hip, knee, and ankle devices.

2. As further detailed below, this litigation concerns the following defective Exactech hip, knee, and ankle implant systems (collectively "Exactech Hip, Knee, and Ankle Devices," "Exactech Devices," or "Devices"):

a. Hip Implant Systems: Connexion GXL, Novation GXL, AcuMatch GXL, MCS GXL (collectively "GXL Devices" or "Exactech Hip Devices");

b. Knee Implant Systems: Optetrak Comprehensive Total Knee System ("Optetrak"), Optetrak Logic Comprehensive Knee System ("Optetrak Logic"), and Truliant Comprehensive Total Knee System ("Truliant") (collectively "Exactech Knee Devices"); and

c. Ankle Implant Systems: Vantage Total Ankle System ("Vantage") ("Exactech Ankle Devices").

3. While each of these Devices is distinct, common among them is Exactech's use of

[1] As the Master Complaint was previously filed in MDL, Plaintiffs are adopting all of those allegations made in it by pleading same as well as those additional allegations and causes of action specifically pled below. Plaintiffs respectfully ask the Court to read this Complaint in the singular where applicable to these individual litigants.

ultra-high molecular weight polyethylene ("UHMWPE") in the inserts or liner components.

4. The UHMWPE components Exactech used in each Device were defectively designed, manufactured, packaged, and labeled, making them susceptible to accelerated wear, which results in tragic outcomes for patients.

5. Exactech sold and distributed these defective Devices without adhering to the established industry standards for: the processing of UHMWPE, thermal treatment of irradiated UHMWPE, packaging of irradiated UHMWPE, and proper testing of the Devices for oxidation, accelerated wear, and delamination.

6. As explained in detail herein, Patients who were implanted with defective Exactech Devices were put at an increased and undue risk of, and have suffered from, adverse events associated with accelerated wear of the UHMWPE components. Such adverse events include, but are not limited to, inflammation causing bone destruction, implant component loosening, adverse local tissue reaction, excessive fluid buildup causing swelling, implant failure, pain, disabling complications, permanent destruction of the hip, knee, and ankle bone and muscular structure, permanent alteration of gait, loss of limb, and in some cases death due to complications associated with revision/corrective surgery.

7. For years, Exactech knew that its Exactech Hip, Knee, and Ankle Devices were defectively designed and manufactured, not properly tested, packaged, stored, or monitored, and improperly marketed via false representations and without proper and adequate warnings. Nonetheless, Exactech continued to market, distribute, and sell these defective Devices, putting thousands of patients at risk and subjecting these patients to debilitating injuries for the sake of increasing sales, saving costs in manufacturing and packaging, and increasing or maintaining their market share.

8. Ultimately, in 2021, following mounting reports of failures, complaints, and exceedingly high revision rates, Exactech started removing these Devices from the market through FDA Recalls.

9. On June 29, 2021, Exactech quietly initiated a recall (Recall Event ID 88126) of

certain Exactech Hip Devices for product families that utilize the Connexion GXL UHMWPE acetabular liner because of accelerated wear to the liner. There was no effort to publicize this recall to healthcare providers and certainly no effort to have surgeons inform their patients of this recall. On August 11, 2022, Exactech issued a second recall (Recall Event ID 90279) for GXL liners after it was discovered that they had been improperly packaged since 2004, which could lead to accelerated wear of the polyethylene acetabular liner and failure of the Exactech Hip Device.

10. On August 30, 2021, Exactech again quietly initiated a recall of certain Exactech Knee Devices and Exactech Ankle Devices (Recall Event ID 88570) due to accelerated wear of their respective polyethylene tibial inserts. There was no effort to publicize this recall to healthcare providers. Exactech further expanded this recall on February 7, 2022. It was months later that surgeons notified patients of the recall and the need to potentially follow up for evaluation.

11. Through these recalls, Exactech admitted that since 2004 it had failed to properly package the polyethylene components of its Exactech Hip, Knee, and Ankle Devices, thereby leaving them vulnerable to oxidation and accelerated wear.

12. Oxidation degradation of UHMWPE deteriorates the polyethylene's mechanical properties and abrasive wear resistance, resulting in wear debris production, bone loss, and/or component fatigue cracking/fracture, all leading to corrective revision surgery.

13. Following an eight day inspection of Exactech's facilities in November 2021, FDA investigators found, *inter alia*, that Exactech had not implemented requirements to prevent device oxidation, Exactech never validated its packaging of implants, Exactech failed to establish procedures for acceptance of incoming product from suppliers, including the supplier of vacuum bags used to package UHMWPE components, and Exactech had no documented evidence to substantiate that sample sizes employed as part of a shelf-life study protocol were based on a valid statistical rationale. *See* FDA Form 483, 1038671.

14. Plaintiffs' claims arise and their injuries and damages are proximately caused by defects in the Exactech Hip, Knee, and Ankle Devices' design, manufacture, testing, materials, packaging, quality controls, storage, distribution, warning and labeling, marketing, post-market

monitoring/surveillance, and regulatory reporting. Additionally, Plaintiffs' injuries and damages arise from the negligent and fraudulent acts and omissions of Exactech.

15. Plaintiffs' claims against TPG Defendants (set forth below), which acquired, merged with, and took control of Exactech in 2018, are based on theories of successor liability and piercing the corporate veil.

16. As a direct and proximate cause of the failure of Exactech's Hip, Knee, and Ankle Devices and Defendants' wrongful acts and omissions described herein, Plaintiffs have suffered and will continue to suffer serious personal injuries, including pain, traumatic revision surgery, impaired mobility, physical disability, amputation, death, medical expense, loss of the enjoyment of life, loss of wages, loss of consortium, and other medical conditions.

PARTIES

I. PLAINTIFFS BRENDAN LEDDY AND PATRICIA LEDDY

17. At all times relevant hereto, Plaintiff BRENDAN LEDDY was and is a resident and citizen of New York, New York, County of Westchester.

18. At all times relevant hereto, Plaintiff PATRICIA LEDDY was and is a resident and citizen of New York, New York, County of Westchester.

19. Plaintiffs BRENDAN LEDDY and PATRICIA LEDDY have been legally married since 1971 and have continuously resided together since that time.

20. Plaintiff, BRENDAN LEDDY, is a 73-year-old citizen and resident of New York.

21. Plaintiff BRENDAN LEDDY is of a healthy weight for a man of his age and height.

22. Plaintiff, BRENDAN LEDDY, does not suffer from or have a family history of any bone disorders or diseases.

23. On November 30, 2015, Plaintiff BRENDAN LEDDY underwent a total knee replacement at the Hospital for Special Surgery (HSS) in New York, New York during which the

defective Exactech Optetrak Logic Total Knee System was implanted into the Plaintiff's right knee cavity (hereinafter the "2015 Defective Implant").

24. The November 30, 2015 total knee replacement included the following parts: Exactech Optetrak Logic Femur Size 3 Right, 3F/3T Cemented Trapezoidal Tray, 13 MM PSC Tibial Insert and a 38MM Patella.

25. In or around 2020, Plaintiff BRENDAN LEDDY required a revision procedure after it was discovered that the plastic tibial insert of the defective Optetrak Logic Total Knee System implant had failed, resulting in synovitis due to polywear, persistent right knee effusion and bone reabsorption.

26. On July 16, 2020, Plaintiff BRENDAN LEDDY had a revision right total knee replacement performed at Stamford Hospital, during which the prior right knee surgery was revised and the plastic tibial insert was replaced with the Optetrak Logic PSC Tibial Insert Posterior Stabilized Size 3, 15mm (Lot 02-012-44-3015, Serial No. 2423732) (hereinafter the "2020 Defective Implant").

27. Upon information and belief, the July 16, 2020 right knee revision was done correctly and did not deviate from accepted medical custom and practice with regards to a revision of an Exactech Optetrak Logic knee and its component parts.

28. Plaintiff BRENDAN LEDDY required and continues to require medical treatment, care and follow-up, including extensive physical therapy, after the July 16, 2020 revision procedure.

29. Upon information and belief, the 2015 Defective Implant failed prematurely, especially in light of the Plaintiff's body mass index and lifestyle.

30. The 2015 and 2020 Defective Implants contain polyethylene plastic inserts that are subject to the February 7, 2022 recall initiated by the Defendants.

31. The 2020 Defective Implant remains in Plaintiff's body and contains defective, recalled plastic components.

32. The 2020 Defective Implant contains plastic components that are defective, unfit for use and/or unreasonably dangerous.

33. The 2020 Defective Implant continues to cause Plaintiff BRENDAN LEDDY pain, stiffness and discomfort requiring medical treatment, monitoring and care.

34. Plaintiff BRENDAN LEDDY is receiving medical treatment, management and care of the 2020 Defective Implant from a revision specialist.

35. An MRI taken in or around December 2022 shows that Plaintiff BRENDAN LEDDY will more likely than not require a second revision surgery or full revision total knee replacement due to defects and failures of the plastic tibial insert components used in the 2020 revision procedure, and he has been informed of same by his doctors.

36. Plaintiff BRENDAN LEDDY was caused to sustain and will continue to sustain serious personal injuries, conscious pain and suffering, physical disability, disabilities in activities of daily living, mental anguish, emotional distress, fear, loss of enjoyment of life, loss of income, medical expenses, and financial losses due to the acts, omissions and conduct of the Defendants, described below.

37. The injuries, damages, harm, and losses sustained by Plaintiff BRENDAN LEDDY were caused solely and wholly by virtue of the following acts, omissions, and conduct of Defendants and were in no way caused and/or contributed to by BRENDAN LEDDY.

38. Plaintiffs' lawful wife of fifty years, PATRICIA LEDDY, has likewise suffered injury including the loss of consortium, society and services of her husband as a result of his injuries from the defective device.

39. By reason of the following, Plaintiffs BRENDAN LEDDY and PATRICIA LEDDY are entitled to monetary damages from Defendants for their past, present, and future non-economic and economic injuries, harm, and losses in an amount that exceeds the jurisdictional minimum.

40. Defendants acted intentionally, recklessly and wantonly without regard for Plaintiff's rights beyond all standards of decency, entitling Plaintiff to recover punitive damages on each of the counts below.

II. EXACTECH DEFENDANTS

41. Defendant Exactech, Inc. is a Florida corporation with its principal place of business at 2320 NW 66th Street, Gainesville, FL 32653. Exactech, Inc. is a citizen of Florida.

42. Defendant Exactech U.S., Inc. is a Florida corporation with its principal place of business at 2320 NW 66th Street, Gainesville, FL 32653. Exactech U.S., Inc. is a citizen of Florida.

43. At all times relevant to this action, Exactech Defendants designed, tested, studied, researched, formulated, manufactured, inspected, labeled, packaged, stored, promoted, advertised, marketed, distributed, and/or sold Exactech Hip, Knee, and Ankle Devices throughout the United States, including in the State of New York and each Plaintiff's forum state.

44. At all times relevant to this action, Exactech Defendants received substantial revenue from goods used or consumed, or services rendered, in the State of New York and each Plaintiff's forum state.

45. At all times relevant to this action, Exactech Defendants were in the business of and profited from the design, manufacture, marketing, distribution and/or sale of medical devices, including the Exactech Hip, Knee, and Ankle Devices that were implanted in Plaintiffs.

46. At all times relevant to this action, Exactech Defendants were responsible for placing the Exactech Devices implanted into Plaintiff into the stream of commerce and advertised, marketed, distributed, and/or sold such products either directly or indirectly to members of the general public, including each Plaintiff.

III. TPG DEFENDANTS

47. Defendant TPG, Inc. ("TPG"), also known as TPG Capital, LP and formerly known as TPG Partners, LLC, is a Delaware corporation that has its principal place of business at 301 Commerce Street, Suite 3300, Fort Worth, TX 76102. TPG, Inc. is a citizen of Delaware and Texas.

48. TPG Partners, LLC converted to TPG Inc. in or around December 2021.

49. TPG is a publicly traded company on the Nasdaq Stock Exchange with a business model based on privatizing companies.

50. TPG is a leading alternative asset manager that works with companies in many sectors, including the medical device sector.

51. The healthcare sector is one of TPG's most active sectors.

52. As set forth in further detail below, in February 2018, TPG paid over $737 million to merge with and acquire Exactech ("2018 Merger").

53. TPG is not a passive investor. It touts its ability to "create products and services [that have] delivered breakthrough innovation" in the healthcare industry, as well as its "unique approach" to "building great companies."

54. Defendant TPG Partners VII, L.P. is a Delaware limited partnership that has its principal place of business at 301 Commerce Street, Suite 3300, Fort Worth, TX 76102. TPG Partners VII, L.P. is an affiliate of Osteon Holdings, Inc. and Osteon Merger Sub, Inc. TPG Partners VII, L.P. is a citizen of Delaware and Texas.

55. Defendant TPG Genpar VII, L.P. is a Delaware limited partnership that has its principal place of business at 301 Commerce Street, Suite 3300, Fort Worth, TX 76102 and is a general partner of TPG Partners VII, L.P. TPG Genpar VII, L.P. is a citizen of Delaware and Texas.

56. Defendant TPG Genpar VII Advisors, LLC is a Delaware limited liability company

that has its principal place of business at 301 Commerce Street, Suite 3300, Fort Worth, TX 76102 and is a general partner of TPG Genpar VII, L.P. TPG Genpar VII Advisors, LLC is a citizen of Delaware and Texas.

57. Osteon Holdings, L.P. is an indirect wholly owned subsidiary or indirect beneficially owned affiliate of TPG.

58. Osteon Holdings, L.P. converted to Osteon Holdings, Inc. in or around February 2018.

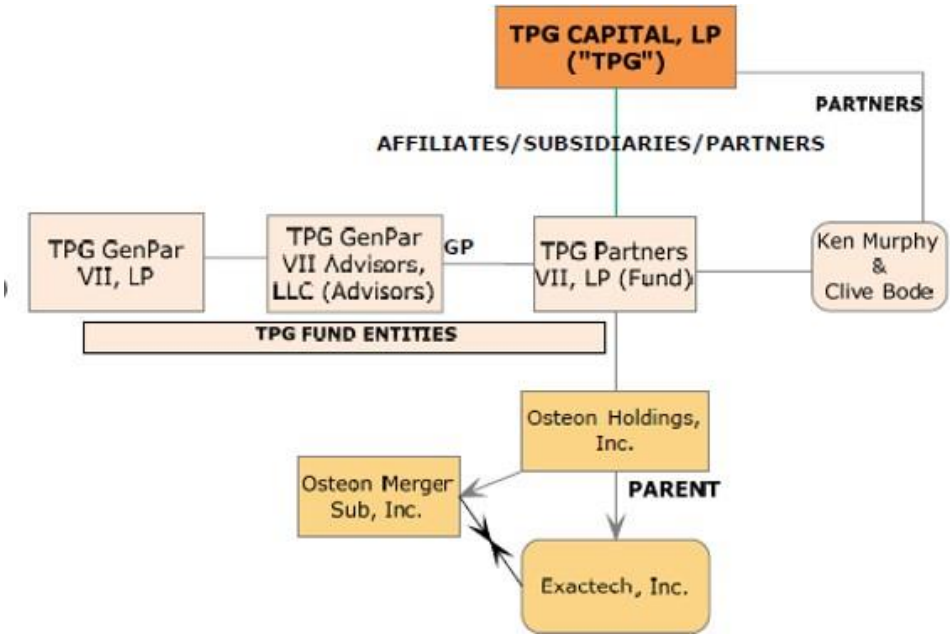
59. Defendant Osteon Holdings, Inc. is a Delaware corporation that has its principal place of business at 301 Commerce Street, Suite 300, Fort Worth, TX 76102, and is an indirect wholly owned subsidiary or indirect beneficially owned affiliate of TPG. Osteon Holdings, Inc. is a citizen of Delaware and Texas.

60. Defendant Osteon Merger Sub, Inc. is a Florida corporation that has its principal place of business at 301 Commerce Street, Suite 3300, Fort Worth, TX 76102, and is a wholly owned subsidiary of Osteon Holdings, Inc. Osteon Merger Sub, Inc. is a citizen of Florida and Texas.

61. Defendant Osteon Intermediate Holdings II, Inc., is a Delaware corporation that has its principal place of business at 2320 NW 66th Court, Gainesville, FL 32653 and has been identified in public court filings as the Parent corporation of Exactech, Inc. Osteon Intermediate Holdings II, Inc. is a citizen of Delaware and Florida.

62. Defendant Osteon Holdings, Inc. (formerly known as Osteon Holdings, LP), Defendant Osteon Merger Sub, Inc., and Defendant Osteon Intermediate Holdings II, Inc. (hereinafter "Osteon") are controlled by TPG.

63. The following chart demonstrates the relationships between these entities, as described in further detail below:



64. Defendant TPG, through and in concert with related Defendant entities TPG Partners VII, L.P., TPG Genpar VII, LP, TPG Genpar VII Advisors, LLC, Osteon Holdings, Inc. (formerly known as Osteon Holdings, LP), Osteon Merger Sub, Inc., and Osteon Intermediate Holdings II, Inc. (collectively, "TPG" or "TPG Defendants") exercised control over the acquisition of Exactech and subsequent operations of Exactech for their direct benefit and they used Exactech to engage in improper conduct as outlined her ein and caused harm to Plaintiffs through such improper conduct.

65. TPG Defendants used Exactech as an agent, alter ego, and mere instrumentality such that TPG Defendants maintained control over Exactech. Moreover, Exactech and TPG Defendants should be held jointly and severally liable for each other's conduct.

66. Other Defendants may be named in the Short Form Complaints.

JURISDICTION AND VENUE

67. The Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between each Plaintiff and each Defendant and the

amount in controversy for each Plaintiff exceeds $75,000, exclusive of interest and costs.

68. The Court has personal jurisdiction over the Exactech Defendants because at all relevant times, they engaged in substantial business activities in the State of New York and in each Plaintiff's forum state. At all relevant times, Exactech Defendants transacted, solicited, and conducted business in New York and in each Plaintiff's forum state through their employees, agents, and/or sales representatives, and authorized distributors and derived substantial revenue from such business in those states, including New York. Indeed, as set forth in further detail below, Exactech Defendants have partnered with the New York based Hospital for Special Surgery (HSS) to develop medical devices, including certain iterations of the Optetrak Knee Devices at issue in this suit. Exactech has also actively fostered its relationship with engineers and surgeons in HSS's New York facilities, resulting in many New York surgeons using Exactech Devices.

69. The Court has personal jurisdiction over the TPG Defendants because at all relevant times, they engaged in substantial business activities in the State of New York and in each Plaintiff's forum state. At all relevant times, TPG transacted, solicited, and conducted business in the State of New York and in each Plaintiff's forum state through TPG's New York office, the NASDAQ Stock Market Exchange on which TPG, Inc. is listed, and TPG's employees and agents, and derived substantial revenue from such business in those states, including New York. Indeed, TPG's Officers in New York are also Officers of Osteon Holdings and the TPG Fund entities that funded the Osteon Holdings and the Merger Sub that merged into Exactech. Furthermore, as set forth above and below, because TPG, its related entities, and Exactech served as agents, alter egos, and instrumentalities for each other, each entity's contacts are attributable to the other entities for purposes of establishing personal jurisdiction.

70. Additionally, as set herein, Exactech Defendants and TPG Defendants are multinational companies that have significant contacts in each Plaintiff's forum state, such that personal jurisdiction is proper in any such forum state. Defendants have each derived substantial revenue from the sale of Exactech Hip, Knee, and Ankle Devices in each of the States and Territories of the United States.

71. Venue is proper in this District on account of the Judicial Panel on Multidistrict Litigation's October 7, 2022 Transfer Order, 28 U.S.C. § 1407, and under 28 U.S.C. § 1391, because a substantial part of the events giving rise to this action occurred in this district.

72. Pursuant to 28 U.S.C. § 1391, venue is also proper in each federal district identified by Plaintiffs in their Short-Form Complaints, because a substantial part of the events giving rise to their respective actions occurred in those districts. Absent direct filing, this Complaint would have been filed in the Southern District of New York given that the place of injury and the Plaintiff's place of residence is within the District.

FACTUAL ALLEGATIONS

I. LIST OF NON-PARTY INDIVIDUALS RELEVANT TO EXACTECH'S HISTORY, MERGER WITH TPG DEFENDANTS, AND PLAINTIFFS' CLAIMS

73. The following list provides information and background regarding non-party individuals referenced throughout this Complaint that are important to Exactech's history, merger with TPG Defendants, and Plaintiffs' claims against Defendants.

74. Dr. William "Bill" Petty is an orthopedic surgeon and was an original founder of Exactech. Dr. Petty served as Exactech's CEO from 1985 until 2014, after which he served as the Executive Chairman and Chairman of the Board of Exactech, Inc. prior to the 2018 merger. Following the 2018 Merger, Dr. William Petty held the same position and later became the Vice Chairman and a Director.

75. Betty Petty is the wife of Dr. William Petty and is an original founder of Exactech. She served in the dual capacities of Human Resources Coordinator and Director of Marketing Communications from the founding of Exactech until 2001. She was Vice President, Human Resources from February 2000 until May 2010. Ms. Petty also served as the Vice President, Administration and Secretary of Exactech, Inc prior to the 2018 Merger. Following the 2018 Merger, Betty Petty served as Secretary for one year and then Vice President, Administration for one year.

76. Gary J. Miller, Ph.D. is an original founder of Exactech. Dr. Miller is a biochemical

engineer and served as an "innovation leader" since Exactech's inception. Dr. Miller served as Exactech's Executive Vice President, Research and Development prior to the 2018 Merger. Following the 2018 Merger, Mr. Miller served in numerous capacities, and currently serves as the Executive Vice President of Research and Development Emeritus.

77. Mr. David W. Petty is the son of Dr. William Petty and Betty Petty. David Petty became Exactech's first employee in 1988. David Petty served as Exactech's Vice President of Operations from April 1991 until April 1993, Vice President of Marketing from 1993 until 2000, the Executive Vice President of Sales and Marketing from February 2000 until December 2007, President from 2007 until 2014, and the CEO from 2014 until January 2020, leading Exactech through the Merger with TPG Defendants. David Petty has been quoted as stating "[t]he secret sauce for Exactech has been the strong patient and people focused culture. . . ."[2]

78. In January 2020, Exactech announced that Dr. William Petty and his wife, Betty Petty would retire from the company. David Petty was transitioned from his role as Chief Executive Officer to Vice Chairman of the Exactech Board of Directors.

79. Joel C. Phillips has worked at Exactech since at least 1996 and served as Exactech's Executive Vice President, Chief Financial Officer, and Treasurer prior to 2018. Following the 2018 Merger, Mr. Phillips served for a certain number of years as Exactech's Chief Financial Officer and Treasurer.

80. Bruce Thompson has been at Exactech since 2004 and served as Exactech's Senior Vice President, Strategic Initiatives prior to the 2018 Merger. Following the 2018 Merger, Mr. Thompson served from 2019 to 2022 as the Senior Vice President, Strategic Initiatives and currently serves as the Senior Vice President, International Sales.

81. Donna Edwards has been at Exactech since 2001 and served as Exactech's Vice President, Legal and General Counsel prior to the 2018 Merger. Following the 2018 Merger, Ms. Edwards served in several roles. In 2019, she served as the Vice President, Legal and from 2020

[2] Press Release, Exactech, Exactech Announces Leadership Transition (Jan. 6, 2020), https://www.exac.com/exactech-announces-leadership-transition (last visited Jan. 9, 2023).

to 2022, Ms. Edwards served as the Senior Vice President, Legal, Officer. Currently, Ms. Edwards serves as General Counsel and Senior Vice President, Legal.

82. Christopher Roche was the Director of Engineering for Exactech Inc., prior to the 2018 Merger. Currently, Mr. Roche serves as Senior Vice President of Extremities at Exactech, Inc.

83. Steven Szabo was the Vice President of Marketing for Exactech, Inc., prior to the 2018 Merger.

84. Michael Mr. LaGatta is a full-time employee of TPG and many of its subsidiaries and affiliates. For example, Mr. LaGatta has signed agreements on behalf of a number of TPG entities, including, but not limited to:

a. TPG Global, LLC - Vice President

b. TPG Holdings, L.P. - Vice President

c. TPG Partner Holdings, L.P. - Vice President

d. TPG Group Advisors (Cayman), Inc. - Vice President

e. Osteon Holdings, L.P. ("Parent") - Vice President

f. Osteon Merger Sub, Inc. - Vice President

85. Jeffrey R. Binder is currently the Chairman and Chief Executive Officer of Exactech, Inc. Since 2015, he has served as a Senior Advisor to TPG Capital.

86. Daniel P. Hann has served as Exactech's Senior Vice President, Business Development since 2019. Mr. Hann has also served as a Senior Advisor to TPG Capital since at least 2017.

87. Kerem Bolukbasi served as Exactech's Chief Financial Officer and Treasurer from 2020 through August 2022, at which time he was relieved of his duties upon the advice and consent of TPG Capital Board Members. Prior to assuming his role as Chief Financial Officer and Treasurer of Exactech, Inc., Mr. Bolukbasi served as a TPG Employee including a private equity operations executive for TPG Capital, providing interim executive leadership and operational support of the management teams and board of directors for TPG portfolio companies. Mr.

Bolukbasi also served as a TPG Advisor to Exactech.

88. Kendall Garrison serves on the nine-member Board of Directors of Exactech Inc. and is employed by TPG Capital. He joined TPG Capital in 2008 and currently serves as Principal of TPG Capital.

89. John Schilling serves on the nine-member Board of Directors of Exactech Inc. and is employed by TPG Capital. He joined TPG Capital in 2011 and currently serves as Partner, Head of Operations, TPG Capital.

90. Todd Sisitsky serves on the nine-member Board of Directors of Exactech Inc. and is employed by TPG Capital. He joined TPG Capital in 2003 and currently serves as President and Co-Managing Partner of TPG Capital.

91. Karen Golz is a member of the Exactech Board of Directors.

92. Darin Johnson joined Exactech and served as the Vice President of Marketing, Extremities from 2002 to 2016. In this role, he led Exactech's global teams of orthopedic surgeons, product managers, engineers, and sales professionals. In January 2020, Mr. Johnson became Exactech's President and Chief Executive Officer. While he continues to serve as Exactech's President, in March 2022, following the recalls discussed herein, Mr. Johnson was replaced as Chief Executive Officer by Jeffrey Binder.

II. EXACTECH'S HISTORY, GROWTH, AND DEVELOPMENT OF RELEVANT HIP, KNEE, AND ANKLE DEVICES

93. Exactech designs, manufactures, markets, distributes, and sells orthopedic implant devices, related surgical instrumentation, and biologic services to hospitals and physicians in the United States and internationally.

94. Exactech's sales and distribution activities are conducted by its wholly owned subsidiary Exactech U.S., Inc.

95. Exactech's motto is "A Great Day in the O.R." In its marketing materials Exactech explains, "Founded by an orthopedic surgeon and biomedical engineer, Exactech is committed to making every day a great day in the O.R. For the surgeon, the O.R. staff, the sales rep and, above

all, for the patient." A Great Day in the O.R. Marketing Materials © 2003.

96. Exactech, Inc. was founded in November of 1985 and was incorporated under the laws of the State of Florida by Dr. William Petty, Betty Petty, and Dr. Miller.

97. In the mid-1980s, Exactech exclusively sold hip reconstruction devices, selling a cemented hip replacement system designed by Dr. William Petty and Dr. Miller.

98. In 1991, Exactech's sales were $2.1 million.

99. To expand its product offerings, Exactech partnered with the New York based hospital, The Hospital for Special Surgery ("HSS"), which held patents for joint arthroplasty designs.

100. Exactech's partnership with HSS proved fruitful, and in 1994, Exactech introduced the Optetrak knee system based on technology licensed from HSS's patented 913 design. The Optetrak design team, under the close direction of Albert Burstein, Ph. D. and in cooperation with engineers at HSS, had developed a knee design based on the Insall/Burstein ("I/B") knee system.

101. In 1996, to raise capital to support full commercialization of the Optetrak knee system, Exactech went public with an IPO on the NASDAQ.

102. In 2005, Exactech introduced the Connexion GXL polyethylene liner for its hip replacement system – the AcuMatch A-Series – to make its hip offerings more competitive.

103. In 2009, Exactech introduced the Optetrak Logic as the next generation of its Optetrak knee system. That year, Exactech's revenue from its knee product lines alone were more than $75 million.

104. According to U.S. Securities & Exchange Commission ("SEC") filings, early in its history Exactech relied on third-party vendors for the manufacturing of all component parts, while it internally performed product design, quality assurance, and packaging. As Exactech grew, however, it began manufacturing an increasing number of device components itself.

105. In May 2010, as a key component of the growth of its internal component production capacity, Exactech completed the acquisition of 100% of the outstanding shares of Brighton Partners, Inc. Brighton Partners had been Exactech's sole source supplier of the net (or

direct) compression molded polyethylene bearings (UHMWPE inserts) used in Exactech's Optetrak knee replacement system. Exactech's May 25, 2010 press release provides in relevant part:

> The acquisition includes the company's assets, technology, and know-how to continue manufacturing at the Sarasota, Fla.-based facility. Exactech plans to retain the Brighton Partners employees and to add additional staff as needed to support the company's future growth.
>
> Exactech President David Petty stressed the importance of this strategic supply chain acquisition. "Protecting this proprietary technology is of critical importance to our knee product line, which represented more than $75 million of our total 2009 revenue. The acquisition also provides structure and resources for production expansion to support our worldwide growth," . . . .
>
> Direct compression molded polyethylene bearings are a key component of Exactech's knee replacement system. The bearings provide a smooth, gliding surface between metal components that are used to replace the damaged ends of a patient's femur (thigh) and tibia (shin) bones. Like a patient's real knee, the surface between these bones is subject to wear, making polyethylene a key factor in knee implant longevity.
>
> Albert Burstein, Ph.D., majority owner of Brighton Partners, was the lead design engineer for the Optetrak knee implant and developed the process for manufacturing the direct compression molded polyethylene used in the Optetrak knee. **This material technology is a distinguishing design feature that has been shown in laboratory studies to deliver very low wear, which contributes to the knee system's excellent long-term clinical results**.
>
> "Exactech has been our major customer throughout our history," Burstein said. "Exactech's acquisition of Brighton Partners is a logical step in assuring continual development and growth in Exactech's knee product line."[3]

(Emphasis added).

106. According to SEC filings, during the period 2002 to 2016, Exactech expanded its internal production capacity from 30% to 64%. According to its SEC Form 10-K for the fiscal year ending December 31, 2016, Exactech manufactured approximately 64% of its implant components at its facility and headquarters in Gainesville, Florida, and in two leased facilities it

[3] Press Release, Exactech & Hawk Assocs., Exactech Acquires Key Supplier, Secures Proprietary Knee Replacement Technology (May 25, 2010), https://www.exac.com/exactech-acquires-key-supplier-secures-proprietary-knee-replacement-technology (last visited Jan. 6, 2023).

operates in Sarasota, Florida, where Exactech produces its net/direct compression molded polyethylene bearings used in its Optetrak knee replacement system, as well as other instrument and implant components.

107. To supplement its manufacturing of components, Exactech formed strategic alliances with suppliers and business partners to externally manufacture the remaining components.

108. Exactech's internal manufacturing, assembly, packaging, and quality control operation were conducted at its principal headquarters in Gainesville, Florida. There, components received from suppliers, as well as those manufactured internally, were supposed to be examined by Exactech personnel to ensure that Exactech's specifications and standards were maintained.

109. In March 2016, Exactech introduced and began marketing the Vantage Total Ankle System.

110. In the first quarter of 2017, Exactech introduced and began selling the Truliant knee system – the next generation of its Optetrak knee system.

111. Later that year, Exactech began discussions about being acquired by and merged with the TPG Defendants.

112. Inventory is a critical component of Exactech's business model.

113. Exactech, through consignment and/or direct sales, provides its U.S. sales representatives and distributors inventories of its products, which remain in their possession until implanted or returned to Exactech.

114. Because the exact size of a particular component for a specific patient is not known until the time of surgery, Exactech's sales force carry a large inventory of each component of the Hip, Knee, and Ankle Devices so as to be available to the surgeon.

115. Accordingly, Exactech's inventory is a significant asset of its business.

116. Exactech has recognized in multiple SEC filings that "[i]n the event that a substantial portion of our inventory becomes obsolete, it would have a material adverse effect on the Company."

III. TPG DEFENDANTS' ACQUISITION AND CONTROL OF EXACTECH

A. TPG's Control over the Acquisition of Exactech

117. On October 22, 2017, Exactech Inc. submitted a Form 8-K Report to the SEC, reporting that it had entered into an Agreement and Plan for Merger ("Merger Agreement") with Osteon Holdings, L.P. ("Parent" and same as Defendant Osteon Holdings, Inc.) and Defendant Osteon Merger Sub, Inc., a corporation and wholly owned subsidiary of Parent.

118. The October 22, 2017 Report describes the parties to the merger acquisition and financing of Defendant Exactech Inc.

119. The Merger Agreement stated that Defendants Exactech Inc. and Osteon Merger Sub, Inc. will be merged, and Exactech Inc. will be the surviving entity and a wholly-owned subsidiary of Defendant Osteon Holdings, Inc.

120. Exhibit 10.1 to the October 22, 2017 8-K Report is a letter from Michael LaGatta, setting forth the commitments of TPG Partners VII, L.P., to purchase certain equity interests of Parent ("Letter Agreement").

121. The Letter Agreement was signed by Michael LaGatta on behalf of TPG Partners VII, L.P. and also "Agreed to and Accepted" on behalf of Parent by Michael LaGatta.

122. As noted above, Mr. LaGatta is a full-time employee of TPG who is an active member of numerous TPG entities, having e.g., signed documents in his capacity as Vice President for TPG Global, LLC, TPG Holdings, L.P., TPG Partner Holdings, L.P., TPG Group Advisors (Cayman), Inc., Osteon Holdings, L.P. ("Parent"), and Osteon Merger Sub, Inc.

123. TPG Capital negotiated the terms of the acquisition of Exactech, as it controls Osteon Holdings, L.P. and Osteon Merger Sub, Inc.

124. TPG Capital also organized and directed the financing of the merger acquisition of Exactech through TPG Partners VII, L.P., which served as the financing entity for the merger acquisition and is controlled by TPG Capital.

B. TPG'S Control over Its Affiliates

125. Osteon Holdings, L.P. and Osteon Merger Sub, Inc. are referred to as "Affiliates"

of TPG Capital in SEC filings related to the Merger Acquisition.

126. Specifically, Exactech, Inc. reported to the SEC that "Parent and Merger Sub are affiliates of global private equity firm TPG Capital." Exactech, Inc., Current Report (Form 8-K) (Oct. 22, 2017).

127. Similarly, on December 4, 2017, Exactech reported to the SEC that:

> Exactech, Inc., . . . announced today that it has entered into an amendment to its merger agreement with TPG Capital and certain of its affiliates which was previously announced on October 23, 2017. Pursuant to the amended merger agreement, the Company's common stock outstanding immediately prior to the effective time of the merger . . . will be converted into the right to receive $49.25 per share in cash. This represents an increase of approximately 17.3% over the $42.00 per share merger consideration previously agreed to by Exactech and TPG Capital. TPG Capital has also increased its equity financing commitment to $737 million for purposes of consummating the merger.
>
> Exactech's Board has approved the amended merger agreement with TPG and has determined that it is advisable, fair to and in the best interest of Exactech and its shareholders. Exactech's Board hereby recommends to Exactech's shareholders that they vote to approve the merger agreement and the merger with TPG.
>
> TPG has arranged fully committed equity financing for the transaction and there is no financing condition to consummation of the merger with the Company. Early termination of the statutory waiting period under the Hart-Scott-Rodino Act was obtained on November 17, 2017 and, accordingly, there are no anti-competitive or other regulatory approvals needed to consummate the merger with TPG Capital's affiliate.

128. In a Form 8-K, dated February 13, 2018, filed with the SEC, Exactech, Inc. reported:

> On February 14, 2018 (the "Closing Date"), pursuant to the terms of that certain Agreement and Plan of merger, dated as of October 22, 2107 (the "Original Merger Agreement"), as amended by Amendment No. 1 thereto ("Amendment No. 1 to Merger Agreement"), dated as of December 3, 2017 (as to amended, the "Merger Agreement") . . . the Company [Exactech, Inc.] became indirectly beneficially wholly owned by affiliates of TPG Capital (the "TPG Investors") and certain management shareholders of the Company.

129. The Securities Act of 1933 defines an Affiliate as an entity that "directly, or indirectly through one or more intermediaries, **controls or is controlled by**, or is under common

control with, the person [entity] specified." 17 C.F.R. § 230.405 Definitions of terms (emphasis added).

130. Osteon Holdings, L.P. ("Parent") and Osteon Merger Sub, Inc. were the corporate vehicles used by TPG Capital to consummate the merger with Exactech, Inc.

131. Both of these entities were affiliates of TPG Capital and, therefore, controlled by TPG Capital under the definition of "Affiliate" as set forth in the Securities Act of 1933.

132. Since Osteon Merger Sub, Inc. was "merged with and into Exactech, Inc.," Exactech, Inc. is considered an affiliate controlled by TPG Capital, pursuant to the merger transaction. TPG Capital accordingly is liable for the improper actions of Exactech that occurred prior to the Merger and also actions that Osteon was aware of and directed subsequent to the Merger.

C. Osteon Holdings' Conversion: Osteon Holdings, L.P. to Osteon Holdings, Inc.

133. In connection with the Exactech Merger, on or about October 22, 2017, a Rollover and Voting Agreement was executed, naming William Petty, Betty Petty, David W. Petty, and Prima Investments Limited Partnership (f/k/a Petty Family Investments, LP) as Shareholders in Osteon Holdings, L.P. Osteon Holdings L.P. was the "Parent" to the Merger.

134. On or about December 3, 2017, an amendment to this Rollover and Voting Agreement, was executed.

135. As part of the December 3, 2017 amendment ("Amendment 1"), Miller Family Holdings, LLC[4], Bruce Thompson, Joel Phillips, Donna Edwards, Chris Roche, and Steve Szabo became shareholders in Osteon Holdings, L.P.

136. According to Schedule A-1 of Exhibit A of the Rollover and Voting Agreement, only those listed on the Agreement, i.e., Exactech pre-merger executives and officers, received subject shares in Osteon Holdings, L.P., in exchange for some of their Exactech shares in the Exactech Merger. For example, Dr. William Petty held 102,400 rollover shares in the Exactech

[4] Miller Family Holdings, LLC is a Florida limited liability company wholly owned by Dr. Gary Miller, his wife, and his children).

Merger, which were exchanged for 5,821,546 shares of Class B common stock of Osteon Holdings L.P.

137. Osteon Holdings, L.P. was a limited partnership. Under basic tenets of corporate law, Limited Partnerships do not have stock or stockholders. A Limited Partnership has a general partner, who takes unlimited liability for a company's obligations, and one or more limited partners – whose liabilities are limited to the size of their investments.

138. On or about February 14, 2018, an amendment to the closing Transaction Statement (the "Final Amendment") was executed in connection with the Exactech Merger.

139. Prior to the execution of the Final Amendment, all original merger agreements and amendments referred to the Parent as Osteon Holdings, L.P.

140. In the Final Amendment, the Parent is no longer referred to as Osteon Holdings L.P. Instead, the Final Amendment refers to the Parent as Osteon Holdings Inc.

141. There is no disclosure explaining why the original Parent company, Osteon Holdings L.P. was converted to Osteon Holdings Inc.

D. TPG's Complete Control over Rollover & Voting Agreement Negotiations with Exactech

142. During the merger negotiations between April 2017 and December 2017, including various amendments to original agreements, Exactech's Executive Chairman Dr. William Petty and founding shareholders ("the Rollover Investors") "had been approached by and had held discussions with TPG . . . to inquire whether such shareholders would be willing to exchange, in connection with the merger, a portion of their shares of Common Stock for a new class of equity securities in [Osteon Holdings]," an affiliate of TPG. *See* Exactech, Inc., Proxy Statement (Form DEF 14A), at 34 (Jan. 16, 2018).

143. "As a condition to receiving new equity securities in [Osteon Holdings], the Rollover Investors have agreed to vote all of their shares of Common Stock [in Exactech] "FOR" the proposal to approve the Merger Agreement and the merger [with TPG]." *Id.* at 96.

144. "TPG and [its outside Counsel] Ropes & Gray, exchanged seven drafts of the

Original Merger Agreement, as well as multiple issues lists, and held multiple telephonic conferences to discuss and negotiate the terms and conditions of the Original Merger Agreement. . .” and reviewed several drafts of the Original Rollover & Voting Agreement (“Rollover Agreement”). *Id.* at 29-30.

145. As a result of these discussions, Osteon Holdings and the pre-merger Exactech Chairman, founding shareholders and other officers, executed the Rollover Agreement on October 22, 2017, as amended on December 3, 2017.

146. The Amended Rollover Agreement added an “automatic conversion” paragraph that allowed Exactech’s Chairman, founding shareholders, and other officers to automatically convert their individually owned shares in Osteon Holdings “immediately prior to an initial public offering” to shares in an anticipated Initial Public Offering (“IPO”) involving TPG, its partners, and affiliates.

147. TPG, Inc. completed its IPO on January 13, 2022.

148. Osteon Holdings, a TPG controlled affiliate and party to the Rollover Agreement, had no authority to commit future TPG IPO shares through an automatic conversion to Osteon Holdings shareholders.

149. TPG Capital, LP, through its common officers with its affiliates, had the authority to implement the automatic conversion of future shares under the anticipated IPO plan, since TPG, Inc. did not exist at the time the Rollover Agreement was executed.

150. TPG Capital, LP officers are also officers of Osteon Holdings. In effect, TPG and its affiliates operate as a single enterprise under the global brand name, “TPG.” Furthermore, as demonstrated by the Rollover Agreement and the Exactech January 16, 2018 Proxy Statement, TPG Capital, LP controlled Osteon Holdings and the negotiations related to the Exactech merger through its common officers, general counsel, and outside counsel.

E. TPG’s Control over the Management Agreement

151. Per the 2017 Amendment to the Rollover and Voting Agreement, Exactech would operate using TPG’s “customary management agreement.” This management agreement did not

require unanimous consent from the Exactech board. This is notable, because as set forth below, TPG placed many of its own employees on Exactech's Board and in key positions throughout the company.

152. TPG requiring Exactech to use of its own management agreement demonstrates that TPG has control over the management of Exactech.

153. The 2017 Amendment to the Rollover and Voting Agreement also said that employment agreements with TPG or its affiliates did not require unanimous consent from the Exactech board.

154. TPG requiring control of employment agreements that involve any affiliates demonstrates that it has direct control over employees at Exactech.

F. Co-Mingling Liability

155. The Merger Agreement demonstrates that the parent company, Osteon Holdings, Inc., assumed certain liabilities of the acquired company, Exactech.

156. The Merger Agreement provides that Defendants Exactech and Osteon Holdings, Inc. will jointly participate in the defense or settlement of any security holder litigation against Exactech or its directors related to the merger.

157. The Merger Agreement provides that Exactech cannot enter into any settlement agreement regarding any securityholder litigation against it or its directors relating to particular transactions without Osteon Holdings' prior written consent.

158. Osteon Holdings and TPG are named as affiliates and grouped together as "the TPG Parties" in the Final Amendment of the SEC Rule 13E-3 Transaction Statement that they jointly filed with Exactech on February 14, 2018.

159. On the SEC's Notice of Exempt Offering of Securities, six directors and seven officers of TPG are listed as "related persons" in connection with Osteon Holdings.

160. Osteon Holdings and TPG, as "the TPG parties," should be grouped together for purposes of liability under the Merger Agreement.

161. The language of the Merger Agreement and SEC filings demonstrates that the TPG

parties and Exactech co-mingle liabilities, share economic resources, and conduct and manage operations through their common officers and directors.

G. TPG's Post-Acquisition Control of Exactech

162. TPG is not a passive investor in Exactech.

163. TPG has undertaken active management of Exactech as part of its ownership of the company.

164. TPG promotes its "distinctive," "alternative," and "unique" approach to growing the companies that it invests in.

165. Part of TPG's promoted approach is being "involved in building really special companies."

166. "Building really special companies" requires more than providing money.

167. Another part of TPG's promoted "unique approach" is bringing a "family office" and "entrepreneurial" perspective to the companies that it partners with.

168. TPG promotes its ability to "create products and services [that have] delivered breakthrough innovation" in the healthcare industry.

169. In the healthcare industry specifically, TPG emphasizes its "differential insights."

170. TPG played an active role in selecting the people who would run the day-to-day operations of Exactech after the merger.

171. In meetings during June and July of 2017, TPG told Exactech that it was important for Jeffrey R. Binder (a TPG advisor) to have a central role in any potential transaction between Exactech and TPG.

172. Jeffrey R. Binder and Daniel Hann both advised TPG Capital on its acquisition of Exactech.

173. Jeffrey R. Binder became CEO of Exactech in March 2022 after joining Dr. William Petty as co-executive Chairman of Exactech in 2018.

174. Daniel Hann became Senior Vice President of Business Development of Exactech.

175. After an Exactech Board of Directors meeting in September 2017, the company's

lead independent director, Mr. James G. Binch, contacted another director, Mr. Todd Sisitsky (TPG President and Co-Managing Partner), to tell him that TPG was now permitted to speak with Exactech's founding shareholders and management team regarding equity participation, employment, and other arrangements for after the merger.

176. Eleven pre-merger officers or directors of TPG became officers or directors of Exactech post-merger.

177. TPG advisors have continued to exert direct control over Exactech since the merger.

178. Defendant Osteon Intermediate Holdings II, Inc. is the certificate holder on a Certificate of Insurance associated with Exactech, Inc. Coverage held by Osteon Intermediate Holdings II, Inc. includes, but is not limited to, products liability.

179. TPG advisors have served in at least six leadership positions for Exactech: three officer positions-filled by Jeffrey R. Binder, Daniel P. Hann, and Kerem Bolukbasi-and three director positions-filled by Kendall Garrison, John Schilling, and Todd Sisitsky.

180. One-third of the nine-member Exactech Board of Directors is composed of TPG employees.

181. As further evidence of TPG's control over Exactech, orthopedic surgeons may be incentivized to utilize Exactech products in exchange for shares of Osteon Holdings. For example, in a 2021 American Association of Hip and Knee Surgeon disclosure report, a Massachusetts-based orthopedic surgeon who is an Exactech "paid consultant" with "IP royalties" disclosed that he has "stock or stock options" in Osteon Holdings.

H. TPG's Direct Involvement in Decision Making Related to the Recall of Exactech's Hip, Knee, and Ankle Devices

182. Upon information and belief, TPG advisors and Officers directed the Exactech Hip, Knee, and Ankle Device recalls caused by accelerated polyethylene wear.

183. TPG Officers and Directors are also Officers and Directors of Osteon Holdings and Exactech. Therefore, TPG was directly involved in decision making related to the recalls.

184. Upon information and belief, in 2017 or 2018, during due diligence prior to the

acquisition of Exactech or shortly after acquiring Exactech, TPG knew or should have known of the clinical evidence of early onset failures of Exactech Devices and Exactech's non-compliance with federal regulations and current good manufacturing practices.

185. Public records reveal that Exactech had a history of device failures that may have required a voluntarily recall before the merger and after the merger.

186. Upon information and belief, in order to increase the value of TPG's ownership of Exactech, TPG chose to continue selling Exactech Hip, Knee, and Ankle Devices despite research and clinical evidence demonstrating significant product defects that were harming patients with those devices implanted in their bodies.

187. TPG's involvement in Exactech presentations after the merger demonstrates that TPG was aware of the clinical evidence of early onset failures of the Exactech Devices and participated in the corrective action plan.

188. The first recall of Optetrak devices was not issued until August 30, 2021, over three years after the 2018 Merger.

189. In November 2021, Exactech CFO and Treasurer Kerem Bolukbasi ("Bolukbasi') gave a "cash flow profile" presentation to the Exactech Board of Directors, including TPG board members and advisors, regarding the August 2021 Exactech recall which "created significant financial difficulty for Exactech . . . reflecting an estimated $60 million cash burn during 2022."[5]

190. Following this presentation and disclosure, Bolukbasi was terminated by TPG and Exactech.

191. To effectuate Bolukbasi's termination, Darrin Johnson conferred with TPG employee, and Exactech board member, John Schilling.

192. Also in November 2021, Karen Golz, a member of the Exactech Board of Directors, was appointed to the Board of Directors of another company, iRobot. The iRobot press release announcing Ms. Golz's appointment stated that Ms. Golz also serves on the Board of Directors of

[5] A cash burn means that the company would be forced to spend large sums of money in connection with the August 2021 recall.

"Osteon Holdings/Exactech, a private company controlled by TPG."

193. At all stages, TPG has been directly involved in and controlled the decision making regarding when and how to recall Exactech's defective Hip, Knee, and Ankle Devices and alert the patients and surgeons to Exactech's years' long failure to manufacture safe devices and comply with good manufacturing practices.

IV. REGULATORY FRAMEWORK APPLICABLE TO THE EXACTECH HIP, KNEE, AND ANKLE DEVICES

A. FDA's Regulatory Process for Medical Devices

194. The Food, Drug, and Cosmetic Act and associated regulations separate medical devices into 3 Classes – Class I, II, and III. Regulatory control increases from Class I to Class III. For example, most Class I devices can be marketed without any prior notification or approval from the FDA. Prior to marketing most Class II devices, however, a manufacturer must submit premarket notification (also known as a 510(k) submission) to and receive marketing clearance from the FDA. Finally, most Class III devices cannot be marketed until they receive Premarket Approval ("PMA") from the FDA.

195. A PMA application requires comprehensive data about the device's safety and efficacy, including human clinical trials, design specifications, manufacturing processes, and quality controls. A PMA application must also include proposed labeling and advertising.

196. A 510(k) submission requires much less. Through a 510(K) submission, a manufacturer must only show that that the device to be marketed is substantially equivalent to one or more legally marketed devices. The FDA does not require clinical data in most 510(k) submissions.

197. The legally marketed device(s) to which equivalence is drawn is commonly known as the "predicate." Although devices recently cleared under 510(k) are often selected as the predicate to which equivalence is claimed, any legally marketed device may be used as a predicate.

198. If FDA agrees the new device is substantially equivalent to a legally marketed device for which premarket approval is not required, the manufacturer may market it immediately.

199. Every Exactech Device at issue in this case received market clearance through the 510(k) process.

200. When a manufacturer files its 510(k) submission, the medical device is assigned a control number known as a "K" number. Where relevant in this Complaint, Plaintiffs will refer to Exactech Devices by their "K" number.

201. Pursuant to federal law, all medical devices must follow regulations that set forth Current Good Manufacturing Practices.

B. The C.F.R. and Current Good Manufacturing Practices

202. Exactech claims in its Annual Reports that its components are inspected to ensure its specifications and standards are maintained.

> Our internal manufacturing, assembly, packaging and quality control operations are conducted at our principal offices in Gainesville, Florida**. Components received from suppliers, as well as those manufactured internally, are examined by our personnel throughout the process and prior to assembly or packaging to ensure that our specifications and standards are maintained**.

(Emphasis added).

203. Exactech also repeatedly recognized, or at least paid lip service to the importance of quality control of its products in its Annual Reports:

> Quality is extremely important to us and our customers due to the serious and costly consequences of product failure. Our quality certifications are critical to the marketing success of our goods and services. If we fail to meet these standards, our reputation could be damaged, we could lose customers, and our revenue and results of operations could decline… Moreover, failure to comply with our internal standards may result in the FDA viewing our products as misbranded or adulterated and subject to voluntary or involuntary recall or seizure or other sanctions including criminal and civil penalties.

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

205. Pursuant to federal law, a device is deemed to be misbranded if, among other things,

its labeling is false or misleading in any particular, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. 21 U.S.C. § 352.

206. Pursuant to federal law, manufacturers are required to comply with FDA regulation of medical devices, including FDA requirements for records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any medical device may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury. Federal law also 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. 21 U.S.C. § 360(i).

207. Pursuant to federal law, the Secretary of Health and Human Services may prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (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.

208. The regulations requiring conformance to good manufacturing practices are set forth in 21 C.F.R. § 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.

209. Pursuant to 21 C.F.R. § 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 Drug & Cosmetic Act ("the Act"). 21 U.S.C. § 351.

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

211. Pursuant to 21 C.F.R. § 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.

212. Pursuant to 21 C.F.R. § 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.

213. Pursuant to 21 C.F.R. § 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.

214. Pursuant to 21 C.F.R. § 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.

215. Pursuant to 21 C.F.R. § 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.

216. Pursuant to 21 C.F.R. § 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.

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

218. Pursuant to 21 C.F.R. § 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.

219. Pursuant to 21 C.F.R. § 820.50, each manufacturer shall establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements. Furthermore, each manufacturer shall evaluate and select suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. This evaluation must be documented. Finally, each manufacturer shall establish and maintain data that clearly describe or reference the specified requirements, including quality requirements, for purchase or otherwise received products or services.

220. Pursuant to 21 C.F.R. § 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.

221. Such process controls shall include:

a. documented instructions, standard operating procedures (SOPs) 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 means of identified and approved representative samples.

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

223. Pursuant to 21 C.F.R. § 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.

224. Pursuant to 21 C.F.R. § 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.

225. Pursuant to 21 C.F.R. § 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.

226. Pursuant to 21 C.F.R. § 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.

227. Pursuant to 21 C.F.R. § 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.

228. Pursuant to 21 C.F.R. § 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 procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained.

229. Pursuant to 21 C.F.R. § 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 C.F.R. § 820.3(z)(1).

230. Pursuant to 21 C.F.R. § 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.

231. Pursuant to 21 C.F.R. § 820.90, each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements.

232. Pursuant to 21 C.F.R. § 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 problems;

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 preventative 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.

233. Pursuant to 21 C.F.R. § 820.130, each manufacturer is required to ensure that device packaging and shipping containers are designed and constructed to prevent the device from alteration or damage during the customary conditions of processing, storage, handling, and distribution.

234. Pursuant to 21 C.F.R. § 820.140, each manufacturer shall establish and maintain procedures to prevent damage, deterioration, contamination, and other adverse effects to their products during handling.

235. Pursuant to 21 C.F.R. § 820.150, each manufacturer shall establish and maintain procedures to prevent damage, deterioration, contamination, and other adverse effects to their products pending use or distribution. Likewise, each manufacturer is required to ensure that no obsolete, rejected, or deteriorated product is used or distributed. When the quality of a manufacturer's products deteriorate over time, the manufacturer is required to store their products in a manner to facilitate proper stock rotation and inspection of product condition.

236. Pursuant to 21 C.F.R. § 820.160, each manufacturer shall establish and maintain procedures to ensure that expired products or devices deteriorated beyond acceptable fitness for use are not distributed.

237. Pursuant to 21 C.F.R. § 820.170, each manufacturer shall establish and maintain adequate installation and inspection instructions, including directions for ensuring proper installation so that the device will perform as intended after installation. Such instructions must be distributed with the device or made available to the person installing the device.

238. Pursuant to 21 C.F.R. § 820.198, each manufacturer shall maintain complaint files. Specifically, each manufacturer is required to establish and maintain procedures for receiving, reviewing, and evaluating complaints. These procedures must ensure that all complaints involving the possible failure of a device, labeling, or packaging to meet any of the manufacturer's

specifications are processed, documented, reviewed, evaluated, investigated, and reported to FDA as required by federal regulations.

239. Pursuant to 21 C.F.R. § 803.50, each manufacturer shall file a report with the FDA no later than 30 calendar days after becoming aware of information, from any source, that reasonably suggests that the manufacturer's device (1) may have caused or contributed to a death or serious injury or (2) has malfunctioned and this device or a similar device would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.

240. As set forth in detail herein, for years Exactech failed to comply with these federal regulations and good manufacturing practices, directly and proximately causing Plaintiffs' injuries.

C. Industry Standards for Medical Device Packaging

241. In addition to these federal requirements, industry standards require medical device manufacturers such as Exactech to utilize an appropriate packaging system to ensure the safety of sterilized medical devices, like the Exactech Hip, Knee, and Ankle Devices at issue in this Complaint.

242. Industry standards and regulatory authorities like the FDA recognize the critical nature of packaging materials by considering them as an accessory or a component of a medical device.

243. Medical devices must be transported and stored under conditions that ensure that the performance characteristics of the product remain within the specified limits.

244. Medical device packaging must be designed to minimize the safety risks and health risks to the patient under the intended specified conditions of use.

245. A medical device manufacturer is required to have procedures for the design and development of packaging systems, and they must be established, documented, implemented, and maintained.

246. The design and development of a medical device package system must consider many factors, including but not limited to: the sensitivity of the product to particular risks including oxidation, radiation, moisture, and temperature, the storage environment, the distribution and

handling environment, and the expiry date limitations of the product.

247. Medical device packaging must provide adequate protection to the medical device during the hazards of handling, distribution, and storage.

248. Performance testing must be conducted on packaging systems comprised of the worst-case sterile barrier system as well as the worst-case protective packaging. The rationale for identifying the worst-case sterile barrier system shall be established and documented.

249. Stability testing must all be performed to demonstrate that the sterile barrier system maintains integrity over time. Stability testing shall be performed using real-time aging.

D. Exactech's Packaging of Polyethylene Components of its Hip, Knee, and Ankle Devices Failed to Meet Regulatory and Industry Standards

250. At all times material hereto, Exactech knew its packaging could have a direct effect on the longevity of its Devices', as the packaging played a large part in reducing the risk of in vitro oxidation during the shelf-life period between the completion of the manufacturing process and implantation in the patient.

251. Additionally, at all times material hereto, Exactech knew it was important to ensure the UHMWPE components of its Hip, Knee, and Ankle Devices were stable from an oxidation standpoint throughout the Devices' shelf-life, which Exactech had determined to be 5 to 8 years.

252. The UHMWPE components of Exactech's Hip, Knee, and Ankle Devices are not irradiation stable. The diffusion of oxygen into gamma sterilized UHMWPE that is not properly thermally treated and packaged will occur during the Devices' shelf life, prior to implantation in patients.

253. Exactech had testing and procedures in place (Process Failure Modes and Effect Analysis/ Packaging of Implants) that identified the associated consequences of the packaging process and the risk of exposure to oxidation. *See* FDA 483 Inspection, 1038671 at 3.

254. In 2007, Exactech established a protocol, "PR-2006-043 Protocol for Shelf Life Testing (5 year, 6 year, 7 year, and 8 year Real Time and Accelerated Aging) of UHMWPE and Metal Products Packaged in PET/ PE Film/ Uncoated [redacted]" and a test report "TR-2007-042

Shelf Life Report – 8 Year Accelerated Aging of UHMWPE and Metal Products Packaged in PET/ PE Film/ Uncoated [Redacted]" to establish the testing required to demonstrate that the packaging configurations for products manufactured at Exactech would remain at an acceptable level of oxidation throughout a 5-year, 6-year, 7-year, and 8-year shelf life. *See* FDA 483 Inspection, 1038671 at 1.

255. The protocol and report indicated that all of Exactech's "device implants manufactured with [redacted] are loaded into an [redacted] vacuum bag, which becomes in direct contact with the implants, and is intended to serve as an oxygen barrier." *Id*. "Acceptance criteria defined within the protocols encompassed package integrity testing for the inner and outer pouches and included leak testing [redacted] and seal strength [redacted]." *Id.*

256. However, in November 2021, FDA investigators found that "no acceptance criteria was established for the vacuum bags by means of related product testing activities, to ensure that oxidation was prevented within the packaging configuration." *Id*. at 2. "Subsequently, acceptance activities were not implemented as part of routine production activities, to ensure the integrity of the vacuum bags and adherence pre-determined product design requirements." *Id*.

257. In other words, Exactech knew of the associated consequences of vacuum sealing and oxidation, yet did no testing and implemented no quality control sampling during the lifetime of its Hip, Knee, and Ankle Devices to ensure that oxidation was prevented.

258. Further, the FDA concluded Exactech had "no documented evidence to substantiate that sample sizes employed as part of shelf-life study protocols were based on a valid statistical rationale." *Id*. at 4. Specifically, the samples that were tested for device density as part of "PR-2006-043 Protocol for Shelf Life Testing (5 year, 6 year, 7 year, and 8 year Real Time and Accelerated Aging) of UHMWPE and Metal Products Packaged in PET/ PE Film/ Uncoated [redacted]" were inadequate and Exactech's sampling plans were not based on valid statistical rationale. *Id*.

259. Despite the inadequate sample size and to deal with excess inventory, in approximately 2007, Exactech extended the shelf life of its Knee Inserts from 5 years to 8 years

and did not report this extended shelf life as a design or labeling change to the FDA.

260. Exactech extended the shelf-life for its Knee Inserts despite knowledge that orthopedic manufacturers impose a shorter shelf life so that the product can be removed from the field/inventory before reaching oxidation thresholds that can compromise the integrity of the device.

261. During the November 2021 FDA inspection, Exactech also disclosed to FDA investigators "that no process validation activities have been conducted since the manufacturing process was first implemented." *Id.* at 3. Accordingly, FDA investigators concluded "process validation activities have not been conducted for manufacturing processes intended to ensure product specifications to prevent device oxidation." *Id.* at 2.

262. FDA investigators also concluded that "acceptance activities for in-coming components have not been adequately established." *Id* at 3.

263. As a direct result of the FDA's inspection and findings of manufacturing defects, Exactech expanded its hip, ankle, and knee recalls in 2022.

264. Specifically, Exactech had packaging specifications in place that required the UHMWPE components of its Hip, Knee, and Ankle Devices be packaged in vacuum bags consisting of layers of low-density polyethylene, nylon, and an ethylene vinyl alcohol ("EVOH") barrier to protect against oxidation.

265. Without the EVOH layer, oxygen is transmitted to the UHMWPE and degrades the mechanical properties of the material.

266. Exactech purchased the vacuum bags that were intended to contain an EVOH layer from a local Florida supplier, Hillman Supply, Inc.

267. On its website, Hillman Supply describes itself as a "stocking distributor of janitorial products, packaging materials, personal protection items, facility, supplies, and much more." Hillman's website homepage features N95 masks, batteries, scotch tape, gloves, Clorox disinfecting wipes, Bounty paper towels, and toilet paper.

268. As described below, in Exactech's recent recalls, Exactech indicates that it

discovered that Hillman provided the wrong packaging for seventeen years, and Exactech failed to recognize this deficiency for seventeen years in violation of its quality assurance and quality control operating procedures, leading to hundreds of thousands of Exactech Devices being manufactured with improper packaging.

E. Exactech's History of Failing to Follow Good Manufacturing Practices, Manufacturing Defective Products, and Choosing Profits over Patient Safety

269. Prior to the Recalls at issue in this Complaint, Exactech had a long history of failing to follow good manufacturing practices, failing to report complaints timely or at all, manufacturing defective devices that cause grievous injuries to consumers, and attempting to hide the existence of product defects in order to maximize profits at the cost of patient safety.

i. Exactech's Finned Tibial Trays

270. The Optetrak knee system has been Exactech's largest product line.

271. In 2007, Exactech's Knee Division accounted for $63.4 million of its total revenue of $124.2 million, or 51% of total revenue.

272. Prior to 2011, Exactech only had two options for tibia trays within the Optetrak product line: (1) the Finned Tibia Tray (cleared in late 1994 via K936079) (typically used in primary/index surgeries) and (2) the "Trapezoid" Tray (cleared in 1995 via K933610) (typically used in revision surgeries).

273. Having only one product line for primary surgeries – the Finned Tibia Tray – was an extremely narrow product line and unusual from standard orthopedic device industry practice.

274. Exactech's Finned Tibia Tray was defective.

275. The first known and substantial disclosure to Exactech of widespread Finned Tibia Tray failures was in approximately 2005. This disclosure came from Exactech Distributor Timothy O'Neill, owner of Surgical Systems Inc. in Gorham, Maine and his primary orthopedic surgeon client, Dr. Wayne Moody.

276. Mr. O'Neill and Dr. Moody made a detailed presentation – including an intraoperation film to Exactech. Mr. O'Neill was then assured by Exactech that it would put

together a "committee" to address the failures.

277. Dr. Moody was subsequently told he was the only surgeon from whom Exactech had heard of device failures and that the problem was not with the Finned Tibia Tray, but instead with Dr. Moody's cement technique.

278. In reality, by approximately 2008, at least ten doctors and Exactech sales representatives and distributors reported that their patients were having abnormal tibial loosening problems with the Finned Tibia Tray, some within 6 to 12 months of implantation.

279. Exactech asked its consultant Dr. Ivan Gradisar, one of the primary designers of the Optetrak knee, to perform an audit of patient outcomes to determine the severity of the tibial loosening problem. The audit included patients from the Summa Health System in Akron, Ohio who received a revision knee replacement surgery between January 1, 2007 to April 1, 2008.

280. The audit was completed on April 1, 2008 and was designed to yield an acknowledgment of the issue, but not memorialize the extent of the known device failures. This was accomplished through a manipulative sample selection designed to skew the true results. First, Dr. Gradisar reviewed patients from the Summa Health System that had received a revision Total Knee Arthroplasty surgery in which an Exactech component was involved as the primary *or revision* device from January 1, 2007 to March 31, 2008. This sample selection is manipulative because it includes surgeries in which a non-Exactech Primary total knee arthroplasty was then revised with an Exactech revision device. These surgeries have no bearing on assessing primary Exactech Optetrak device failures. Including them in the audit, however, expanded the sample size to reduce the percentage of failed Exactech Primary Optetrak devices.

281. Dr. Manuel Fuentes, an orthopedic trained physician with over 20 years of experience in the orthopedic device industry who was employed by Exactech from 2006 to 2011, was able to determine that Dr. Gradisar's audit was also flawed because it excluded specific patients from being reported as "loose Exactech tibial trays," even though that was their reported condition. Moreover, Dr. Fuentes was able to identify several patients who had both knees replaced with Exactech Optetrak primary devices and both knees failed due to tibia loosenings—

but Dr. Gradisar only reported these patients as one loosening or did not categorize the failures as due to tibial loosening.

282. Despite the manipulations of the audit, Dr. Gradisar opined that four revisions of Exactech Finned Tibial Trays were attributed to a "broken tibial spine;" also a secondary condition usually caused by a loose tibial tray.

283. Further, Dr. Gradisar only categorized 33 of the 47 charts he reviewed, leaving many questions about the validity of his investigation. Nevertheless, a review of his patient summaries shows, in his self-selected sample, at least 24 Exactech Finned Tibia Trays failed, requiring a revision, due to tibial loosenings or tibial loosening related problems.

284. Dr. Gradisar also provided a description of his audit, methods, and his opinion of the causes of the tibial loosening issues. Dr. Gradisar begins "I have taken the list of all knee revisions at Summa done between 7/1/07 and 4/1/08 supplied by Mosher Medical [the Exactech distributor in the Akron, Ohio area] and reviewed the office charts looking for information regarding a possible tibia loosening issue." Gradisar continues: "I believe the issue has multiple causes and the order of significance may be different for each surgeon or even each patient." Dr. Gradisar then lists three cosmetic causes of the tibial loosening issue, the first of which becomes Exactech's primary excuse for the tibial loosening problem: problems with the surgeon's cement technique. The second and third causes are equally cosmetic and innocuous: 2. "never fail in varus particularly on the tibia" and 3. "avoid doing the morbidly obese patients." However, the fourth listed cause for the tibial loosening problem is "some implants may have a greater margin of error than others…"

285. Dr. Gradisar then describes basic orthopedic surgery protocol as "certain precautions that tilt the odds [against tibial loosening and device failure] favorably." Yet, in a recommendation to do more than follow basic orthopedic standards to "tilt the odds of device failure favorably," Dr. Gradisar opines: "It may be possible to design a stem that is more forgiving, avoid features that lead to canal pressurization but develop a secure initial mechanical fit." In other words, the design of the Finned Tibia Tray "may be" flawed.

286. Despite the lack of objective data, the carefully crafted language, and the deliberate shortcomings of Dr. Gradisar's patient audit, his report provided Exactech with sufficient information demonstrating the Optetrak Finned Tibia Tray was failing at alarming rates well outside the industry norm.

287. In spite of internal meetings regarding issues with the Finned Tibia Tray, Exactech decided a recall of the Finned Tray inventory would be financially detrimental and too much for the company to write off.

288. Instead, Exactech continued selling these defective devices while it scrambled to design a replacement product. These re-design efforts ultimately led to the development of what became known as the "Fit" tray.

289. As explained in a 2014 memorandum titled "Exactech Knee Sales Problems," the tibial component of the "Fit" Tray was rapidly developed in 2009 because the tibial components were "very sensitive to cementation technique" and "in some instances resulted in unacceptable rates of tibial loosening" and was to "reduce inventory."

290. In 2010, researchers presented an article in France ("Thelu Article") that was later published in 2012 showing that the Exactech Optetrak system had a "cumulated" survival rate at 36 months of 80.97 ± 9.1% and 76.74 ± 12% at 45 months.[6] Such a high revision rate is generally recognized as very unacceptable.

291. Exactech's Chairman and CEO, Dr. Bill Petty, Executive Vice President of Research and Development, Dr. Gary Miller and Optetrak Design Team Member, Dr. Albert Burstein responded to the Thelu Article and asserted it was "regretful" and "surprising" that Thelu "omitted important study shortcomings that would assist readers in fully understanding the reported performance of the device" and in doing so "the authors produce[d] a biased conclusion that will mislead readers."[7]

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[6] C.-E. THELU, ET AL. *Poor Results of the Optetrak Cemented Posterior Stabilized Knee Prosthesis After a Mean 25-month Follow-up: Analysis of 110 Protheses*, 98 ORTHOPAEDICS & TRAUMATOLOGY: SURGERY & RESEARCH 413, 413 (2012).

[7] William Petty et al., *Commentary on an Article by C.E. Thelu et al.: "Poor Results of the Optetrak Cemented Posterior Stabilized Knee Prosthesis After a Mean 25-month Follow-up: Analysis of 110*

292. The Finned Tibia Tray continued to be sold in the United States through at least 2018, despite Exactech's knowledge that it was defective. Exactech continued to aggressively market the Finned Tibial Tray to diminish its large inventory even though the Fit Tray was available.

293. In 2018, a qui tam action was brought by former Exactech employees accusing Exactech of violating and conspiring to violate the federal False Claims Act ("FCA") and corresponding state false claims laws as a result of Exactech submitting to federal and state healthcare programs for defective knee replacement devices surgically implanted by unsuspecting physicians and by using false statements material to those claims. The relators also allege that Exactech violated the Anti-Kickback statute and the FCA by paying remuneration to physicians who suspected the defects in order to induce them to continue to buy Exactech products. The qui tam case is set for trial in May 2023 in the Northern District of Alabama. *See U.S. ex rel. Wallace v. Exactech, Inc.*, Case No. 2-18-cv-01010-LSC (NDAL).

294. Exactech has submitted affidavits stating that following reports of revisions due to tibial loosening, Exactech determined "that the cause of the loosening was unrelated to the Device itself and instead caused by intraoperative factors." Exactech concluded that no MDR or Adverse Event report was required" to be submitted to the FDA. *See U.S. ex rel. Wallace v. Exactech, Inc.*, Case No. 2-18-cv-01010-LSC (NDAL), DE 145-1, Affidavit of Laurent Angibaud, Exactech Corporate Representative at ¶ 11.

295. Additionally, Exactech concluded that when doctors reported aseptic-loosening (loosening of the device not caused by infection), they were related to the surgeon's technique, not the device. *Id.* at Exactech Motion for Summary Judgment, DE 144 at ¶ 29.

296. While attempting to deflect blame, Exactech knowingly failed to report Adverse Events related to the loosenings and subsequent revision surgeries to the FDA, a violation of federal reporting requirements. In so doing, Exactech materially misled the FDA and the public.

Prostheses," 98 ORTHOPAEDICS & TRAUMATOLOGY: SURGERY & RESEARCH 706, 706-08 (2012).

297. Furthermore, despite having knowledge of the early onset failures of the Finned Trays, Exactech continued to manufacture, promote, sell, supply, and distribute the defective Finned Trays. Exactech failed to alert surgeons of the potential risks associated with the Finned Trays and continued to supply surgeons with marketing materials that contained false information about the safety of these devices.

298. Exactech continues to follow this same script with regard to its failed polyethylene inserts.

ii. FDA's Citations of Exactech for Failing to Follow Federal Regulations

299. On repeated occasions, the FDA has found Exactech in violation of federal regulations and good manufacturing practices.

300. On March 10, 2017, the FDA inspected Exactech to ensure its devices were in compliance and following regulations regarding post market assurances. As a result of the March 10, 2017 inspection, Exactech received multiple citations for CGMP quality system violations including:

a. Lack of or inadequate complaint procedures in violation of 21 C.F.R. § 820.198(a) – procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established;

b. Lack of or inadequate corrective and protective action ("CAPA") procedures in violation of 21 C.F.R. § 820.100(a) – procedures for corrective and preventative actions have not been adequately established;

c. Lack of or inadequate procedures for purchasing controls in violation of 21 C.F.R. § 820.50 – procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established;

d. Lack of or inadequate procedures for design validation in violation of 21 C.F.R. § 820.30(g) – procedures for design validation have not been

adequately established;

e. Lack of or inadequate procedures for design validation in violation of 21 C.F.R. § 820.30(g) – risk analysis is incomplete;

f. Lack of or inadequate training procedures in violation of 21 C.F.R. § 820.25(b) – procedures for training and identifying training needs have not been adequately established.

g. Failing to report death or serious injury in violation of 21 C.F.R. § 803.50(a)(1) – An MDR was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury.

301. Following the FDA's March 2017 inspection of Exactech, an FDA investigator found Exactech had not established procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. 2017 FDA Establishment Inspection Report, 1038671 at 28.

302. The FDA also found Exactech had no requirement or definition of good faith effort to obtain full complaint details in its complaint handling procedures.

303. The FDA further found Exactech's Complaint Handling Standard Operating Procedure 701-103-007, Rev. T dated May 3, 2016, did not require clear identification of the awareness date of complaints, the date that *any* employee of Exactech became aware of the complaint, not just Exactech's designated complaint department. *Id*. at 13, 29. Exactech also failed to include the results of specific investigations in MDR Reports and failed to send the FDA supplemental MDRs to make the FDA aware of the investigations' conclusion. *Id*. at 13.

304. Additionally, the FDA found Exactech had received 24 complaints from November 2013 to February 2017 and "did not complete an adequate investigation of 19 of the 24 complaints." *Id.* at 29.

305. When the FDA asked Exactech if it had documented any consideration it had of a field action regarding the complaints being investigated by the FDA, Exactech's Vice President, Regulatory and Clinical Affairs indicated Exactech failed to document consideration of initiation

of field action regarding the issue.

306. After reviewing specific complaints, the FDA told Exactech that "the fact that the firm did not get devices back and could not identify the lot number should not be the only reason why no corrective action is required." *Id*. at 14.

307. The FDA also found that Exactech had failed to identify actions as "Corrective Actions" pursuant to Exactech's definition in its Corrective and Preventive Actions Standard Operating Procedure 701-103-137. *Id*. at 16.

308. As a result of the FDA's March 2017 inspection, on September 19, 2017, Exactech initiated a Class II recall of its Optetrak Tibial Tray Line Extension (K023186).

309. On January 31, 2020, the FDA again inspected Exactech and found multiple CGMP quality system violations and cited Exactech for the following:

a. Lack of or inadequate procedures for purchasing controls in violation of 21 C.F.R. § 820.50 – procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established;

b. Lack of or inadequate procedures for design transfer in violation of 21 C.F.R. §820.30(h) – procedures for design transfer have not been adequately established;

c. Lack of or inadequate procedures for design validation in violation of 21 C.F.R. § 820.30(g) – procedures for design validation have not been adequately established;

d. Lack of or inadequate procedures for design validation in violation of 21 C.F.R. § 820.30(g) – risk analysis is incomplete; and

e. Lack of or inadequate design verification procedures in violation of 21 C.F.R. § 820.30(f).

310. As discussed above in Section IV(D), on November 17, 2021, following Exactech's August 30, 2021 Knee and Ankle Recall, the FDA again inspected Exactech and again found multiple CGMP quality system violations and cited Exactech for the following violations:

a. Sampling plans were not based on valid statistical rationale in violation of 21 C.F.R. § 820.250(b);

b. Lack of or inadequate receiving acceptance procedures in violation of 21 C.F.R. § 820.80(b) – procedures for acceptance of incoming product have not been established;

c. Lack of or inadequate process validation in violation of 21 C.F.R. § 820.75 (a) – a process whose results cannot be fully verified by subsequent inspection and test has not been validated according to established procedures; and

d. Incorrect translation to production specifications in violation of 21 C.F.R. § 820.30 (h) – the design device was not correctly translated into product specifications.

311. Exactech's history of regulatory violations, failure to follow good manufacturing practices, and choice of profits over safety directly relate to the problems giving rise to Plaintiffs' claims.

V. EXACTECH DEVICES AT ISSUE

A. Exactech's Total Hip Replacement Systems

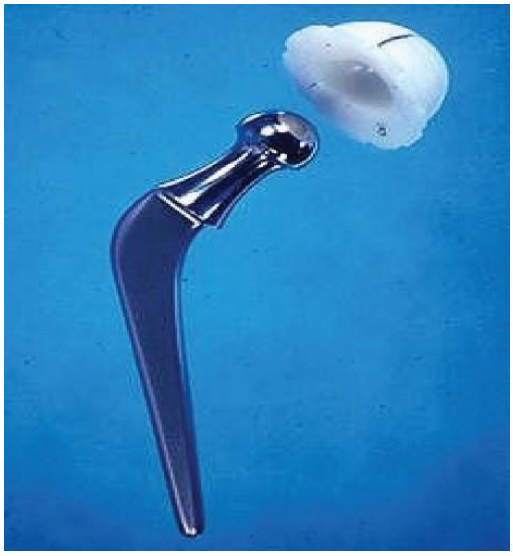
i. Total Hip Replacement Surgery

312. Total hip replacement ("THR") or total hip arthroplasty ("THA") involves the implantation of a hip implant prothesis where the natural bone and cartilage have become diseased because of osteoarthritis, osteonecrosis, or due to trauma to the hip joint.

313. Total hip replacement surgery is a surgical procedure where an incision is made near the hip to gain access to the hip joint. The surgeon will dislocate the leg from the hip and remove the natural femoral head from the femur. The surgeon will create a pocket in the femur and implant an artificial femoral stem made of a metal alloy. In the acetabulum, the hip socket where the femoral head rotates in the pelvis, the surgeon will ream a round area by using a tool that removes the bone and cartilage. The surgeon will then place or impact a metallic cup or shell that is designed to fit the size of the reamed area. The surgeon will insert a liner into the metallic

shell creating the prosthetic hip socket. The surgeon will place a metal or ceramic ball on the top end of the femoral stem and then connect the leg to the hip by placing the prosthetic femoral head that is connected to the femoral stem inside the hip socket. Once the leg is tested as to movement and range of motion, the incision is closed, and surgery is complete.

314. In the 1960s, Sir John Charnley, considered the creator of the "modern" hip implant, designed and developed a modular hip prosthesis utilizing metal alloy and UHMWPE that could be manufactured as stock and not requiring the prosthesis to be customized for an individual patient.



315. Dr. Charnley's device utilized UHMWPE as an acetabular cup that was cemented in the pelvis/acetabulum and coupled with a metal alloy femoral stem that included a metal femoral head that was cemented in the femoral canal.

316. The femoral ball would articulate within the UHMWPE acetabular cup to allow for range of motion of the leg. This bearing surface is lubricated by the patient's natural synovial fluid located in the hip capsule.

317. Through his work, Dr. Charnley quickly recognized that the amount of wear in the UHMWPE was important to the success or failure of the hip implant.

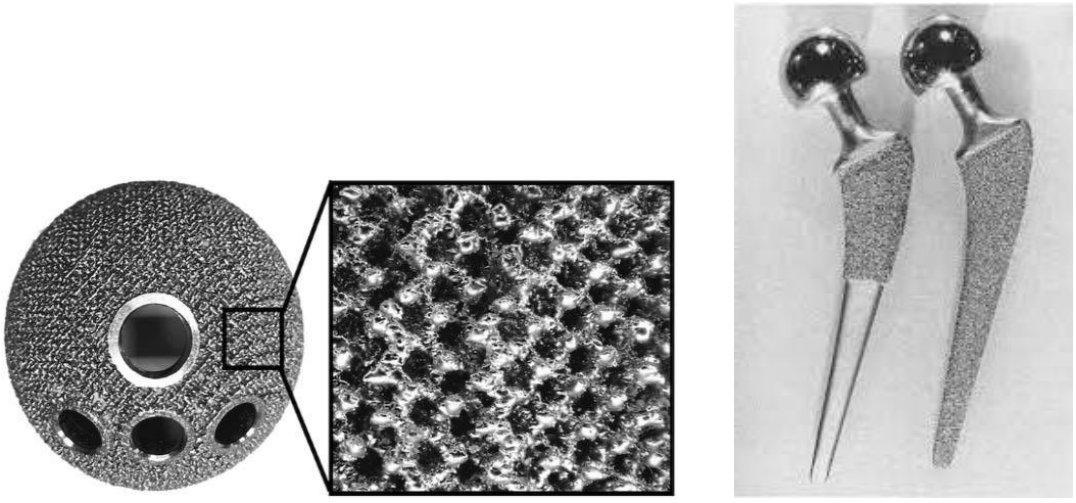
318. Early on, Dr. Charnley and others focused on the amount of wear caused by the bearing articulation of the femoral head and the acetabular liner of the hip prosthesis and the

physiologic reaction patients had to polyethylene wear debris.

319. Dr. Charnley's design of the hip device focused on low-friction with the use of UHMWPE, a highly polished stainless steel femoral head that was small in diameter (22mm) relative to the natural femoral head to reduce the surface area, and minimizing the surface roughness of the UHMWPE.

320. Through his studies and work, Dr. Charnley designed a hip implant in the 1960s that resulted in a success rate ("survivorship") where up to 90% of the devices implanted were still functioning 20 years after the primary surgery.

321. The application of bone cement to gain fixation of (1) the acetabular component to the pelvis and (2) the femoral stem to the femur has largely been replaced in the United States with device components designed to bind with bone tissue (grit blast, porous coating, plasma coating). The outer surface of the device components is made to have a rough surface that allows bone tissue to grow in and around the rough area to create "natural" fixation. This is often referred to as bony integration of the device components or bone ingrowth.



322. The surgical technique for implanting components that rely on bony integration for fixation is often referred to as press fit. In essence, the surgeon creates a hole slightly smaller than the component and then forces the device to fit in the smaller space.

323. Some acetabular shells are initially fixed to the pelvis with screws. This is an option provided to the surgeons, but long-term fixation requires bony integration. Bony integration is a crucial element in the success of any hip implant device.

ii. Polyethylene Manufacturing, Sterilization, and Adverse Events Associated with Wear Debris

324. Historically, manufacturers of orthopedic implant devices used two main types of sterilization processes to sterilize the polyethylene components prior to delivery to surgeons: gamma radiation and ethylene oxide ("ETO").

325. As early as the 1960s, it was found that exposing UHMWPE to high-energy radiation during the sterilization process altered the crystalline structure of polyethylene by creating crosslinking within the polymer structure.

326. This crosslinking enhanced the wear characteristics of the UHMWPE. Specifically, lab tests showed the wear rate of UHMWPE decreased as exposure to gamma radiation increased.

327. In the 1990s, hip implant manufacturers started using *highly* cross-linked polyethylene ("HXLPE") in acetabular liners to increase the wear resistance of the UHMWPE.

328. Specifically, in the late 1990s, manufacturers determined that exposing polyethylene hip implant liners to gamma radiation in a range between 50 to 100 kilogray (kGy) created a highly crosslinked polyethylene that performed well in wear testing. Accordingly, to achieve more dense crosslinking to decrease wear, they started to use gamma radiation above the 25 to 40 kGy range, which had been the typical range for sterilization of hip implant liners.

329. Exposing UHMWPE to radiation, however, has risks associated with the degradation of the polymer over time through an oxidative process.

330. Exposing UHMWPE to high-energy radiation breaks the carbon-hydrogen chains and creates highly reactive free radicals that recombine with adjacent molecules that form the crosslinking.

331. The crosslinking density increases with the higher the dose of radiation. If the highly reactive free radicals are exposed to oxygen, a process of oxidative degradation takes place

leading to the embrittlement of the polyethylene.

332. Even after the irradiation induced crosslinking process, there will remain highly reactive residual free radicals that, if exposed to oxygen during storage and clinical use can lead to an oxidation cascade that will degrade the polyethylene.

333. The oxidative degradation of the polyethylene component of the hip implant device clinically can lead to accelerated wear resulting in adverse tissue reactions, such as periprosthetic osteolysis and tissue necrosis.

334. For decades, hip implant manufacturers have used thermal treatments (annealing or remelting) to address the risks associated with the creation of residual free radicals as part of the radiation process. Specifically, post-irradiation remelting, heating the polyethylene past its melting point of 135 degrees Celsius, eliminates free radicals.

335. Manufacturers that anneal the crosslinked polyethylene acetabular liners below the melting point will barrier-package the liner thereby making the packaging impermeable to oxygen. Without this barrier-packaging, the oxidative degenerative process will continue during storage.

336. Furthermore, infusing the crosslinked polyethylene with vitamin E is a common added measure against oxidation. Indeed, in 2007, polyethylene hip implant liners infused with vitamin E were on the market.

337. The physiologic response to polyethylene wear debris (e.g. osteolysis) has been studied from the beginning of the use of UHMWPE as part of hip implant devices and continues to be a point of study.

338. Osteolysis is an immunologic adverse bodily reaction of bone degeneration (bone resorption) where bone is destroyed as a part of a pathological response to inflammation.

339. Periprosthetic Osteolysis is osteolytic bone resorption associated with an autoimmune response to chronic inflammation caused by particle wear debris from implanted medical devices. Periprosthetic osteolysis may result in the failure of a hip implant device.

340. Periprosthetic osteolysis associated with UHMWPE wear debris in hip implant devices is a recognized phenomenon that may occur in a small percentage of patients over time

after years of exposure to polyethylene wear debris.

341. Periprosthetic osteolysis may result in catastrophic failure of the hip implant device by destroying the bony integration between the component parts of the prosthetic and the patient's anatomy resulting in loose components. Such failure requires corrective surgery to replace the components of the hip implant device (revision surgery).

342. In some cases, periprosthetic osteolysis destroys portions of the patient's femur and/or pelvis. These types of failures greatly increase the complications of corrective surgeries and outcomes for patients.

343. Historically, in the small percentage of patients that experience periprosthetic osteolysis, hip device failure typically occurs after more than fifteen years of service.

344. Earlier failures of hip implant devices due to periprosthetic osteolysis are associated with increased amounts of polyethylene wear debris as part of an accelerated wear process.

345. Periprosthetic osteolysis is not the only adverse reaction to accelerated wear debris. Adverse local tissue reactions such as soft tissue necrosis, bone tissue necrosis, periprosthetic fluid collection, and muscle tissue necrosis, are some but not all complications associated with accelerated polyethylene wear debris.

346. Highly crosslinked polyethylene is the predominant industry standard material for the acetabular liners in THAs, particularly when used in tandem with proper thermal treatment and vitamin E dosing. The highly crosslinked polyethylene provides increased wear resistance over traditional UHMWPE or moderately crosslinked products. Post crosslinked thermal treatments (annealing or remelting) are employed to quench any remaining free radicals that could otherwise contribute to future damage by oxidation. Infusing the UHMWPE with vitamin E is commonly employed as an added measure against oxidation.

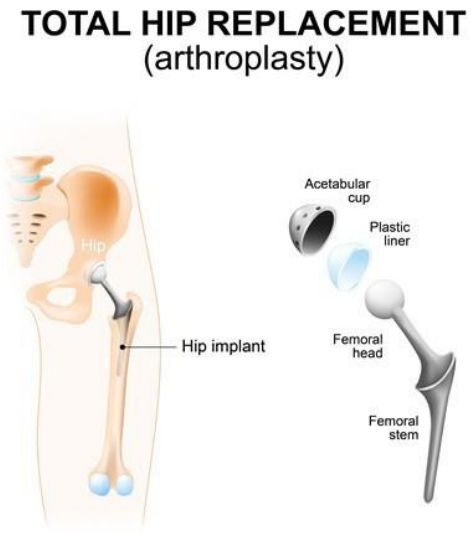
347. In fact, in March 2018 Exactech developed a new hip liner that was highly crosslinked and infused with Vitamin E and admitted "bench testing reveals that Exactech's new XLE liner does outperform the Connexion GXL liner in both volumetric wear and edge loading assessments."

iii. Exactech's Connexion GXL, Novation GXL, AcuMatch GXL, and MCS GXL Total Hip Systems

348. Throughout the relevant period, Exactech designed, developed, tested, assembled, manufactured, packaged, labeled, distributed, marketed, supplied, warranted, and/or sold the subject defective total hip replacement systems and components for use in THAs under the trade names: Connexion GXL, Novation GXL, AcuMatch GXL, MCS GXL (collectively "GXL Devices" and "Exactech Hip Devices").

349. Exactech describes its "intended use" for the Exactech Hip Devices as being "indicated for use in skeletally mature individuals undergoing primary surgery for total hip replacement due to osteoarthritis, osteonecrosis, rheumatoid arthritis, and/or post traumatic degenerative problems [and] are also indicated for revision or failed previous reconstructions where sufficient bone stock and soft tissue integrity are present."

350. The basic components associated with the Exactech Hip Devices include: a (1) acetabular cup/shell, (2) acetabular liner that fits inside the acetabular shell; (3) femoral stem that fits inside the femoral shaft; and (4) femoral head or ball that mechanically connects to the femoral stem.



351. The acetabular liners in Exactech's Hip Devices are made of UHMWPE.

352. Deviating from the industry standard, Exactech chose to use moderately crosslinked polyethylene (UHMWPE) for the acetabular liners in the Exactech Hip Devices without providing sufficient thermal treatment after crosslinking to fully quench the free radicals spawned by its crosslinking process. Nor did Exactech add an antioxidant to its UHMWPE.

353. This manufacturing process defect was exacerbated by use of gamma sterilization and out-of-specification packaging.

354. As set forth below, the Exactech Hip Devices are all adulterated and misbranded medical devices and subject to a recall due to accelerated wear of their UHMWPE liners.

iv. Exactech Total Hip Systems 510(k)

355. The polyethylene GXL Liners used with the AcuMatch A-Series and MCS Acetabular Shells were first cleared to market in 2005, via K051556. These GXL Liners were marketed as being "Enhanced Polyethylene Acetabular liners" that were "sterilized by a precision gamma irradiation dose of 25.2 – 30.8 kGy" and packaged in two sealed Tyvek® pouches.

356. Exactech marketed the GXL Liners to surgeons as a softer crosslinked UHMWPE that was less susceptible to fatigue fractures and with better wear characteristics than highly crosslinked UHMWPE acetabular liners. Exactech further touted its GXL Liners as showing less wear debris generated from use than highly crosslinked liners.

357. On its website, Exactech touted its design by criticizing competitors' gold standard manufacturing processes of UHMWPE.

> There are two general types of highly cross linked UHMWPE with post processing regimens used to address the oxidation and mechanical property degradation. Both have advantages and disadvantages, depending on the application being considered. Annealed highly cross linked UHMWPE still contains residual free radicals making it susceptible to continued oxidation. Re-melted highly cross linked poly has fewer retained free radicals, however, its mechanical and fatigue/fracture toughness properties are compromised with documented potential for structural problems. More recently, antioxidant-treated polymers (vitamin E) have also been introduced, however, the treatment does not fully eliminate oxidation potential, and the long-term effects on the body are unknown.

Gary Miller, *Optimizing Polyethylene Materials to the Application: When it Comes to*

Manufacturing Methods, Hips Are Not Knees, EXACTECH (Mar. 14, 2017), https://www.exac.com/optimizing-polyethylene-materials-to-the-application (last visited Jan. 24, 2023).

358. Exactech knew or should have known that the use of moderately crosslinked UHMWPE without proper heat treatment would create a higher risk of wear debris, periprosthetic osteolysis, component loosening, pain, adverse tissue reaction, and device failure than would the highly crosslinked thermally treated UHMWPE components used by virtually all other medical device manufacturers.

359. Furthermore, Exactech knew or should have known that failing to properly thermal treat UHMWPE after irradiation would substantially increase the risk of oxidation resulting in accelerated wear and early failure.

360. Exactech's Novation GXL liners were cleared with the Novation Crown Cup via K070479 in 2007, with the listed modifications from the predicate AcuMatch A-Series being:

a. No-Hole and Cluster Hole [shell] design options;

b. Shells manufactured from titanium (Ti) alloy with plasma coating and an additional hydroxylapatite (HA) coating option; and

c. Sphere and taper [shell] inner diameter geometry

361. The Novation GXL Liners are of the same material, design, and manufacturing processing as the GXL Liners used with the AcuMatch and the MCS hip implant systems.

362. In 2010, Exactech submitted a Special 510(k) Clearance application to modify the already cleared Novation Crown Cup and Liners, via K100269, citing modifications of hemispherical overall height of the cups and liners, modifications of cup and liner thickness, and modification of the inner diameter of the liners from predicate and previously cleared Novation Crown Cup and Liners, K070479. These modified devices replaced the then current Novation Crown Cup and Liners cleared under K070479.

363. After hearing continued complaints from surgeons about early failures of the GXL Liners for accelerated UHMWPE wear related periprosthetic osteolysis, device loosening, and adverse local tissue reactions, Exactech failed to conduct a proper root cause analysis, and instead

marketed the K100269 redesign and sold the same to surgeons as the solution to the early polyethylene failure problems.

364. After the K100269 redesign, early failures associated with accelerated wear continued. Surgeon complaints continued as well. This is unsurprising, as all of Exactech's GXL Liners were created from the same material, formulation, and manufacturing process. Accordingly, despite new iterations of the GXL Liners, they all contained the same defects: they remained moderately crosslinked, without proper thermal treatment of the irradiated UHMWPE to rid the polyethylene of free radicals, without proper packaging to protect against in vitro oxidation, without proper quality control of aging inventory, without a safe expiration date, and without proper warnings to surgeons concerning the risks of these Devices.

365. As it had in the past with prior defective products, Exactech began designing a new acetabular liner, while leaving its defective GXL Liners on the market.

366. In 2017, the same year Exactech claimed "the long-term effects" of vitamin E treated polymers are "unknown," Exactech submitted a 510(k) application for clearance to market a vitamin E infused highly crosslinked acetabular liner – the Exactech Novation and AcuMatch XLE Acetabular liners.

367. In March of 2018, Exactech received marketing clearance for the Novation and AcuMatch XLE Acetabular Liner, via K173583. Exactech frequently refers to this liner as the XLE liner or E-HXL Liner.

368. The manufacturing process used for the XLE Liners is significantly different than how Exactech manufactured its moderately crosslinked GXL Liners. Specifically, the XLE Liners, through the irradiation process, are highly crosslinked as a result of their exposure to radiation doses of 100kGy. This is far more than the approximate 50kGy exposure used in the moderately crosslinked GXL Liners. Additionally, the polyethylene used in the XLE Liners is infused with vitamin E as an added measure to combat against oxidation. The XLE Liners are also thermally treated in an annealing process to address free radicals.

369. In 2019, Exactech decided to "transition GXL liners out of the US Market in favor

of the XLE liner." *See* June 24, 2021 Hip FAQ to Exactech US Agents/Surgeons Re: GXL Liners for Novation, AcuMatch and MCS Systems at ¶ 2, attached as Exhibit A to Plaintiffs' Master Personal Injury Complaint ("MPIC") in MDL No. 3044 filed on January 26, 2023 [ECF No. 94-1].

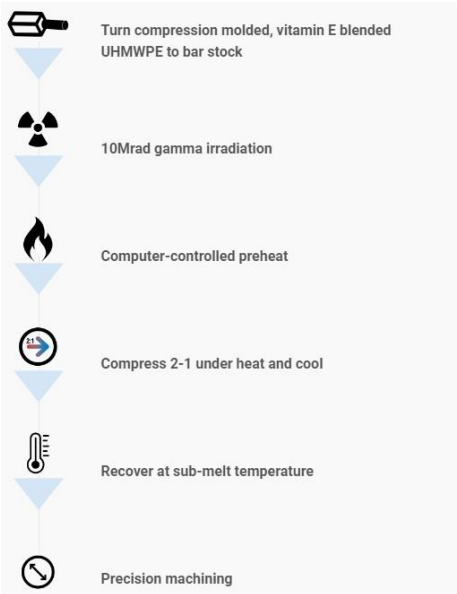
370. From 2019 until June 2021, however, Exactech never informed physicians, patients, or the medical community of this decision.

371. Exactech failed to inform the medical community that "bench testing reveals that Exactech's new XLE liner does outperform the Connexion GXL liner in both volumetric and edge loading assessments."

372. Exactech failed to inform the medical community of its "transition" to XLE Liners because it wanted to sell off its remaining inventory.

373. Now, however, Exactech promotes the XLE Liners as being superior to the GXL Liners, in that the XLE Liners have much more oxidative stability with an improved manufacturing process.

374. As part of its XLE marketing efforts, Exactech illustrates its reformulated UHMWPE manufacturing process developed by Massachusetts General Hospital in conjunction with the Cambridge Polymer Group:



See XLE Liner, EXACTECH, https://www.exac.com/hip/xle-liner (last visited Jan. 9, 2023).

375. Exactech promotes the manufacturing process of its new "next generation" XLE Liners to convince surgeons that Exactech has addressed the defects in the processing of its UHMWPE. *See* June 24, 2021 Hip FAQ to Exactech US Agents/Surgeons Re: GXL Liners for Novation, AcuMatch and MCS Systems at ¶ 2, attached as Exhibit A to Plaintiffs' MPIC in MDL No. 3044 filed on January 26, 2023 [ECF No. 94-1].

376. Exactech further promotes the use of XLE Liners when surgeons perform a "poly swap" and substitute the GXL Liner with an XLE Liner.

v. Exactech's False and Misleading Marketing, Sale, and Distribution of its Total Hip Systems

377. At all relevant times, Exactech marketed, sold, and distributed its Exactech Hip Devices internationally and throughout the United States, including New York and each Plaintiffs' forum state. Exactech generated substantial revenue as a result.

378. From 2005 up to the first recall of the GXL Liners on June 29, 2021, Exactech made false and misleading statements about the GXL Liners in order to sell its Exactech Hip Devices to surgeons. Surgeons relied on these false and misleading statements in their decisions to implant Exactech Hip Devices in their patients.

379. In promoting its Exactech Hip Devices to surgeons, Exactech, knowing them to be false, made the following misrepresentations.

a. Connexion GXL has robust wear resistance and fracture resistance properties as evidenced by bench testing and large long-term clinical follow-up series.

b. The GXL liner UHMWPE undergoes two precision split-doses of 25kGy irradiation for a total of 50kGy.

c. All Exactech acetabular liners (including all UHMWPE components) are vacuum packaged in sterile-barrier packaging materials to maintain oxidative stability in storage until implantation.

d. Our manufacturing process typically involves the final machining of semi-

completed raw materials of both our metal and polyethylene, or compression molded plastic, components that make up our joint replacement systems. After parts are machined, they are inspected and processed for final polishing and finishing as needed. Prior to packaging, our parts are inspected again to ensure that they are within approved specifications. Packaged finished parts are then made sterile and ready for surgery through gamma irradiation performed by an outside vendor. *See* Exactech, Inc., Annual Report (Form 10-K), at 6-7 (Mar. 3, 2016).

e. "Connexion GXL uses two split-precision irradiation doses of 25kGy each for a total of 50kGy of irradiation utilizing compression-molded UHMWPE. This process provides reduced wear by 59 percent over the clinically successful, standard Exactech polyethylene while maintaining an acceptable level of fracture toughness." *Connexion GXL Polyethylene Liner*, EXACTECH, https://www.exactech.co.jp/hip/connexion-gxl-polyethylene-liner (last visited Jan. 18, 2023).

f. "Connexion GXL enhanced polyethylene acetabular liners provide a low wear rate while maintaining an appropriate level of fracture toughness." *Id.*

g. Defendants told their sales representatives in a document labelled "For Internal Use Only" that "Connexion GXL acetabular liners were developed to create a polyethylene articular couple that creates a robust arthroplasty respecting the need for lower wear, sufficient fracture toughness, and oxidation behavior to provide a **lifelong implant for patients."** (Emphasis added). (See Peterson, M. J., Yassaman, N., Assessing the Long-Term Clinical Performance of Connexion GXL Polyethylene Acetabular Liners in Total Hip Arthroplasty. 2017 Exactech Brochure.)

h. "Connexion GXL liners are a result of development programs that are advancing bearing surface technology *while focusing on increasing the*

longevity of total hip prostheses." (Emphasis added). http://www.exac.com/products/hip/emerging- technologies/connexion-gxl-polyethylene, as of May 25, 2008, as available on The Internet Archive.

i. The GXL "provides a 59% wear reduction" over what it deemed was their "clinically successful" standard polyethylene liners.

j. Components received from suppliers, as well as those manufactured internally, are examined by our personnel throughout the process and prior to assembly or packaging to ensure that our specifications and standards are maintained. *See* Exactech, Inc., Annual Report (Form 10-K), at 7 (Mar. 3, 2016).

k. We have implemented strict quality control measures and currently maintain product liability insurance in amounts that we believe are typical in the industry for similar companies. *See Id.* at 8.

vi. Exactech's Total Hip Systems Class 2 Device Recalls

380. Following mounting complaints and reports of failed Exactech Hip Devices, on June 24, 2021, Exactech published Frequently Asked Questions (FAQs) regarding Exactech's Connexion GXL acetabular polyethylene liners for its US Sales Agents and surgeon customers. Therein, Exactech claims that it is not removing or recalling the GXL Liners from the field, but admits that patients are at a higher risk of lysis from "premature" wear of the GXL UHMWPE acetabular liner. *See* June 24, 2021 Hip FAQ to Exactech US Agents/Surgeons Re: GXL Liners for Novation, AcuMatch and MCS Systems at ¶ 2 attached as Exhibit A to Plaintiffs' MPIC in MDL No. 3044 filed on January 26, 2023 [ECF No. 94-1].

381. In the FAQs, Exactech downplays the risks and scope of the problem with the GXL Liners in an effort to minimize the magnitude of its GXL Liner issues to its sales force and surgeons. Exactech deceptively suggests that the defects with the GXL Liners are not a risk to all patients that have been implanted with these defective products. Specifically, Exactech states, "[b]y analyzing post-market data, Exactech has become aware of certain conditions that may put

certain patients at higher risk of premature wear of the GXL UHWPE (sic) acetabular liner." *Id.* 1.

382. Exactech also used these FAQs to blame surgeons and patients for the defects of the GXL Liners by claiming that the accelerated wear of the GXL Liners is due to:

a. Improper surgical positioning of the hip implant components; and

b. High activity level of patients.

Id. ¶ 3.

383. Furthermore, Exactech shamelessly employs the FAQs to promote its XLE Liners by urging surgeons to utilize the XLE Liners when performing corrective revision surgeries on those patients suffering from a failed Exactech hip implant caused by the accelerated wear of the GXL Liners. *Id.* at ¶ 4.

384. In its FAQs, Exactech represents that laboratory testing proves that the highly crosslinked XLE liners outperform the moderately crosslinked GXL Liners in both volumetric wear and edge loading assessments and are a safer alternative to the defective GXL Liners. *Id.* ¶ 2, 5.

385. In its FAQs, Exactech instructed surgeons to report failures of the GXL Liners to their local Exactech Agent and they in turn would report same to "Exactech's Post Market Quality department for investigation, potential reporting to the FDA (MDR), and continuous monitoring." *Id.* ¶ 11.

386. Exactech, in its FAQs, failed to require or even request that surgeons maintain, store, or provide Exactech the explanted GXL Liners for investigation and/or analysis. It also failed to request radiographs or any medical records that would assist in evaluating the root cause of failures.

387. On June 28, 2021, four days after issuing its Frequently Asked Questions letter, Exactech issued an Urgent Dear Healthcare Professional Communication ("June 28, 2021 Hip DHCP Letter") concerning Exactech Connexion GXL acetabular polyethylene liners to surgeons, hospitals, and healthcare professionals, attached as Exhibit B to Plaintiffs' MPIC in MDL No.

3044 filed on January 26, 2023 [ECF No. 94-2].

388. Exactech used this June 28, 2021 Hip DHCP Letter to attempt to deflect academically published criticism of early clinical failures of GXL Liners due to accelerated wear and osteolysis associated therewith. Such articles include:

a. *Early Polyethylene Failures in a Modern Total Hip Prosthesis*: *A Note of Caution* – a 2019 article published in the widely circulated Journal of Arthroplasty. The authors, after review of patient records for a ten year time period between 2009 and 2019 of individuals implanted with the GXL Liners, concluded that after "[c]onsidering that no identifiable risk factors related to patient demographics or implant position were identified, the Exactech Connexion GXL liner may be prone to a high rate of early failure from wear and secondary osteolysis."[8];

b. *Early Failure of a Modern Moderately Cross-Linked Polyethylene Acetabular Liner* – a 2020 article published in ARTHROPLASTY TODAY. The authors reviewed five cases of catastrophic early polyethylene wear of patients implanted with the GXL liner. The authors concluded that the "catastrophic early polyethylene wear demonstrates a concerning trend with the use of the Exactech Connexion GXL liner."[9]; and

c. *Unexpected Wear of a Moderately Crosslinked Polyethylene in Total Hip Arthroplasty* – a 2021 article in which the authors reviewed the clinical data of patients implanted with the GXL Liners and concluded that "[t]he data suggest unexpectedly high wear rates for a moderately crosslinked polyethylene. Nearly half (43%) of the study cohort cases could be at risk for osteolysis. . . "[10]

[8] W. CHRISTIAN THOMAS, ET AL., *Early Polyethylene Failure in a Modern Total Hip Prosthesis: A Note of Caution,* 35 J. ARTHROPLASTY 1297 (2020).
[9] CYNTHIA A KAHLENBERG, ET AL., "*Early Failure of a Modern Moderately Cross-Linked Polyethylene Acetabular Liner,*" 6 ARTHROPLASTY TODAY 224, 226 (2020)
[10] RAMANKANTH R. YAKKANTI, ET AL., *Unexpected Wear of a Moderately Crosslinked Polyethylene in*

389. Exactech's June 28, 2021 Hip DHCP Letter did not inform surgeons that it was recalling the GXL Liners from the market. Rather, it downplayed the extent of the clinical problems associated with the GXL Liners. For example, in the letter Exactech states, a "small percentage of patients (.118%)" that are 3-6 years from the initial implant surgery have experienced "early linear and volumetric wear." It further states that "[i]n some of these patients, wear has led to proximal femoral and acetabular lysis." Exhibit B to Plaintiffs' MPIC in MDL No. 3044 filed on January 26, 2023 [ECF No. 94-2], June 28, 2021 Hip DHCP Letter at 1.

390. As with the FAQs, the June 28, 2021 Hip DHCP Letter again pointed to surgeons' techniques and patients' activity levels as the root cause of the failures in an effort to avoid blame for and publicity of the defects in its Hip Devices that would jeopardize sales and market share. *Id*.

391. Exactech disingenuously made the above statements regarding surgeons' techniques and patients' activity levels without performing post-revision surgery investigation of individual patient medical records and radiographs.

392. On June 29, 2021, the day after issuing its Dear Healthcare Provider Letter, Exactech initiated a Class 2 product recall with the FDA, FDA Event ID 88126 (June 2021 Hip Recall), for all Exactech hip systems that utilize the GXL Liners. The recall was issued due to the identified increased risk of adverse health effects and high failure rates from "premature" polyethylene wear of the GXL Liners. *See* June 29, 2021 Hip FDA Recall attached as Exhibit C to Plaintiffs' MPIC in MDL No. 3044 filed on January 26, 2023 [ECF No. 94-3].

393. In addition to not alerting surgeons that the GXL Liners were going to be recalled, Exactech's June 28, 2021 Hip DHCP Letter also did not suggest or encourage healthcare providers to reach out to their patients to inform them of the issue or Recall with the GXL Liners. The only "actions to be taken" were for the healthcare provider to review the communication, contact their local Exactech representative with any questions, and sign a form confirming receipt of the letter.

Total Hip Arthroplasty, ARTIC. PRESS, 2021.

394. Unlike subsequent recall communications, Exactech did not draft an exemplar letter for healthcare providers to provide to patients, nor did it offer to provide a list of patients who had received the affected devices.

395. As a result, many patients with GXL Liners were unaware of the June 2021 Recall.

396. Prior to the June 29, 2021 recall, Exactech had already transitioned the GXL Liners out of the U.S. market and replaced them with the highly crosslinked vitamin E infused XLE liners.

397. Exactech had a duty to know and knew or should have known that there were defects in the manufacture of the GXL Liners and that the defects resulted in the embrittlement and accelerated degradation of the UHMWPE prior to implantation in patients.

398. Exactech knew or should have known that there were defects in the design of the GXL Liners and that the defects resulted in the accelerated degradation of the UHMWPE prior to implantation in patients.

399. Exactech failed to timely investigate the root causes of early failures of the GXL Liners, and had it done so, the defects in manufacture and design of these devices would have been identified much earlier and many patients would have been spared debilitating injuries and unnecessary surgeries.

400. As discussed above, in November 2021, the FDA sent investigators to Exactech and following an eight-day inspection they found multiple CGMP quality system violations and cited Exactech for:

a. Lack of or inadequate procedures for purchasing controls in violation of 21 C.F.R. § 820.50 – procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established;

b. Lack of or inadequate procedures for design transfer in violation of 21 C.F.R. §820.30(h) – procedures for design transfer have not been adequately established;

c. Lack of or inadequate procedures for design validation in violation of 21

C.F.R. § 820.30(g) – procedures for design validation have not been adequately established;

d. Lack of or inadequate procedures for design validation in violation of 21 C.F.R. § 820.30(g) – risk analysis is incomplete; and

e. Lack of or inadequate design verification procedures in violation of 21 C.F.R. § 820.30(f).

401. More than a year after the June 2021 Hip Recall, on August 11, 2022, Exactech initiated a second Class 2 Recall, FDA Recall Event ID 90279 (August 2022 Hip Recall), of all moderately crosslinked GXL acetabular Liners. This expanded recall included the AcuMatch GXL, MCS GXL, and the Novation GXL liners. *See* August 2022 Hip Recall attached as Exhibit D to Plaintiffs' MPIC in MDL No. 3044 filed on January 26, 2023 [ECF No. 94-4].[11]

402. That same day, Exactech sent an Urgent Dear Healthcare Professional Communication (August 11, 2022 Hip DHCP Letter) to Surgeons, Hospitals, and Healthcare Professionals, attached as Exhibit E to Plaintiffs' MPIC in MDL No. 3044 filed on January 26, 2023 [ECF No. 94-5].

403. The August 11, 2022 Hip DHCP Letter refers to a July [sic] 2021 Urgent Dear Healthcare Professional communication and provides that "[t]he purpose of the July [sic] 2021 communication was to inform surgeons that Exactech had observed a higher-than-expected number of cases in which the Connexion GXL liner Exhibited early linear and volumetric wear with associated periacetabular and proximal femoral osteolysis." *Id.* at 1.

404. Additionally, the August 11, 2022 Hip DHCP Letter admits that Exactech had improperly packaged its GXL Liners in out of specification vacuum bags since 2004, which could lead to accelerated wear, early failure, and osteolysis in patients. *Id.* at 2.

405. Interestingly, Exactech's new XLE Liners, which have been on the market since 2018, were not identified as being affected by the August 2022 non-conforming packaging recall.

406. Regarding the risks associated with the use of non-conforming packaging, the

[11] This expanded Recall also included conventional UHMWPE acetabular liners.

August 11, 2022 Hip DHCP Letter specifically states:

> **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.**

Id. at 2 (emphasis in original).

407. Accordingly, more than a year after its initial hip recall, Exactech advised it was expanding the scope of the June 2021 recall because "the previous [recall] letter included only surgeons that had implanted Connexion GXL liners between 2015 and 2021" and the expanded recall went back another eleven years to GXL Liners implanted since 2004. *Id*. at 2.

408. Notably, the prior June 28, 2021 Hip DHCP Letter does not limit its application to devices implanted between 2015 and 2021.

409. In addition to discussing its defective packaging, Exactech's August 11, 2022 Hip DHCP Letter contains a section regarding its "background and synthesis of worldwide clinical data regarding Exactech Connexion GXL and conventional hip polyethylene" in which Exactech admits:

> Our analysis shows that this moderately cross-linked material, which is unique to the Connexion GXL liner, is inherently more susceptible to oxidation and polyethylene wear in the hip versus modern, highly crosslinked Vitamin E polyethylene liners. This susceptibility is heightened when it is packaged in non-conforming bags, which allow increased oxygen diffusion.

Exhibit E to Plaintiffs' MPIC in MDL No. 3044 filed on January 26, 2023 [ECF No. 94-5] at 3.

410. Importantly, Exactech recognizes that "[w]hile it appears that most patients with premature wear have symptoms of hip and / or groin pain, we have also observed that premature wear and lysis can occur in asymptomatic patients." *Id*.

411. Exactech provided surgeons with two draft letters directed to patients and recommended surgeons customize the letters and send them to patients to notify them of their

recalled implants. *Id.* at 4.

412. In its August 11, 2022 Hip DHCP Letter, Exactech recommended that if the surgeon desired to perform an isolated polyethylene exchange (versus a full revision surgery), Exactech could provide the surgeon with its new Vitamin E infused XLE Liner.

413. At all relevant times, Exactech knew or should have known that the UHMWPE components of its Hip Devices were improperly packaged.

414. The packaging method, process, and requirements for the polyethylene components of the Exactech Hip Devices are an integral part of Exactech's manufacturing process.

415. Exactech knew that if its packaging lacked an EVOH barrier, oxygen would diffuse into the gamma sterilized GXL Liners, the oxygen would react with free radicals created and not properly addressed by thermal treatments in the manufacturing process, and this oxygen exposure and reaction would result in high rates of oxidation and embrittlement of the GXL Liners' UHMWPE.

416. This problem was made worse by Exactech failing to determine the proper shelf life for its GXL Liners.

417. This improper shelf-life, coupled with the failure to barrier package the devices to prevent oxidation, greatly increased the risk of oxidation and embrittlement of the UHMWPE of the devices.

418. For seventeen years, Exactech failed in its Quality Systems by not identifying that the packaging for its UHMWPE components were defective because they did not contain an EVOH barrier per its material certification and design specifications.

419. At all times material hereto, Exactech failed to sample and audit its Hip Devices including its acetabular liners to determine that the packaging did not conform to specification requirements.

420. Exactech knew at least as early as 2018 that the GXL Liners were not properly packaged in accordance with its material certification and design specification.

421. Nonetheless, Exactech risked patients' safety in hopes that the defects would not

result in high failure rates.

422. The use of moderately crosslinked polyethylene, failure to properly heat treat the UHMWPE during manufacturing, the failure to properly package the devices, and/or the failure to have an appropriate expiration date were all defects in the design and manufacture of the GXL Liners.

423. Had Exactech properly tested, investigated, and/or had appropriate quality systems in place, Plaintiffs would have been spared debilitating injuries and unnecessary surgeries due to wear debris from the GXL Liners' use *in situ.*

424. Exactech's failures and defects in the design and manufacture of the GXL Liners are the direct and proximate cause of Plaintiffs' injuries and damages.

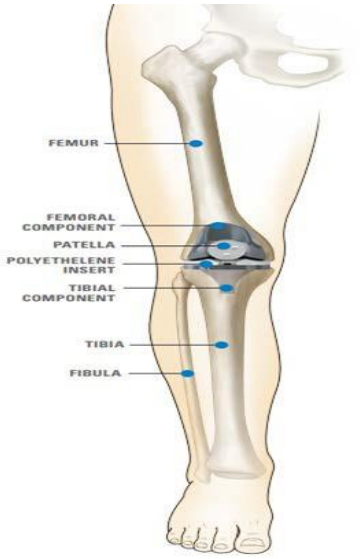
425. Because of Exactech's tortious acts and omissions, including but not limited to its negligence in design and manufacture, including packaging, of its GXL Liners, patients implanted with the GXL Liners have had to undergo (or likely will have to undergo) significant revision surgeries to remove and replace the defective devices.

426. Patients implanted with Exactech GXL Liners that failed due to accelerated wear have suffered significant and continuing pain and personal injuries as well as substantial medical bills and expenses.

B. Exactech's Total Knee Arthroplasty Systems

i. Total Knee Arthroplasty

427. The knee is the largest joint in the body and is made up of the lower end of the thigh bone (femur), the upper end of the shin bone (tibia), and the kneecap (patella). The surfaces where these three bones touch are covered with cartilage, a smooth substance that cushions the bones and allows them to move easily. Healthy cartilage allows movement in the knee without pain while walking, running, or going up stairs. All remaining surfaces of the knee are covered by a thin smooth liner that releases a special fluid to lubricate the knee. This eliminates friction, or rubbing, almost completely in a healthy knee.



428. Normally, all of the knee components work in harmony. But disease or injury can disrupt this harmony, resulting in pain, muscle weakness, and increased friction.

429. Osteoarthritis, the most common form of arthritis, is a condition that causes wear and tear to the joint cartilage. It develops after years of constant motion and pressure in the joints. As the cartilage continues to wear away, the joint becomes painful and difficult to move. If non-surgical treatment options are unsuccessful, surgeons may recommend total knee revision surgery.

430. Total Knee Arthroplasty ("TKA") or alternatively Total Knee Index surgeries are the surgical procedure that replaces the natural knee structure and articulation with prosthetic devices. This surgical procedure was developed in the 1970s.

431. Total knee replacement surgery is a major operation to remove the damaged parts of the knee joint and replace them with manufactured parts, including metal femoral and tibial components and a polyethylene insert component to replace the cartilage and facilitate the smooth articulation of the metal tibial and femoral components. During surgery, the joint is exposed by an incision made down the center or off to the side of the knee. The damaged bone ends are removed and replaced with components designed to recreate the natural contours of the bones in a healthy knee. The metal and polyethylene implants are intended to allow the bones to smoothly glide against each other, like natural cartilage.

ii. Polyethylene Manufacturing, Sterilization, and Adverse Events Associated with Wear Debris

432. UHMWPE is used as the predominant bearing material (the polymer tibial insert or polyethene insert) in TKAs.

433. The use of UHMWPE as a bearing material (polymer tibial insert) for knee transplants was pioneered by Dr. Frank Gunston while studying under the tutelage of hip arthroplasty advocate Sir John Charnley at the Wrightington Hospital in the United Kingdom. Industry acceptance and adaptations of Dr. Gunston's utilization of UHMWPE as a principal bearing material for knees was fully entrenched in the 1970s and 1980s.

434. UHMWPE, in its original form, is a resin powder and accordingly must be consolidated into a uniform solid before it can be used in the production of medical devices. The three methods for consolidation include ram extrusion, compression molding, and direct compression molding ("DCM"), sometimes referred to as net compression molding.

435. With DCM, UHMWPE is converted into sheet under controlled time, pressure, and temperature and then turned into rod or other shapes to facilitate machining operations by orthopedic manufacturers. Using DCM, the manufacturer converts the resin into finished or semifinished components.

436. The predominant industry standard for consolidation is sheet compression molding. Exactech deviates from this standard through its utilization of direct compression molding to produce its knee inserts.

437. Historically, manufacturers of orthopedic implant devices used two main types of sterilization processes to sterilize the components prior to delivery to surgeons: gamma radiation and ethylene oxide ("ETO").

438. As early as the 1960s, it was found that exposing UHMWPE to high-energy radiation during the sterilization process altered the crystalline structure of the polyethylene, creating crosslinking within the polymer structure.

439. This crosslinking enhanced the wear characteristics of the UHMWPE. Specifically,

lab tests showed that the wear rate of UHMWPE decreased as exposure to gamma radiation increased.

440. In the 1990s, orthopedic implant manufacturers started using highly cross-linked polyethylene (HXLPE) to increase the wear resistance of the UHMWPE. HXLPE was clinically introduced in 2001 for the tibial inserts in total knee arthroplasties.

441. In the 1990s, manufacturers used gamma radiation above the 25 to 40 kilogray (kGy) range, typical for sterilization of knee implant tibial inserts, to achieve more dense crosslinking to decrease wear.

442. In the late 1990s, manufacturers determined that exposing polyethylene knee inserts to gamma radiation in a range greater than 50 kGy to 100 kGy created a highly crosslinked polyethylene that performed well in wear testing.

443. Exposing UHMWPE to radiation, however, has risks associated with the degradation of the polymer over time through an oxidative process.

444. Exposing UHMWPE to high-energy radiation breaks the carbon-hydrogen chains and creates highly reactive free radicals that recombine with adjacent molecules that form the crosslinking.

445. The crosslinking density increases with the higher the dose of radiation. If the highly reactive free radicals are exposed to oxygen, a process of oxidative degradation takes place leading to the embrittlement of the polyethylene.

446. Even after the irradiation induced crosslinking process there will remain highly reactive residual free radicals that if exposed to oxygen during storage and clinical use, can lead to an oxidation cascade that will degrade the polyethylene.

447. The oxidative degradation of the polyethylene component of the knee implant device clinically can lead to accelerated wear resulting in adverse tissue reactions, such as periprosthetic osteolysis and tissue necrosis.

448. For decades, knee implant manufacturers have used thermal treatment (heat) to address the risks associated with the creation of residual free radicals as part of the radiation

process. Specifically, post-irradiation remelting, heating the polyethylene past its melting point of 135 degrees Celsius, eliminates free radicals.

449. Manufacturers that anneal the crosslinked polyethylene tibial inserts below the melting point will barrier-package the insert, making the packaging impermeable to oxygen. Without this barrier-packaging, the oxidative degenerative process will continue during storage.

450. Furthermore, infusing the crosslinked polyethylene with vitamin E is a common added measure against oxidation. Indeed, in 2007, vitamin E infused polyethylene components of orthopedic implant devices were on the market.

451. The physiologic response to polyethylene wear debris (e.g. osteolysis) has been studied from the beginning of the use of UHMWPE as part of knee implant devices and continues to be a point of study.

452. Osteolysis is an immunologic adverse bodily reaction of bone degeneration (bone resorption) where the tissue is destroyed as a part of a pathological response to inflammation.

453. Periprosthetic Osteolysis is osteolytic bone resorption associated with an autoimmune response to chronic inflammation caused by particle wear debris from implanted medical devices. Periprosthetic osteolysis may result in the failure of a knee implant device.

454. Periprosthetic osteolysis associated with UHMWPE wear debris in knee implant devices is a recognized phenomenon that may occur in a small percentage of patients over time after years of exposure to polyethylene wear debris.

455. Periprosthetic osteolysis may result in catastrophic failure of the knee implant device by destroying the bony integration between the component parts of the prosthetic and the patient's anatomy resulting in loose components. Such failure requires corrective surgery to replace the components of the knee implant device (revision surgery).

456. In some cases, periprosthetic osteolysis destroys portions of the patient's femur and/or tibia. These types of failures greatly increase the complications of corrective surgeries and outcomes for patients.

457. Historically, in the small percentage of patients that experience periprosthetic

osteolysis, device failure typically occurs after more than fifteen years of service.

458. Early failures of knee implant devices due to periprosthetic osteolysis are associated with increased amounts of polyethylene wear debris as part of an accelerated wear process.

459. Periprosthetic osteolysis is not the only adverse reaction to accelerated wear debris. Adverse local tissue reactions such as soft tissue necrosis, bone tissue necrosis, periprosthetic fluid collection, and muscle tissue necrosis, are some but not all of the complications associated with accelerated polyethylene wear debris.

460. HXLPE is the predominant industry standard bearing material for the tibial insert component of TKAs, particularly when used in tandem with proper thermal treatment and vitamin E dosing. The highly crosslinked polyethylene provides increased wear resistance over traditional UHMWPE or moderately crosslinked products. Post crosslinked thermal treatments (annealing or remelting) are employed to quench any remaining free radicals that could otherwise contribute to future damage by oxidation. Infusing the UHMWPE with vitamin E is commonly employed as an added measure against oxidation.

iii. Exactech's Optetrak, Optetrak Logic, and Truliant Knee Systems

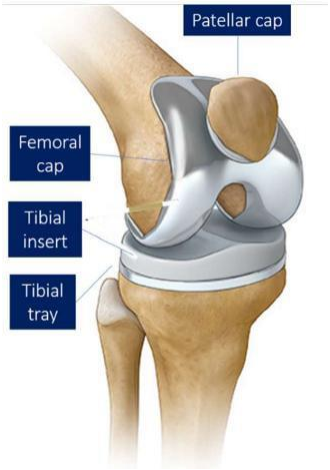
461. Throughout the relevant period, Exactech designed, developed, tested, assembled, manufactured, packaged, labeled, distributed, marketed, supplied, warranted, and/or sold total knee replacement systems and components for use in TKAs under the trade names Optetrak Comprehensive Total Knee System ("Optetrak"), the Optetrak Logic Comprehensive Knee System ("Optetrak Logic"), and the Truliant Comprehensive Total Knee System ("Truliant") (collectively, "Exactech Knee Devices").

462. The Optetrak was introduced in 1994, the Optetrak Logic in 2009, and the Truliant in 2017. The Optetrak knee systems were initially built upon technology licensed from the Hospital for Special Surgery (HSS). The Exactech Knee Devices feature a mix of polyethylene and metal-based components.

463. Exactech describes the "intended use" for the Optetrak, Optetrak Logic, and Truliant total knee systems as being indicated for use in skeletally mature individuals undergoing

primary surgery for total knee replacement due to osteoarthritis, osteonecrosis, rheumatoid arthritis, and/or post traumatic degenerative problems. They are also indicated for revision for failed previous reconstructions where sufficient bone stock and soft tissue integrity are present.

464. The basic components associated with the Optetrak, Optetrak Logic, and Truliant total knee systems include: a (1) patellar cap, (2) femoral cap, (3) tibial insert, and (4) tibial tray, as illustrated below.



465. The patellar cap and tibial inserts of the Exactech Knee Devices are made of UHMWPE.

466. In a 2011 Exactech marketing brochure relating to its Optetrak Logic TKS, Exactech acknowledged that the manufacturing, packaging, and sterilization processes have a significant impact on the resulting properties of the final polyethylene components; that variations in consolidation, oxidation level, amount of cross-linking, and mechanical properties can have a pronounced effect on the wear performance and longevity of the implant, and that post consolidation treatments, such as radiation, annealing, and re-melting can be used to improve the wear characteristics of the polyethylene device. *See* Product Brochure, Optetrak Logic Design Rationale 1012, When Innovation and Intuition Align, 712-25-40 Rev. A, © 2011.

467. Deviating from the industry standard, Exactech chose to use moderately crosslinked polyethylene (UHMWPE) for the bearing material of is tibial inserts without providing sufficient thermal treatment after crosslinking to fully quench the free radicals spawned by its

crosslinking process. Nor did Exactech add an antioxidant to its UHMWPE.

468. Specifically, Exactech represents that its Knee Devices' net compression molded polyethylene is sterilized with gamma radiation (2.5-4.0 Mrad) in a vacuum.

469. Exactech claims, "[w]hile the molecular chains of net molded polyethylene are moderately crosslinked due to the irradiation process in the absence of oxygen molecules, this material retains all of its mechanical properties (yield strength, fatigue strength and fracture resistance), avoiding the generation of free radicals. This balances the equation between wear, mechanical properties, and oxidation." *See* Optetrak Main Brochure 0410, 712-01-21 Rev. D, © 2010.

470. Exactech knew or should have known that its manufacturing processes would introduce free radicals into the knee insert but it did not employ thermal treatments recognized in the industry to eliminate or reduce the production of free radicals.

471. Exactech knew or should have known that the unquenched free radicals it introduced into the product would create a fertile postproduction environment for oxidation and oxidative generation of the UHMWPE insert throughout the product's shelf life.

472. This manufacturing process defect was exacerbated by use of gamma sterilization and out-of-specification packaging.

473. Accordingly, as set forth herein, the Exactech Knee Devices are all adulterated and misbranded medical devices and subject to recall due to accelerated wear of their UHMWPE inserts.

iv. Exactech Total Knee Systems 510(k)

474. As noted above, Exactech received clearance to market the Optetrak system in 1994, the Optetrak Logic system in 2009, and the Truliant system in 2017.

475. Each of these device's designs have also been altered over the years. Accordingly, over the lifespan of this product line, Exactech had at least thirty-five 510(k) submissions to the FDA for its Knee Devices.

476. Of these, eighteen 510(k) numbers are implicated by the 2021 and 2022 Recalls of

Exactech's Knee Devices: K932776, K933610, K932690, K010434, K011976, K033883, K040889, K082002, K093360, K110547, K111400, K121307, K123342, K132161, K150890, K152170, K160484, and K171045.

477. Despite frequent redesigns, early failures associated with accelerated wear continued. This is unsurprising, as all of the polyethylene inserts used in Exactech's Knee Devices were created from the same material, formulation, and manufacturing process. Accordingly, despite new iterations of the Knee Devices, they all contained the same defects: they remained moderately crosslinked, without proper thermal treatment of the irradiated UHMWPE to rid the polyethylene of free radicals, without proper packaging to protect against in vitro oxidation, without proper quality control of aging inventory, without a safe expiration date, and without proper warnings to surgeons concerning the risks of these Devices.

478. As it had in the past with prior defective products, Exactech began designing a new polyethylene insert, while leaving its defective Knee Devices on the market.

479. On November 4, 2022, Exactech announced 510(k) clearance of the TriVerse primary knee replacement system using highly cross-linked vitamin E-stabilized polyethylene and that the system would launch in the second quarter of 2023. Exactech is not listed on the 510(k) summary of this device, rather an Australian manufacturer is, Signature Orthopaedics Pty Ltd. The predicate devices are the Biomet Vanguard Total Knee System (K113550) and several reference devices manufactured by Signature Orthopaedics.

v. Exactech's False and Misleading Marketing, Sale, and Distribution of Total Knee Replacement Systems

480. At all relevant times, Exactech marketed, sold, and distributed its Exactech Knee Devices internationally and throughout the United States, including New York and each Plaintiff's forum state. Exactech generated substantial revenue as a result.

481. Exactech utilized, among other things, on-line and other brochures and on-line videos of Exactech "team surgeons," to market and sell its Exactech Knee Devices.

482. Exactech distributes and otherwise directly provides Orthopedic Surgeons

instructions for use (IFU) and instructions for implantation of the Exactech Knee Devices.

483. As stated in Exactech's promotional materials, while the design of its Exactech Knee Devices has evolved over time, "the [polyethylene] materials have been consistent."

484. Exactech represented to surgeons that its UHMWPE tibial inserts are designed to resist oxidation, reduce wear, and improve longevity of the knee prosthesis.

485. Exactech represented to surgeons that its UHMWPE tibial inserts have "a long clinical history of excellent wear characteristics."

486. Exactech represented to surgeons that "Exactech's comprehensive knee systems address your concerns for contact stress, patellar tracking, polyethylene wear, joint stability and bone preservation . . ."

487. Exactech represented to surgeons that the Exactech Knee Devices have "excellent long-term clinical outcomes."

488. Exactech represented to surgeons that "surgeons and patients can have every confidence in the performance and longevity of the [Exactech Knee Devices]."

489. In addition to the statements set forth above, Exactech's materials provided to physicians warranted that its products "are designed with a singular purpose: to improve patient outcomes."

490. Exactech represented to surgeons that the Optetrak knee system had "excellent long-term clinical performance with 98% survival rates."

491. Exactech utilized paid consultants and/or members of its design teams to champion its devices. According to CMS Open Payment data, since 2015, Exactech has paid physicians $45 million for e.g., consulting fees, travel and lodging, food and beverage, and royalty or license fees.

492. Indeed, two of Exactech's main device champions – Raymond P. Robinson, MD and Ivan A. Gradisar, MD – have received significant compensation from Exactech and are featured heavily in Exactech's marketing materials for Exactech's Knee Devices. Specifically, between 2015-2021, Exactech paid Dr. Robinson $680,455.60 in consulting fees, travel and lodging, and food and beverage. In 2018 alone, Exactech paid Dr. Robinson more than $222,000.

Payment information is not available prior to 2015 to know how much Exactech has paid Dr. Robinson or Dr. Gradisar (now retired) over the last twenty-five years.

493. At all times material hereto, Exactech knew the representations being made by its product champions, which were cleared and authorized by Exactech, were untrue or misrepresented the actual clinical performance of the Devices to the detriment of patients.

494. Exactech repeatedly endeavored to squelch concerns by surgeons as to polyethylene failures and would have Dr. William Petty or Gary Miller visit with any concerned surgeon or fly the surgeons to their Gainesville headquarters for a dog and pony show and meetings with the founders and executives to reassure them of the safety of the product and affirmatively discourage the publication of any critical information or medical literature.

495. On repeated occasions, different surgeons complained to Exactech of premature revisions and Exactech falsely claimed that their experience was an anomaly not experienced by other surgeons in an effort to dissuade them from challenging the safety of the Devices and raising insecurity amongst such surgeons that the problem was their patient population or technique and certainly not with the Device.

496. In promoting the Optetrak Device as part of a continuously improving evolution of knee-replacement devices, Exactech warranted that the Optetrak Device's predecessor, the I/B knee design is a "prosthesis that is likely to outlive the patients." (Internal brackets omitted.) Optetrak Logic Design Rationale 1012, 712-25-40 Rev. A © 2011.

497. Exactech specifically warrants that its Optetrak net compression molded polyethylene "retains all of its mechanical properties (yield strength, fatigue strength, and fracture resistance), avoiding the generation of free radicals." *See* Optetrak Main Brochure 0410, 712-01-21 Rev. D, © 2010.

498. Exactech further justified and warranted its manufacturing process claiming:

> Since the Optetrak tibial locking mechanism is proven to resist micro-motion and abrasive backside wear, a high level of cross-linking is not necessary. By avoiding a high level of cross-linking, Optetrak Logic's NCM polyethylene tibial inserts retain oxidation resistance and fracture

> toughness, which, when combined with the articular design, has demonstrated excellent wear resistance on both the topside and backside.

(Internal citations omitted). Optetrak Logic Design Rationale 1012, 712-25-40 Rev. A © 2011.

499. Exactech also touted that its Optetrak net compression molded polyethylene tibial inserts "demonstrated an 83 percent reduction in wear rate [] and 52 percent less damaged area [] than the I/B [Insall/Burstein) II machined tibial inserts." *See* Optetrak Main Brochure 0410, 712-01-21 Rev. D, © 2010.

500. Exactech also promoted the "solid results" of its polyethylene inserts in its Optetrak Main Brochure warranting: "Recent studies documenting the backside wear of polyethylene inserts call into question the stability of locking mechanisms in some modular tibial components. In contrast, indicators on Optetrak inserts substantiate its locking mechanism's ability to reduce backside wear". *See* Optetrak Main Brochure 0410, 712-01-21 Rev. D, © 2010. "Retrieved Optetrak insert demonstrates minimal wear with no measurable material loss." *Id.*

501. In recognizing knee components "dominant wear mechanisms are delamination and pitting (highly affected by fracture toughness)," Exactech said its knee insert components are "made with Exactech's proprietary net compression molding technology do not require high levels of radiation cross linking and the subsequent post-processing treatments to create the preferred performance properties for knee applications." Gary Miller, *Optimizing Polyethylene Materials to the Application: When it Comes to Manufacturing Methods, Hips Are Not Knees*, EXACTECH (Mar. 14, 2017), https://www.exac.com/optimizing-polyethylene-materials-to-the-application (last visited Jan. 24, 2023).

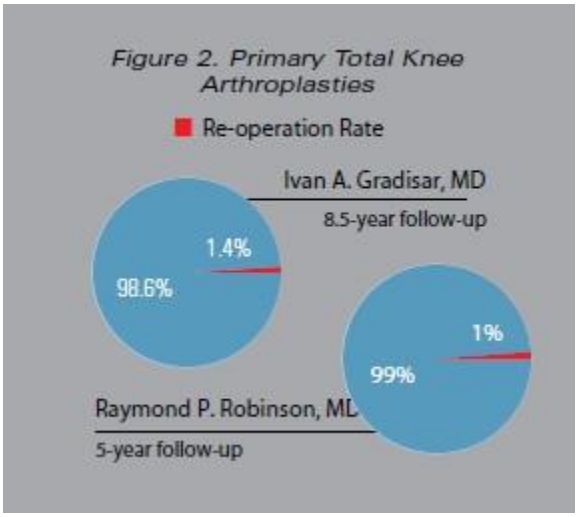
502. Exactech further warrants: "All of the articular surfaces of Exactech tibial polyethylene inserts are carefully molded into the part and not machined as in other processes. By the nature of this proprietary, net compression molding consolidation process, the inserts have high fatigue strength, high fracture toughness, low wear rates and are much less sensitive to oxidation after sterilization." *Id.*

503. Exactech compares its wear rates to competitors and states: "Comparative laboratory testing published by various manufacturers and researchers shows that Exactech's net

compression molded polyethylene has demonstrated approximately 6X less wear than extruded UHMWPE. This is achieved without sacrificing other important mechanical properties." *Id.*

504. Exactech represented that the Optetrak devices provide longevity, warranting the Devices' long-term clinical success: "The rate of reoperation for any reason was extremely low (1 percent). No re-operations were required for either design-related problems, component fault or failure, patellar or tibial-femoral instability, for insufficient motion or for repair or release of collateral or posterior soft tissue." *See* Optetrak Main Brochure 0608, 712-01-21, Rev. C, © 2008; Optetrak Main Brochure 0410, 712-01-21 Rev. D, © 2010 (amending to increase 1 percent to 1.4 percent).

The rate of re-operation for any reason was extremely low (1.4 percent). No re-operations were required for either design-related problems, component fault or failure, patellar or tibial-femoral instability, for insufficient motion or for repair or release of collateral or posterior soft tissue *(Figure 2)*.



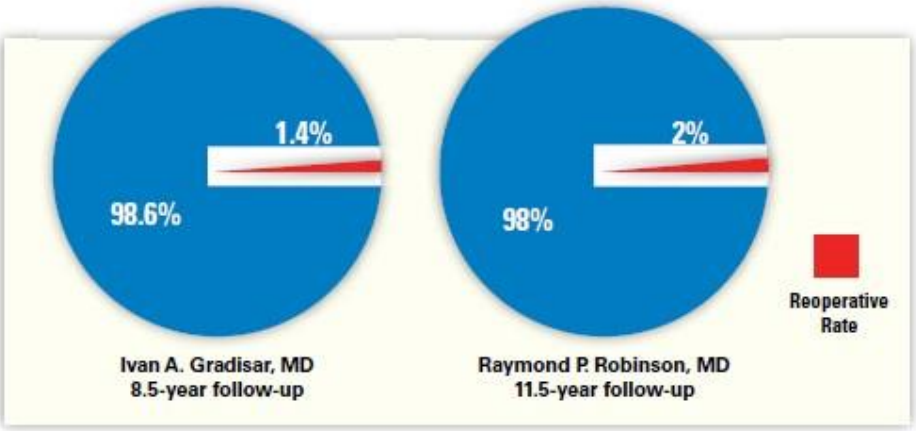
505. However, these statements are based on a survival rate study conducted by paid Exactech consultant and device champion Dr. Raymond P. Robinson, who limited the study exclusively to the survival rate of the Exactech Optetrak Posterior Stabilized knee. Dr. Robinson's 2005 study is based on a sample of 66 knee replacements in 47 patients that were implanted between April 27, 1996 and November 11, 1996. *See* ROBINSON, *Five-Year Follow-up of Primary*

Optetrak Posterior Stabilized Total Knee Arthroplasties in Osteoarthritis, J. OF ARTHROPLASTY, *Vol. 20 No. 7* (2005).

506. In the 2011 Optetrak Logic Design Rationale brochure, Exactech further warrants:

> In a peer-reviewed study, led by Raymond Robinson, MD, Optetrak demonstrated 98 percent implant survival rates in patients followed up to 15 years with a mean follow-up of 11.5. In a study led by Ivan Gradisar MD, the Optetrak knee system showed a 98.6 percent implant survival rate at 8.5 years. (Figure 2). With a design evolving for more than three decades and demonstrating excellent clinical and laboratory results, surgeons and patients can have every confidence in the performance and longevity of the Optetrak knee system.

Figure 2: Published Clinical Results



(Internal citations omitted). Optetrak Logic Design Rationale 1012, 712-25-40 Rev. A © 2011; Optetrak Logic Comprehensive Knee System Brochure, 712-25-20, Rev. E, 1215 © 2015.

507. The 98.6% figure for Dr. Gradisar – a paid Exactech consultant and device champion – is based on an unpublished, non-peer-reviewed presentation by Dr. Gradisar which was made in 2004. It was also not updated to reflect Dr. Gradisar's findings in his 2008 audit that revealed 24 Optetrak knee revision surgeries that occurred from January 1, 2007 to March 2008 in just one hospital. Instead of recording each of these internally reported 24 revision surgeries, Exactech only attributed one revision surgery to Dr. Gradisar in 2008.

508. In 2020, Exactech continued to use misleading and decades old data, citing the reoperative rates of 1.4 and 2% by Dr. Gradisar and Dr. Robinson to tout the clinical results of its knee systems. *See* Exactech Knee Design Rationale, 12-0000131 Rev. A, 0120 © 2020.

509. Exactech never updated its marketing materials to disclose the truth expressed by David Petty in his 2014 internal "Exactech Knee Sales Problems" memorandum that one of Exactech's "tibial components was very sensitive to cementation technique and in some instanceswe had unacceptable rates of tibial loosening (meaning the component loses its fixation within the bone and the patient must have a revision procedure)."

510. Exactech's marketing materials omit the findings of higher revision rates in independent peer reviewed studies.

511. Indeed, in 2015, the Australian Joint Registry determined the Optetrak PS had a revision rate of 19.4% in seven years. In 2016, the Australian Joint Registry determined that the Optetrak PS had a high cumulative percent revision of 22.0% at ten years.

512. Exactech's marketing materials never disclosed that the Australian joint registry determined that the Finned Tibia Tray had the worst failure rate of any implant on the Australian market—information that was known to Exactech.

513. Exactech's marketing materials were never updated to reflect the complaints, revisions, and adverse events reported to Exactech by physicians, Exactech sales representatives, and other members of the medical community.

514. It was not until Exactech was forced to recall its Exactech Knee Devices in 2021 due to defective packaging that Exactech disclosed to surgeons and patients the true scope of the risks associated with Exactech's Knee Devices.

515. As discussed in further detail below, in a letter accompanying Exactech's 2022 Recall of its Knee Devices, Exactech admitted "the original Optetrak Knee system, introduced in 1992, has shown statistically significant higher overall revision rates as compared to other TKAs in the Australian, United Kingdom and New Zealand Registries." *See* Exhibit F to Plaintiffs' MPIC in MDL No. 3044 filed on January 26, 2023 [ECF No. 94-6], Feb. 7, 2022 Knee and Ankle DHCP Letter at 2.

516. Exactech further admitted that "[e]very Exactech Optetrak TKR polyethylene component combination demonstrated statistically significant increased revision rates compared

to other TKR systems." *See* Exhibit F to Plaintiffs' MPIC in MDL No. 3044 filed on January 26, 2023 [ECF No. 94-6] at 2. Exactech then cited to "statistically significant increased cumulative revision rates" in the United Kingdom Registry and the New Zealand Registry. *Id.*

517. Exactech also admitted the reasons for revision potentially associated with polyethylene wear (e.g., loosening, lysis, pain) were increased three-to seven-fold in the most used Exactech Optetrak combination (Optetrak-PS/Optetrak) when compared to other TKRs in the Australian Registry. Exactech went on to admit that it had failed to properly package its Knee Devices since 2004 and that failure may be related to the increased revision diagnoses related to accelerated polyethylene wear.

518. Despite knowledge of high revision rates associated with its Knee Devices, Exactech failed to update its marketing materials for at least twelve years (between 2008-2020) and, until its February 7, 2022 Recall, continued to provide the same false and misleading survival and revision rates mentioned above.

519. At all times material hereto, Exactech falsely conflated the survival and revision rates of the Optetrak line of devices as one device, when in fact it was based on limited, outdated, and inaccurate information.

520. Despite knowledge of high revision rates in its Knee Devices, Exactech continued to sell these products for implantation and disseminate false, misleading, and inaccurate marketing materials to Plaintiffs, their physicians, and the medical community.

521. Despite having knowledge of the early onset failures of its Knee Devices, Exactech continued to manufacture, promote, sell, supply, and distribute the defective Devices without alerting surgeons of the potential risks associated with such and continued to supply them with the false survival rate information contained in their marketing materials.

vi. Exactech's Total Knee System Class 2 Device Recall

522. On or about August 30, 2021, Exactech issued a partial recall of the "Optetrak Comprehensive Knee System" (August 2021 Partial Knee Recall).

523. The August 2021 Partial Knee Recall states only that polyethylene "inserts were packaged in vacuum bags that lacked an additional oxygen barrier layer."

524. Based on information provided by Exactech, on October 4, 2021, the FDA published the following on its Recall website:

> Manufacturer Reason for Recall: Inserts were packaged in vacuum bags that lacked an additional oxygen barrier layer.
>
> FDA Determined Cause: Process Control:
>
> Action: Exactech notified distributors and sales representatives on about 08/30/2021 via letter titled" URGENT MEDICAL DEVICE RECALL." Actions included removing all Knee and Ankle UHMWPE products labeled with an 8-year shelf life and not packaged in EVOH/Nylon bags, in a phased approach over 12 months. Phase 1: immediately return all knee and ankle UHMWPE devices labeled with an 8-year shelf life that will be 5 years old or older by 08/31/2022 not packaged in EVOH/Nylon bags. Phase 2: between 05/31/2022 to 08/31/2022, returning all remaining knee and ankle UHMWPE devices labeled with an 8-year shelf life not packaged in EVOH/Nylon bags. A communication to healthcare professionals should follow.

See Exhibit G to Plaintiffs' MPIC in MDL No. 3044 filed on January 26, 2023 [ECF No. 94-7], Aug. 30, 2021 FDA Recall Notification.

525. Critically, Exactech did not send notification of this August 2021 Partial Knee Recall to medical providers or patients. Instead, Exactech chose to direct this Recall to its distributors and sales representatives.

526. On September 15, 2021, Exactech issued a "Urgent Field Safety Notice Medical Device Recall" (September 2021 Field Safety Notice) to "Exactech Agents, Representatives, and Distributors in Possession of Affected Products" attached as Exhibit H to Plaintiffs' MPIC in MDL No. 3044 filed on January 26, 2023 [ECF No. 94-8].

527. The September 15, 2021, Field Safety Notice indicated:

> Description of Issue: Exactech is recalling Exactech Knee and Ankle Ultra-High Molecular Weight Polyethylene (UHMWPE) inserts labeled with an 8-year shelf life. These inserts were packaged in vacuum bags that did contain a nylon barrier, which does substantially limit oxygen transmission, but did not contain an additional oxygen barrier layer consisting of Ethylene Vinyl Alcohol (EVOH) as

specified on the packaging drawing.

Use of vacuum bags without an EVOH layer may result in elevated transmission of oxygen to the UHMWPE insert packaged therein which can potentially result in increased oxidation of the material relative to inserts packaged with EVOH over time.

….

As of August 5, 2021, all products manufactured by Exactech are being packaged in EVOH vacuum bags to ensure adequate oxygen barrier properties and protection from oxidation of polyethylene inserts throughout the 8-year shelf life.

Id. at H.

528. Describing the "Clinical Impact" of the product defects addressed in the recall, Exactech acknowledged that "[e]xposure to oxygen over time can allow oxidation of the UHMWPE implant leading to a reduction of mechanical properties, which may ultimately require revision of the implant (UHMWPE Component)." *Id*.

529. As with the August 30, 2021 Recall, Exactech failed to send any similar notification to medical providers or patients.

530. As discussed above in Section IV(D), in November 2021, the FDA sent investigators to Exactech and following an eight-day inspection they found multiple CGMP quality system violations and cited Exactech for:

a. Lack of or inadequate procedures for purchasing controls in violation of 21 C.F.R. § 820.50 – procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established;

b. Lack of or inadequate procedures for design transfer in violation of 21 C.F.R. §820.30(h) – procedures for design transfer have not been adequately established;

c. Lack of or inadequate procedures for design validation in violation of 21 C.F.R. § 820.30(g) – procedures for design validation have not been adequately established;

d. Lack of or inadequate procedures for design validation in violation of 21 C.F.R. § 820.30(g) – risk analysis is incomplete; and lack of or inadequate design verification procedures in violation of 21 C.F.R. § 820.30(f).

531. All of these violations stem from manufacturing defects related to Exactech's packaging and shelf-life of products with UHMWPE.

532. As a result of the FDA's findings, about five months later on, February 7, 2022, Exactech issued an URGENT MEDICAL DEVICE CORRECTION to "Exactech Knee and Ankle Surgeons, Hospitals, Healthcare Professionals" advising the healthcare professionals of the product defect, recall, and its clinical significance and expanding the August 31, 2021 recall to include "all knee and ankle arthroplasty polyethylene inserts packaged in non-conforming bags regardless of label or shelf life." *See* Exhibit F, Feb. 7, 2022 Knee and Ankle DHCP Letter attached to Plaintiffs' MPIC in MDL No. 3044 filed on January 26, 2023 [ECF No. 94-6].

533. Exactech further advised that most of its inserts 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 barrier layer containing ethylene vinyl alcohol ("EVOH") that further augments oxygen resistance. *Id*. The clinical significance was described as follows:

> **The use of these non-conforming bags may enable increased oxygen diffusion to the UHMWPE (ultra-high molecular weight 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 conventional UHMWPE, which, in conjunction with other surgical factors, can lead to both accelerated wear debris production and bone loss, and/or component fatigue cracking/fracture, all leading to corrective revision surgery.**

Id. at 2 (emphasis in original).

534. This February 7, 2022 communication was the first time Exactech directly notified healthcare providers about any problem with its UHMWPE inserts.

535. Notably, Exactech did not inform healthcare providers that for seventeen years it had failed to ever inspect the bags to ensure they complied with design specifications and that no process validation activities had been conducted since the manufacturing process was first implemented.

536. Exactech has acknowledged the UHMWPE material has remained consistent and that the defect is applicable to all three generations of Exactech Knee Devices: Optetrak, Optetrak Logic, and Truliant, including the polyethylene inserts used therein.

537. During their market tenure all three generations of Exactech Knee Devices have been packaged in non-conforming bags, i.e., not packaged in EVOH/Nylon bags.

538. At all relevant times, Exactech knew or should have known that the UHMWPE components of these Knee Devices were improperly packaged.

539. The packaging method, process, and requirements for the polyethylene components of the Exactech Knee Devices are an integral part of Exactech's manufacturing process.

540. Exactech knew that if its packaging lacked an EVOH barrier, oxygen would diffuse into the gamma sterilized UHMWPE inserts, the oxygen would react with free radicals created and not properly addressed by thermal treatments in the manufacturing process, and this oxygen exposure and reaction would result in high rates of oxidation and embrittlement of the UHMWPE inserts.

541. In fact, Exactech admits the accelerated wear and failure of its Knee Replacement Systems is due to the improper, out of specification packaging of the polyethylene component, which exposes the part to oxygen, causing advanced oxidation and deterioration at an accelerated rate. This leads to premature failure of the Exactech Knee Replacement Systems.

542. This problem was made worse by Exactech failing to determine the proper shelf life for its UHMWPE inserts.

543. This improper shelf-life, coupled with the failure to barrier package the devices to prevent oxidation, greatly increased the risk of oxidation and embrittlement of the UHMWPE of the devices.

544. As a direct result of Exactech's use of moderately crosslinked polyethylene, failure to properly heat treat the UHMWPE during manufacturing, failure to properly package the devices, and/or the failure to have an appropriate expiration date, the Exactech Knee Devices experience accelerated wear, delamination, and fail more readily and often than other total knee arthroplasty devices on the market.

545. Had Exactech properly tested, investigated, and/or had appropriate quality systems in place, Plaintiffs would have been spared debilitating injuries and unnecessary surgeries due to wear debris and delamination from the UHMWPE inserts' use *in situ.*

546. As set forth above, the Exactech Knee Devices are adulterated and misbranded and subject to recall due to accelerated wear of the UHMWPE inserts.

547. Because of Exactech's tortious acts and omission, including but not limited to its negligence in design and manufacture, including packaging, of its Knee Device inserts, patients implanted with the Exactech Knee Devices have had to undergo (or likely will have to undergo) significant revision surgeries to remove and replace the defective devices.

548. Patients implanted with Exactech Knee Devices that failed due to accelerated wear have suffered significant and continuing pain and personal injuries as well as substantial medical bills and expenses.

C. Exactech's Total Ankle Replacement System

i. Total Ankle Replacement Surgery

549. Total ankle replacement surgery involves replacing the articular surfaces of the joint with smooth metal and polyethylene plastic.

550. Modern total ankle replacement devices are typically composed of the following:

a. a metal tibial component that attaches to the shinbone (tibia)

b. a metal talar component that fits into the footbone (talus)

c. a polyethylene (plastic) insert that fits between the tibia and talar components and acts as the new cushion or cartilage for the replaced ankle joint.

551. Total ankles have been implanted since the 1970s and have utilized UHMWPE inserts based on the pioneering work of Sir John Charnley.

552. The first-generation ankle replacements were formed by two components: a concave polyethylene tibial (shin bone) component and a convex metal talar (footbone) component. Constrained and non-constrained designs were used.

553. First generation total ankle replacement designs required large bone resection and cement fixation.

554. Second generation total ankle replacement designs were introduced in the 1980s, such as Stryker's Scandinavian Total Ankle Replacement (STAR) in 1981. The first U.S. designed total ankle, DePuy Synthes' Agility LP Total Ankle Replacement System (1984), was launched in 1992.

555. Second generation ankle replacements were semi-constrained, cementless, and used porous coatings to encourage bone growth.

556. Third generation ankle implants were introduced globally with the launches of, for example, the Salto (Tornier 1997), Hintegra (Allegra 2000), Mobility (DePuy 2002), and the Rizzoli Institute designed Box (Matothro 2003). Most of these designs were three-part, mobile bearing implants.

557. Third and fourth generations total ankle replacement designs include, for example, the STAR (1990), INBONE (Wright 2005), Salto Talaris (2006) and the Zimmer Biomet Trabecular Metal Total Ankle (2012).

558. Clinically, over the years total ankle replacement pain and function scores have improved; this includes varying patient ages, sizes, and preoperative deformities.

ii. Polyethylene Manufacturing, Sterilization, and Adverse Events Associated with Wear Debris

559. Historically, manufacturers of orthopedic implant devices used two main types of sterilization processes to sterilize the components prior to delivery to surgeons: gamma radiation and ethylene oxide.

560. As early as the 1960s, it was found that exposing UHMWPE to high-energy radiation during the sterilization process altered the crystalline structure of the polyethylene, creating crosslinking within the polymer structure.

561. This crosslinking enhanced the wear characteristics of the UHMWPE. Specifically, lab tests showed that the wear rate of UHMWPE decreased as exposure to gamma radiation increased.

562. In the 1990s, manufacturers used gamma radiation above the 25 to 40 kilogray (kGy) range, typical for sterilization of UHMWPE, to achieve more dense crosslinking to decrease wear.

563. In the late 1990s, manufacturers determined that exposing orthopedic polyethylene components to gamma radiation in a range greater than 50 kGy to 100 kGy created a highly crosslinked polyethylene that performed well in wear testing.

564. Exposing UHMWPE to radiation, however, has risks associated with the degradation of the polymer over time through an oxidative process.

565. Exposing UHMWPE to high-energy radiation breaks the carbon-hydrogen chains and creates highly reactive free radicals that recombine with adjacent molecules that form the crosslinking.

566. The crosslinking density increases with the higher the dose of radiation. If the highly reactive free radicals are exposed to oxygen, a process of oxidative degradation takes place leading to the embrittlement of the polyethylene.

567. Even after the irradiation induced crosslinking process, there will remain highly reactive residual free radicals that if exposed to oxygen during storage and clinical use can lead to an oxidation cascade that will degrade the polyethylene.

568. The oxidative degradation of the polyethylene component of the ankle implant device clinically can lead to accelerated wear resulting in adverse tissue reactions, such as periprosthetic osteolysis and tissue necrosis.

569. For decades, device manufacturers have used thermal treatment (heat) to address

the risks associated with the creation of residual free radicals as part of the radiation process. Specifically, post-irradiation remelting, heating the polyethylene past its melting point of 135 degrees Celsius, eliminates free radicals.

570. Manufacturers that anneal the crosslinked polyethylene below the melting point will barrier-package the insert, making the packaging impermeable to oxygen. Without this barrier-packaging, the oxidative degenerative process will continue during storage.

571. Furthermore, infusing crosslinked polyethylene with vitamin E is a common added measure against oxidation. In 2007, vitamin E infused polyethylene components of orthopedic implant devices were on the market.

572. The physiologic response to polyethylene wear debris (e.g. osteolysis) has been studied from the beginning of the use of UHMWPE as part of the joint replacement devices and continues to be a point of study.

573. Osteolysis is an immunologic adverse bodily reaction of bone degeneration (bone resorption) where the tissue is destroyed as a part of a pathological response to inflammation.

574. Periprosthetic osteolysis is osteolytic bone resorption associated with an autoimmune response to chronic inflammation caused by particle wear debris from implanted medical devices. Periprosthetic osteolysis may result in the failure of an ankle implant device.

575. Periprosthetic osteolysis associated with UHMWPE wear debris in ankle implant devices is a recognized phenomenon that may occur in a small percentage of patients over time after years of exposure to polyethylene wear debris.

576. Periprosthetic osteolysis may result in catastrophic failure of the ankle implant device by destroying the bony integration between the component parts of the prosthetic and the patient's anatomy resulting in loose components, which requires corrective surgery to replace the components of the ankle implant device (revision surgery).

577. In some cases, periprosthetic osteolysis destroys portions of the patient's tibia and/or talar bone. These types of failures greatly increase the complications of corrective surgeries and outcomes for patients.

578. Historically, in the small percentage of patients that experience periprosthetic osteolysis, device failure typically occurs after more than fifteen years of service.

579. Early failures of ankle implant devices due to periprosthetic osteolysis are associated with increased amounts of polyethylene wear debris as part of an accelerated wear process.

580. Periprosthetic osteolysis is not the only adverse reaction to accelerated wear debris. Adverse local tissue reactions such as soft tissue necrosis, bone tissue necrosis, periprosthetic fluid collection, and muscle tissue necrosis, are some but not all complications associated with accelerated polyethylene wear debris.

581. HXLPE is the predominant industry standard bearing material for total ankle prosthesis articulating components. The highly crosslinked polyethylene provides increased wear resistance over traditional UHMWPE or moderately crosslinked products. Post crosslinked thermal treatments (annealing or remelting) are employed to quench any remaining free radicals that could otherwise contribute to future damage by oxidation.

iii. Exactech's Vantage Total Ankle System

582. Throughout the relevant period, Exactech designed, developed, tested, assembled, manufactured, packaged, labeled, distributed, marketed, supplied, warranted, and/or sold a total ankle replacement system and components under the trade name Vantage Total Ankle System ("Exactech Ankle Device").

583. The Vantage Total Ankle System has been marketed since March 2016.

584. Exactech describes the "intended use" for the Vantage Total Ankle System as being indicated for treatment of patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis, and revision of failed reconstructions where sufficient bone stock and soft tissue integrity are present.

585. The basic components associated with the Vantage Total Ankle System include: a (1) tibial plate, (2) tibial insert, (3) locking piece, and (4) a talar component.

586. The tibial insert of the Vantage Total Ankle System is made of UHMWPE.

587. Exactech's design and manufacturing process for the polyethylene inserts utilized in its Vantage® Total Ankle System is substantially similar to the inserts utilized in Exactech's Total Knee Replacement Systems.

588. Deviating from the industry standard, Exactech chose to use moderately crosslinked polyethylene (UHMWPE) for the bearing material of is ankle devices without providing sufficient thermal treatment after crosslinking to fully quench the free radicals spawned by its crosslinking process.

589. This manufacturing process defect was exacerbated by use of gamma sterilization and out-of-specification packaging.

590. As set forth below, the Exactech Ankle Device is an adulterated and misbranded medical device subject to recall due to accelerated wear of the UHMWPE insert.

iv. Exactech Vantage Total Ankle System 510(k)

591. The Vantage Total Ankle System is a Class II device.

592. On or about August 7, 2015, Exactech submitted to the FDA a section 510(k) premarket notification of intent to market the Exactech Vantage Total Ankle System (510(k) No. K152217).

593. On or about March 10, 2016, the FDA determined the Exactech Vantage Total Ankle System (K152217) was substantially equivalent to the following legally marketed predicate devices (for the indications for use stated by Exactech): Salto Talaris Total Ankle Prosthesis (K090076) from Tornier and INFINIY Total Ankle System (K123954, and K1407490 line extension to devices cleared in K123954) from Wright Medical Technology, Inc.

594. To demonstrate that the Vantage Total Ankle System performed as intended and is substantially equivalent to the identified devices, Exactech purportedly performed non-clinical testing, including: sizing studies, locking integrity testing, fatigue analysis, wear evaluation, contact area/contact stress study, constraint evaluation, bone stability testing, range of motion study, and finite element analysis.

v. Exactech's False and Misleading Marketing, Sale, and Distribution of the Vantage Total Ankle System

595. At all relevant times, Exactech marketed, sold, and distributed its Vantage Total Ankle System internationally and throughout the United States, including New York and each Plaintiff's forum state. Exactech generated substantial revenue as a result.

596. According to Exactech, total units sold globally (2004-2/22/2022) were: Vantage Fixed-Bearing Polyethylene Liner Component 2,959 (Product Lines 350-21-xx (1,422) and 350-22-xx (1,537)); Vantage Mobile-Bearing Polyethylene Liner Component 761 (Product Lines 350-41-xx (352) and 350-42-xx(409)).

597. Exactech utilized, among other things, on-line and other brochures and on-line videos of Exactech "team surgeons," to market and sell its Vantage Total Ankle System. Brochures include, for example, those titled "Vantage Total Ankle System \ A New Perspective in Total Ankle" and "Exactech/Extremities Design Rationale VANTAGE TOTAL ANKLE Fixed Bearing Design Rationale."

598. Exactech distributes and otherwise directly provides to Orthopedic Surgeons instructions for use (IFU) and instructions for implantation of the Vantage Ankle System, including "Vantage Total Ankle Operative Technique" and Vantage Ankle Fixed Bearing System Operative Technique."

599. Exactech represented to doctors, patients, and the general public that its Vantage® Total Ankle System was excellent, high quality, and reliable.

600. Exactech represents its Vantage Total Ankle System includes "proprietary net compression molded polyethylene inserts for minimized surface damage and wear." Exactech also represents its Vantage Total Ankle System uses a "polyethylene that has a high fracture toughness and low wear."

601. Exactech's marketing materials boasted a low revision rate for its Vantage Total Ankle System.

602. Exactech's marketing materials did not disclose several investigations and ongoing

claims that its total ankle replacement system was, in fact, experiencing accelerated wear and failing much sooner and at a much higher rate than others on the market.

603. Despite Exactech's knowledge of accelerated wear and early failures of its Vantage Total Ankle System, Exactech continued to warrant, manufacture, promote, sell, and distribute them without alerting surgeons or patients of their increased risks of accelerated wear and production of wear debris, resulting in clinical issues including failures and revision surgery.

604. Exactech never changed the labeling, marketing materials, or product inserts to adequately and accurately warn patients or doctors of the associated increased risks concerning its defective Vantage Ankle and the polyethylene inserts in particular, including polyethylene wear, loosening, pain, and revision surgery.

vi. Exactech's Vantage Total Ankle System Class 2 Device Recall

605. On or about August 30, 2021, Exactech initiated a Class 2 Device Recall of its Vantage Total Ankle System, including the Vantage Fixed-Bearing Polyethylene Liner Component and the Vantage Mobile-Bearing Polyethylene Liner Component.

606. On or about August 31, 2021, Exactech notified distributors and sales representatives of the Vantage Total Ankle System Recall via letter titled "URGENT MEDICAL DEVICE RECALL." ("August 2021 Recall"). *See* Exhibit G to Plaintiffs' MPIC in MDL No. 3044 filed on January 26, 2023 [ECF No. 94-7].

607. Exactech's stated reason for the August 2021 Recall was polyethylene (knee and) ankle inserts were packaged in vacuum bags that lacked an additional oxygen barrier layer consisting of Ethylene Vinyl Alcohol ("EVOH").

608. Based on information provided by Exactech, on October 4, 2021, the FDA published the following on its Recall website:

Manufacturer Reason for Recall: Inserts were packaged in vacuum bags that lacked an additional oxygen barrier layer.

FDA Determined Cause: Process Control:

Action: Exactech notified distributors and sales representatives on about

> 08/30/2021 via letter titled" URGENT MEDICAL DEVICE RECALL." Actions included removing all Knee and Ankle UHMWPE products labeled with an 8-year shelf life and not packaged in EVOH/Nylon bags, in a phased approach over 12 months. Phase 1: immediately return all knee and ankle UHMWPE devices labeled with an 8-year shelf life that will be 5 years old or older by 08/31/2022 not packaged in EVOH/Nylon bags. Phase 2: between 05/31/2022 to 08/31/2022, returning all remaining knee and ankle UHMWPE devices labeled with an 8-year shelf life not packaged in EVOH/Nylon bags. A communication to healthcare professionals should follow.

See Exhibit G to Plaintiffs' MPIC in MDL No. 3044 filed on January 26, 2023 [ECF No. 94-7], Aug. 30, 2021 FDA Recall Notification.

609. Critically, Exactech did not send notification of this August 2021 Ankle Recall to medical providers or patients. Instead, Exactech chose to direct this Recall to its distributors and sales representatives.

610. On September 15, 2021, Exactech issued a "Urgent Field Safety Notice Medical Device Recall" (September 2021 Field Safety Notice) to "Exactech Agents, Representatives, and Distributors in Possession of Affected Products" attached as Exhibit H to Plaintiffs' MPIC in MDL No. 3044 filed on January 26, 2023 [ECF No. 94-8].

611. The September 15, 2021, Field Safety Notice indicated:

> Description of Issue: Exactech is recalling Exactech Knee and Ankle Ultra-High Molecular Weight Polyethylene (UHMWPE) inserts labeled with an 8-year shelf life. These inserts were packaged in vacuum bags that did contain a nylon barrier, which does substantially limit oxygen transmission, but did not contain an additional oxygen barrier layer consisting of Ethylene Vinyl Alcohol (EVOH) as specified on the packaging drawing.
>
> Use of vacuum bags without an EVOH layer may result in elevated transmission of oxygen to the UHMWPE insert packaged therein which can potentially result in increased oxidation of the material relative to inserts packaged with EVOH over time.
> ….
>
> As of August 5, 2021, all products manufactured by Exactech are being packaged in EVOH vacuum bags to ensure adequate oxygen barrier properties and protection from oxidation of polyethylene inserts throughout the 8-year shelf life.

Id. at 1.

612. Describing the "Clinical Impact" of the product defects addressed in the recall, Exactech acknowledged that "[e]xposure to oxygen over time can allow oxidation of the UHMWPE implant leading to a reduction of mechanical properties, which may ultimately require revision of the implant (UHMWPE Component)." *Id.*

613. As with the August 30, 2021 Recall, Exactech failed to send any similar notification to medical providers or patients.

614. As discussed above in Section IV(D), in November 2021, the FDA sent investigators to Exactech and following an eight-day inspection they found multiple CGMP quality system violations and cited Exactech for:

a. Lack of or inadequate procedures for purchasing controls in violation of 21 C.F.R. § 820.50 – procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established;

b. Lack of or inadequate procedures for design transfer in violation of 21 C.F.R. §820.30(h) – procedures for design transfer have not been adequately established;

c. Lack of or inadequate procedures for design validation in violation of 21 C.F.R. § 820.30(g) – procedures for design validation have not been adequately established;

d. Lack of or inadequate procedures for design validation in violation of 21 C.F.R. § 820.30(g) – risk analysis is incomplete; and

e. Lack of or inadequate design verification procedures in violation of 21 C.F.R. § 820.30(f).

615. All of these violations stem from manufacturing defects related to Exactech's packaging and shelf-life of products with UHMWPE.

616. As a result of the FDA's findings, about five months later on, February 7, 2022, Exactech issued an URGENT MEDICAL DEVICE CORRECTION to "Exactech Knee and Ankle

Surgeons, Hospitals, Healthcare Professionals" advising the healthcare professionals of the product defect, recall, and its clinical significance and expanding the August 31, 2021 recall to include all "all knee and ankle arthroplasty polyethylene inserts packaged in non-conforming bags regardless of label or shelf life." *See* Exhibit F, Feb. 7, 2022 DHCP Letter, attached to Plaintiffs' MPIC in MDL No. 3044 filed on January 26, 2023 [ECF No. 94-6].

617. Exactech further advised that most of its inserts 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 barrier layer containing ethylene vinyl alcohol (EVOH) that further augments oxygen resistance. *Id*. The clinical significance was described as follows:

> **The use of these non-conforming bags may enable increased oxygen diffusion to the UHMWPE (ultra-high molecular weight 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 conventional UHMWPE, which, in conjunction with other surgical factors, can lead to both accelerated wear debris production and bone loss, and/or component fatigue cracking/fracture, all leading to corrective revision surgery.**

Id. at 2 (emphasis in original).

618. This February communication was the first time Exactech notified medical providers about any problem with its UHMWPE inserts.

619. Notably, Exactech did not inform healthcare providers that for seventeen years, and the entire time the Vantage Total Ankle System was on the market, it had failed to ever inspect the bags to ensure they complied with design specifications and that no process validation activities had been conducted since the manufacturing process was first implemented.

620. During the entirety of its market tenure, the Vantage Total Ankle System has been packaged in non-conforming bags, i.e., not packaged in EVOH/Nylon bags.

621. At all relevant times, Exactech knew or should have known that the UHMWPE components of its Vantage Total Ankle System were improperly packaged.

622. The packaging method, process, and requirements for the polyethylene components of the Vantage Total Ankle System are an integral part of Exactech's manufacturing process.

623. Exactech knew that if its packaging lacked an EVOH barrier, oxygen would diffuse into the gamma sterilized UHMWPE inserts, the oxygen would react with free radicals created and not properly addressed by thermal treatments in the manufacturing process, and this oxygen exposure and reaction would result in high rates of oxidation and embrittlement of the UHMWPE inserts.

624. As a direct result of Exactech's use of moderately crosslinked polyethylene, failure to properly heat treat the UHMWPE during manufacturing, failure to properly package the devices, and/or the failure to have an appropriate expiration date, the Vantage® Total Ankle System experiences accelerated wear and fails more readily and often than other total ankle replacement devices on the market.

625. Had Exactech properly tested, investigated, and/or had appropriate quality systems in place, Plaintiffs would have been spared debilitating injuries and unnecessary surgeries due to wear debris from the UHMWPE inserts' use *in situ.*

626. Because of Exactech's tortious acts and omission, including but not limited to its negligence in design and manufacture, including packaging, of its UHMWPE inserts, patients implanted with the Vantage Total Ankle System have had to undergo (or likely will have to undergo) significant revision surgeries to remove and replace the defective devices.

627. Patients implanted with the Vantage Total Ankle System that failed due to accelerated wear have suffered significant and continuing pain and personal injuries as well as substantial medical bills and expenses.

VI. SUMMARY OF EXACTECH'S ACTS AND OMISSIONS

628. At all times relevant to this action, Exactech was aware of the propensity of its Exactech Hip, Knee, and Ankle Devices to undergo substantial accelerated polyethylene wear caused by the degradation and breakdown of plastic chemicals. Likewise, Exactech knew that toxicity associated with accelerated polyethylene wear would result in patients experiencing

adverse reactions, osteolysis, component loosening and/or other failure causing serious complications and injuries, and the need for revision surgery and its attendant complications.

629. At all times prior to the 2022 Recalls, Exactech has shown a wanton and reckless disregard for public safety. Exactech failed to notify surgeons and patients of the manufacturing defects (which includes packaging) in the Exactech Devices. Exactech admits to having poor and inadequate quality systems procedures and decades long manufacturing defects. Exactech also failed to implement or utilize adequate safeguards, tests, inspections, validation, monitoring, and quality assessments to ensure the safety of the Exactech Devices.

630. At all times the Exactech Devices were manufactured and sold to patients, including Plaintiffs, the devices were defectively designed, manufactured, improperly packaged and unreasonably dangerous, and did not conform to federal regulations, subjecting patients to unreasonable risks of injury.

631. At all times relevant to this action, Exactech's inadequate manufacturing processes also led to material flaws in the quality systems at its manufacturing, packaging, storage, and distribution facilities.

632. During the course of manufacturing and distributing the Exactech Devices, Exactech failed in several ways, including without limitation, by:

a. Manufacturing processes that did not follow design specifications;

b. Manufacturing devices outside design specifications;

c. Failing to implement acceptance activities to ensure the integrity of the vacuum bags and adherence to pre-determined product design requirements;

d. Failing to implement process validation activities;

e. Failing to implement acceptance activities for incoming components, including but not limited to vacuum bags;

f. Failing to ensure final device packaging was within design specifications;

g. Failing to use proper sample sizes to determine the shelf-life of UHMWPE liners and inserts;

h. Failing to determine the proper shelf-life for UHMWPE liners and inserts;

i. Failing to conduct adequate mechanical testing, including oxygen-resistance or other wear testing for the components, subassemblies, and/or finished Exactech Devices;

j. Failing to test an adequate number of sample devices on an ongoing basis;

k. Failing to take an adequate number of sample devices on an ongoing basis;

l. Failing to take adequate steps to specifically identify failure modes with clarity and to suggest methods to monitor, avoid, and/or prevent further failures;

m. Failing to take corrective actions to eliminate or minimize further failures of Exactech Devices;

n. Failing to adequately explain packaging specifications for the components, subassemblies, and/or finished Exactech Devices;

o. Failing to perform adequate quality control before the components, subassemblies, and/or finished Exactech Devices were distributed;

p. Failing to properly address reports from their sales representatives who reported their observations while attending revision surgeries where evidence of polyethylene debris and osteolysis was apparent and noted by the surgeons and the sales representatives themselves;

q. Failing to timely implement corrective action and investigations to understand the root cause of these failures while continuing to sell the components knowing they would be implanted into the bodies of thousands of people; and

r. Becoming aware of the potential cause or causes of failure but unreasonably avoiding warning and otherwise informing patients and surgeons and delaying the ability to minimize damages as the devise continued to degrade and do damage in the patients' bodies.

633. On or before the date of Plaintiffs' initial replacement surgeries, Exactech knew or should have known the Exactech Devices were failing and causing serious complications after implantation in patients. Such complications included, but were not limited to, catastrophic, polyethylene wear including the depositing of plastic particulate wear debris throughout the joint, a high rate of component loosening, and overall early system failure resulting in tissue destruction, osteolysis, and other injuries causing severe pain, swelling, instability and dysfunction in the hip, knee, and/or ankle necessitating revision surgery.

634. As manufacturer of orthopedic devices, Exactech knew that each surgery is fraught with serious risks of infection, anesthesia errors, dislocations, and other serious complications that should be avoided. Exactech was also aware that patients are at greater risk of complications during and after revision surgeries than index joint surgeries.

635. Exactech, however, ignored reports of early failures of its Exactech Devices and failed to promptly investigate the cause of such failures or issue any communications or warnings to orthopedic surgeons and other healthcare providers.

636. Before the date of Plaintiffs' initial replacement surgeries, Exactech knew or should have known the Exactech Devices were defective and unreasonably dangerous to patients, that the Exactech Hip, Knee, and Ankle Devices had an unacceptable failure and complication rate, and that the Devices had a greater propensity to undergo accelerated 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 in patients.

637. Exactech, through its affirmative misrepresentations and omissions, actively and fraudulently concealed from Plaintiffs and Plaintiffs' health care providers the true and significant risks associated with the Exactech Devices and the need to vigilantly do diagnostic procedures to promptly diagnose the process of the toxic polyethylene particles degrading and causing osteolysis.

638. As a direct, proximate, and legal consequence of Exactech's conduct and the defective nature of the Exactech Devices as described herein, Plaintiff has suffered and continue to suffer permanent and debilitating injuries and damages, including but not limited to, significant

pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening; soft tissue damage; bone loss; and other injuries, which all require ongoing medical care.

639. As further direct, proximate, and legal consequence of the defective nature of the Exactech Devices, Plaintiffs have sustained and will sustain future damages, including but not limited to the costs of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; and pain and suffering.

VII. TOLLING OF THE STATUTES OF LIMITATIONS

A. Latent Injury

640. To the extent it is claimed that Plaintiffs suffered symptoms prior to undergoing revision surgery, the statute of limitations is tolled because development of osteolysis, bone loss, and device loosening are latent conditions caused by years of exposure to toxic polyethylene wear debris that could not be appreciated until the date Exactech disseminated the information justifying its recall of the Exactech Hip, Knee, and Ankle Devices.

641. As a plastic, polyethylene wear debris contains chemicals or additives and may contain impurities such as catalyst residues, unreacted monomers, or breakdown products which possess toxic properties that can adversely affect human health. *See* Matthias C. Rillig et al., *The Global Plastic Toxicity Debt*, 55 ENV'T. SCI. & TECH. 2717, 2717–19 (2021).

642. As described above, such toxic effects on the human body include, but are not limited to, osteolysis, tissue necrosis, and destruction of the bony integration between the component parts of the prosthetic and the patient's anatomy.

643. Prior to Exactech initiating its recall and disseminating information about the recalls to Plaintiffs, technical, scientific, or medical knowledge and information sufficient to ascertain the cause of the failure of the Exactech Hip, Knee, and Ankle Devices had not been known.

644. Thus, Plaintiffs exhibited due diligence and did not possess "technical, scientific, or medical knowledge" and information sufficient to ascertain the cause of their injuries until after Exactech recalled their Exactech Hip, Knee, and Ankle Devices.

B. Fraudulent Concealment

645. Exactech, through its affirmative misrepresentations and omissions, actively concealed from Plaintiffs and Plaintiffs' healthcare providers the defects in and true and significant risks associated with Exactech's Hip, Knee, and Ankle Devices, claiming any failures were due to surgical technique, positioning, or patient characteristics.

646. Following implantation of the Devices, Plaintiffs and Plaintiffs' healthcare providers relied on Exactech's continued representations that the Devices, including their polyethylene components, had excellent long-term clinical outcomes.

647. Exactech made these representations with knowledge of their falsity, an intent to defraud, and/or disregard for the truth given its knowledge of reports of high failure rates.

648. Furthermore, following implantation of the Devices, Plaintiffs and Plaintiffs' healthcare providers relied on Exactech to provide them with urgent safety information regarding Exactech's Hip, Knee, and Ankle Devices, including recalls, communications regarding defects and increased rates of failure, and warnings and instructions on how to assess, diagnose, and mitigate risks associated with the defects in these Devices.

649. Although clinical evidence demonstrated that the polyethylene used in Exactech Hip, Knee, and Ankle Devices was failing at a rate higher than promoted, with instances of excessive revision rates due to device loosening and polyethylene wear, Exactech failed to initiate recalls earlier or issue any communications to healthcare providers that Exactech Hip, Knee, and Ankle Devices were defective and patients should be monitored.

650. Until recently, Exactech lacked highly-crosslinked polyethylene for its Hip, Knee, or Ankle Devices. Accordingly, without a viable substitute, earlier disclosure of these failure rates could have negatively impacted Exactech's ongoing business and sale to TPG in 2017/2018.

651. As a result of Exactech's actions, omissions, and misrepresentations, Plaintiffs and their healthcare providers were unaware, and could not have reasonably known, learned, or discovered that any Plaintiffs' symptoms or radiological findings indicative of a potential problem with Plaintiffs' joints were the result of defects in Exactech's Hip, Knee, and Ankle Devices.

652. Furthermore, had Exactech not actively concealed evidence of growing reports of accelerated polyethylene wear and Device failures, Plaintiffs' surgeons would have not implanted Exactech devices in them, and for those patients already implanted with Exactech devices, their surgeons would have initiated monitoring for device failures at an earlier time.

653. Such intervention would have led to an earlier diagnosis of loosening and bone loss, and earlier removal of the Exactech Hip, Knee, and Ankle Devices, thereby reducing damage to bone and tissue.

654. As a result of Exactech's actions, omissions, and misrepresentations, many Plaintiffs underwent revision surgeries during which they received new Exactech polyethylene components, subjecting them to a new exposure to the defective polyethylene and the need for yet another revision in the following years, while Exactech profited from selling more of its products.

655. As a result of Exactech's actions, omissions, and misrepresentations, Plaintiffs and Plaintiffs' healthcare providers were unaware, and could not have reasonably known, learned, or discovered through reasonable diligence, that Plaintiffs had been exposed to the risks identified herein, and that those risks were the result of defects in Exactech's Hip, Knee, and Ankle Devices.

633. Accordingly, no limitations period should accrue until such time as Plaintiffs knew or reasonably should have known of some causal connection between Plaintiffs being implanted with Exactech's Hip, Knee, and Ankle Devices, and the resulting harm later suffered by Plaintiffs as a result and by reason of Exactech's fraudulent concealment.

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

635. Further, the limitations period should be tolled under principles of equitable tolling.

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

636. 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.

637. 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 his injuries until after Defendants initiated a recall process of the Optetrak Device in February of 2022, and Plaintiff received the recall letter from HSS in April 2022 advising the implants were subject to the recall.

D. TOLLING PURSUANT TO EXECUTIVE ORDER 202.80 (9 NYCRR 8.202.8)

638. To the extent it is claimed that Plaintiff suffered symptoms prior to undergoing revision surgery, the statute of limitations is further tolled pursuant to Governor Cuomo's Executive Order 202.80 (9 NYCRR 8.202.8) with regards to COVID-19, wherein all Statutes of Limitations and deadlines were tolled from March 20, 2020 until November 3, 2020, or a total of 228 days, which means the aforementioned 228 days are "excluded from the calculation of the [relevant time period]." See, et. al., Brash v. Richards, 195 A.D.3d 582, 149 N.Y.S.3d 560, 561 (2d Dep't 2021). Thus, extending the Statute of Limitations for that period of time subject to tolling.

CAUSES OF ACTION

FIRST CAUSE OF ACTION: STRICT LIABILITY – MANUFACTURING DEFECT

(Against Exactech Defendants and TPG Defendants[12])

639. Plaintiffs hereby incorporate by reference as if fully set forth herein, the factual allegations set forth in the paragraphs above and further allege as follows.

640. Prior to the initial surgeries in which Plaintiff's Exactech Knee Devices were implanted, and at all times relevant to this action, Exactech designed, tested, studied, researched, formulated, manufactured, inspected, labeled, packaged, stored, promoted, advertised, marketed,

[12] Plaintiffs' claims against TPG Defendants are based on the general concepts of successor liability and piercing the corporate veil and include without limitation any similar doctrines for imposing liability on affiliated companies that may be available under any particular state's governing law.

distributed, and/or sold Exactech Hip, Knee, and Ankle Devices for implantation into consumers by orthopedic surgeons in the United States, including the Devices implanted into Plaintiff.

641. The Exactech Knee Devices implanted into Plaintiff were defective in their manufacture and construction when they left Exactech's hands in that they deviated from product specifications and applicable state and federal requirements.

642. Such manufacturing defects include, but are not limited to:

a. The vacuum bags used to package the polyethylene components of the Exactech Hip, Knee, and Ankle Devices failed to comply with Exactech's specifications in that they lacked a secondary barrier layer containing ethylene vinyl alcohol (EVOH) to prevent the components from undergoing increased oxidation;

b. The materials used to package the Exactech Hip, Knee, and Ankle Devices were of an inferior grade or quality;

c. The polyethylene components of Exactech's Hip, Knee, and Ankle Devices were degraded/deteriorated prior to implantation as a result of factors that include but are not limited to: (1) storage in vacuum bags that lacked a secondary oxygen barrier containing EVOH; (2) storage in packaging of inferior quality; (3) storage in facilities with inadequate environmental controls; (4) inadequate quality control, process validation, and inspection and correction of non-conformities; (5) inadequate inventory control, testing, inspection, and rotation; (6) inadequate procedures for receiving, documenting, reviewing, evaluating, and inspecting product complaints; and (7) improper and unreasonably long and thus unsafe shelf-life designations.

643. As a result of these manufacturing defects, Exactech's Hip, Knee, and Ankle Devices were unreasonably dangerous.

644. As a result of these manufacturing defects, Exactech's Hip, Knee, and Ankle

Devices were not reasonably safe or fit for their expected, intended, and/or foreseeable uses, functions, and purposes.

645. As alleged herein, Exactech knew or had reason to know that the Devices caused an increased risk of harm to Plaintiffs and other consumers due to the Devices' propensity to undergo substantial accelerated 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 in patients.

646. An ordinarily prudent company, being fully aware of the risks associated with the defective condition of Exactech's Hip, Knee, and Ankle Devices, would not have put these Devices on the market.

647. An ordinarily prudent company, being fully aware of the risks associated with the defective condition of Exactech's Hip, Knee, and Ankle Devices, would have immediately removed/recalled all distributed Devices from the market.

648. Plaintiff was implanted with Exactech Knee Devices that contained the manufacturing defects set forth above.

649. These defects existed when the Exactech Hip, Knee, and Ankle Devices left Exactech's control.

650. No material, substantial, and/or unforeseeable changes in the condition of the Exactech Hip, Knee, and Ankle Devices occurred between the time the Devices left Exactech's control and were implanted into Plaintiff.

651. Plaintiff's physicians implanted the Exactech Knee Devices in the manner in which Exactech intended and recommended they be used, making their use reasonably foreseeable to Exactech.

652. As a result of the manufacturing defects in Exactech's Knee Devices implanted into Plaintiff, the Devices failed.

653. The manufacturing defects in Exactech's Knee Devices implanted into Plaintiff were a substantial factor in causing Plaintiffs' injuries.

654. Plaintiffs could not, by the exercise of reasonable care, have discovered these manufacturing defects, perceived their dangers, or avoided injury.

655. As a direct and proximate result of the failure of Exactech's Knee Devices, Plaintiff has suffered and will continue to suffer damages and harm including serious personal injuries, conscious pain and suffering, physical disability, disabilities in activities of daily living, mental anguish, emotional distress, fear, loss of enjoyment of life, loss of income, medical expenses, and financial losses.

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

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

658. Defendants' actions and omissions alleged in this Complaint were intentional, malicious, reckless, wanton, fraudulent, beyond all standards of decency, and without regard for human life or Plaintiffs' rights, thereby warranting the imposition of punitive damages.

SECOND CAUSE OF ACTION: STRICT LIABILITY – DESIGN DEFECT

(Against Exactech Defendants and TPG Defendants[13])

659. Plaintiffs hereby incorporate by reference as if fully set forth herein, the factual allegations set forth in the paragraphs above and further allege as follows.

660. Prior to the initial surgeries in which Plaintiff's Exactech Knee Devices were implanted, and at all times relevant to this action, Exactech designed, tested, studied, researched, formulated, manufactured, inspected, labeled, packaged, stored, promoted, advertised, marketed, distributed, and/or sold Exactech Hip, Knee, and Ankle Devices for implantation into consumers

[13] Plaintiffs' claims against TPG Defendants are based on the general concepts of successor liability and piercing the corporate veil and include without limitation any similar doctrines for imposing liability on affiliated companies that may be available under any particular state's governing law.

by orthopedic surgeons in the United States, including the Devices implanted into Plaintiff.

661. The Exactech Knee Devices implanted into Plaintiff and the Devices' corresponding packaging were defective in their design.

662. The Devices and their packaging and labeling were defective in design and unreasonably dangerous when they left Exactech's hands, entered the stream of commerce, and were received by Plaintiff, because the foreseeable risks exceeded or outweighed the purported benefits associated of their design and the Devices were more dangerous than an ordinary consumer would expect when used in their intended and reasonably foreseeable manner.

663. As a result of these design defects, Exactech's Hip, Knee, and Ankle Devices were unreasonably dangerous.

664. As a result of these design defects, Exactech's Hip, Knee, and Ankle Devices were not reasonably safe or fit for their expected, intended, and/or foreseeable uses, functions, and purposes.

665. As alleged herein, Exactech knew or had reason to know that the Devices caused an increased risk of harm to the Plaintiff and other consumers due to the Devices' propensity to undergo substantial accelerated 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 in patients. Exactech has not and cannot identify product benefits which outweigh these increased risks.

666. An ordinarily prudent company, being fully aware of the risks associated with the defective condition of Exactech's Hip, Knee, and Ankle Devices, would not have put these Devices on the market.

667. An ordinarily prudent company, being fully aware of the risks associated with the defective condition of Exactech's Hip, Knee, and Ankle Devices, would have immediately removed/recalled all distributed Devices from the market.

668. Safer feasible alternative designs that would have avoided Plaintiff's injuries and provided the same functional purpose were available to Exactech at the time the Devices were

designed, packaged, labeled, and offered for sale in the market, including but not limited to: polyethylene formulations with greater resistance to oxidation; polyethylene packaging that contained an additional EVOH layer; higher quality oxygen resistant packaging for storing polyethylene components; the storage of polyethylene components in oxygen controlled environments; and shorter shelf-life designations.

669. Plaintiff was implanted with Exactech Knee Devices that contained the design defects set forth above.

670. These defects existed when the Exactech Hip, Knee, and Ankle Devices left Exactech's control.

671. No material, substantial, and/or unforeseeable changes in the condition of the Exactech Hip, Knee, and Ankle Devices occurred between the time the Devices left Exactech's control and were implanted into Plaintiff.

672. Plaintiff's physicians implanted the Exactech Hip, Knee, and Ankle Devices in the manner in which Exactech intended and recommended they be used, making their use reasonably foreseeable to Exactech.

673. As a result of the design defects in Exactech's Knee Devices implanted into Plaintiff, the Devices failed.

674. The design defects in Exactech's Knee Devices implanted into Plaintiff were a substantial factor in causing Plaintiff's injuries.

675. At no time prior to implantation did Plaintiffs or Plaintiffs' healthcare providers have reason to believe that the Devices were in a condition not suitable for their proper and intended use.

676. Plaintiffs could not, by the exercise of reasonable care, have discovered these design defects, perceived their dangers, or avoided injury.

677. As a direct and proximate result of the failure of Exactech's Knee Devices, Plaintiff has suffered and will continue to suffer damages and harm including serious personal injuries, conscious pain and suffering, physical disability, disabilities in activities of daily living, mental

anguish, emotional distress, fear, loss of enjoyment of life, loss of income, medical expenses, and financial losses.

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

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

680. Defendants' actions and omissions alleged in this Complaint were intentional, malicious, reckless, wanton, fraudulent, beyond all standards of decency, and without regard for human life or Plaintiffs' rights, thereby warranting the imposition of punitive damages.

THIRD CAUSE OF ACTION:
STRICT LIABILITY – DEFECT DUE TO INADEQUATE WARNINGS OR INSTRUCTIONS
(Against Exactech Defendants and TPG Defendants[14])

681. Plaintiffs hereby incorporate by reference as if fully set forth herein, the factual allegations set forth in the paragraphs above and further allege as follows.

682. Prior to the initial surgeries in which Plaintiff's Exactech Knee Devices were implanted, and at all times relevant to this action, Exactech designed, tested, studied, researched, formulated, manufactured, inspected, labeled, packaged, stored, promoted, advertised, marketed, distributed, and/or sold Exactech Hip, Knee, and Ankle Devices for implantation into consumers by orthopedic surgeons in the United States, including the Devices implanted into Plaintiff.

683. The Exactech Hip, Knee, and Ankle Devices implanted into Plaintiff and the Devices' corresponding packaging were defective due to inadequate warnings and instructions.

684. The Devices were defective due to inadequate and improper warnings and

[14] Plaintiffs' claims against TPG Defendants are based on the general concepts of successor liability and piercing the corporate veil and include without limitation any similar doctrines for imposing liability on affiliated companies that may be available under any particular state's governing law.

instructions because at the time they left Exactech's hands, entered the stream of commerce, and were received by Plaintiffs and/or Plaintiff's healthcare providers, Exactech knew or should have known that the Devices were unreasonably dangerous due to their increased risk of failure. Despite this, Exactech failed to adequately warn of the increased failure risk or provide adequate instructions to mitigate this risk.

685. Likewise, the Devices were defective due to inadequate post-sale warnings and instructions, because following Plaintiff's implantation with these Devices, Exactech knew or should have known that their Devices were unreasonably dangerous due to their increased risk of failure. Despite this, Exactech failed to adequately warn of the increased failure risk or provide adequate instructions to mitigate this risk.

686. As a result of these warning defects, Exactech's Hip, Knee, and Ankle Devices were unreasonably dangerous.

687. As a result of these warning defects, Exactech's Hip, Knee, and Ankle Devices were not reasonably safe or fit for their expected, intended, and/or foreseeable uses, functions, and purposes.

688. As alleged herein, Exactech knew or had reason to know that the Devices caused an increased risk of harm to Plaintiffs and other consumers due to the Devices' propensity to undergo substantial accelerated 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 in patients.

689. An ordinarily prudent company, being fully aware of the risks associated with the defective condition of Exactech's Hip, Knee, and Ankle Devices, would not have put these Devices on the market.

690. An ordinarily prudent company, being fully aware of the risks associated with the defective condition of Exactech's Hip, Knee, and Ankle Devices, would have immediately removed/recalled all distributed Devices from the market.

691. Plaintiff was implanted with Exactech Knee Devices that contained the warning

defects set forth above.

692. These defects existed when the Exactech Hip, Knee, and Ankle Devices left Exactech's control and continued to exist until Exactech issued its Recalls in 2021 and 2022.

693. No material, substantial, and/or unforeseeable changes in the condition of the Exactech Knee Devices occurred between the time the Devices left Exactech's control and were implanted into Plaintiff.

694. Plaintiff's physicians implanted the Exactech Knee Devices in the manner in which Exactech intended and recommended they be used, making their use reasonably foreseeable to Exactech.

695. As a result of the warning defects in Exactech's Knee Devices implanted into Plaintiff, the Devices failed.

696. As a result of the warning defects in Exactech's Knee Devices, Plaintiff's and Plaintiff's surgeons lacked critical information to mitigate harm after the Devices failed.

697. The warning defects in Exactech's Hip, Knee, and Ankle Devices implanted into Plaintiff were a substantial factor in causing Plaintiffs' injuries.

698. At no time prior to implantation did Plaintiff or Plaintiff's healthcare providers have reason to believe that the Devices were in a condition not suitable for proper and intended use.

699. Plaintiff could not, by the exercise of reasonable care, have discovered these defects, perceived their dangers, or avoided injury.

700. Indeed, Plaintiff and his surgeons relied upon Exactech to provide adequate warnings about the dangers and risks associated with Exactech's Hip, Knee, and Ankle Devices, and instructions to mitigate those risks.

701. Had Exactech provided adequate warnings and instructions prior to or following the sale of the Devices implanted into Plaintiff, Plaintiff and his surgeons would have heeded those warnings and avoided or, in the alternative, mitigated the injuries suffered by Plaintiffs.

702. As a direct and proximate result of the failure of Exactech's Knee Devices, Plaintiff has suffered and will continue to suffer damages and harm including serious personal injuries,

conscious pain and suffering, physical disability, disabilities in activities of daily living, mental anguish, emotional distress, fear, loss of enjoyment of life, loss of income, medical expenses, and financial losses.

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

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

705. Defendants' actions and omissions alleged in this Complaint were intentional, malicious, reckless, wanton, fraudulent, beyond all standards of decency, and without regard for human life or Plaintiffs' rights, thereby warranting the imposition of punitive damages.

FOURTH CAUSE OF ACTION: NEGLIGENCE

(Against Exactech Defendants and TPG Defendants[15])

706. Plaintiffs hereby incorporate by reference as if fully set forth herein, the factual allegations set forth in the paragraphs above and further allege as follows.

707. Prior to the initial surgeries in which Plaintiff's Exactech Knee Devices were implanted, and at all times relevant to this action, Exactech designed, tested, studied, researched, formulated, manufactured, inspected, labeled, packaged, stored, promoted, advertised, marketed, distributed, and/or sold the Devices for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

708. Prior to, on, and after the dates of Plaintiff's implant surgeries, and at all times relevant to this action, Exactech had a duty to exercise reasonable care in the testing, study, research, design, formulation, manufacture, inspection, labeling, packaging, storage, promotion,

[15] Plaintiffs' claims against TPG Defendants are based on the general concepts of successor liability and piercing the corporate veil and include without limitation any similar doctrines for imposing liability on affiliated companies that may be available under any particular state's governing law.

advertisement, marketing, distribution, and sale of the Devices for implantation into consumers, such as Plaintiff, by physicians and surgeons in the United States.

709. Prior to, on, and after the dates of Plaintiff's implant surgeries, Exactech breached this duty and failed to exercise reasonable care and was negligent and careless in the testing, study, research, design, formulation, manufacture, inspection, labeling, packaging, storage, promotion, advertisement, marketing, distribution, and sale of the Devices.

710. Following Plaintiff's implant surgeries, Exactech breached this duty and failed to exercise reasonable care and was negligent and careless in failing to issue adequate warnings and/or recall the Devices more quickly.

711. At all times material hereto, Exactech had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care of the hazards and dangers associated with the Devices.

712. Despite the fact that Exactech knew or should have known the Devices were defectively manufactured and designed and therefore that the Devices posed a serious risk of bodily harm to consumers, Exactech continued to manufacture and market the Devices for implantation into consumers.

713. Despite the fact that Exactech knew or should have known the Devices posed a serious risk of bodily harm to consumers, Exactech continued to manufacture and market the Devices for implantation into consumers without providing adequate warnings, revising existing warnings, or issuing an earlier recall.

714. Exactech failed to exercise due care under the circumstances and its negligence and recklessness includes, but is not limited to the following acts and omissions:

a. Negligently failing to properly package the polyethylene components of the Devices;

b. Negligently failing to select appropriate third-parties to supply packaging for the polyethylene components used in the Devices;

c. Negligently failing to properly supervise and monitor the packaging of the

polyethylene components used in the Devices;

d. Negligently failing to properly and thoroughly select the material that would be used in the packaging of the Devices;

e. Negligently failing to properly and thoroughly select the materials that would be used in the Devices, including failing to select highly-crosslinked polyethylene and polyethylene that contains Vitamin E;

f. Negligently failing to properly and adequately test the Devices and their attendant parts before releasing the Devices to market;

g. Negligently failing to conduct sufficient post-market testing and surveillance of the Devices;

h. Negligently failing to adequately prevent, identify, mitigate, and fix defective designs and hazards associated with the Devices in accordance with good manufacturing practices;

i. Continuing to negligently manufacture and distribute the Devices after Exactech knew or should have known of their adverse effects and/or increased early onset failure rates;

j. Negligently misrepresenting the safety of the Devices;

k. Negligently failing to warn consumers, doctors, users, and patients that the Devices would contain polyethylene materials not properly packaged and/or in accordance with Exactech's specifications;

l. Negligently failing to provide pre and post-sale warnings, instructions, or other information that accurately reflected the risks of accelerated polyethylene wear, Device failure rates, and revision surgery associated with the Devices;

m. Negligently failing to provide pre and post-sale warnings, instructions, or other information that would allow patients and surgeons' to mitigate the harm caused by polyethylene degradation and the failure of Exactech's

Devices;

n. Negligently failing to exercise due care in the advertisement and promotion of the Devices;

o. Negligently disseminating information that was inaccurate, false, and misleading which failed to communicate accurately or adequately the high early failure rate associated with the implantation of the Devices;

p. Aggressively promoting the Devices without proper warnings of the risk of early failure or material degradation in the average user;

q. Aggressively promoting the Devices even after Exactech knew or should have known of the unreasonable risks from implantation;

r. Negligently diminishing or hiding the risks associated with the implantation of the Devices;

s. Negligently failing to recall the Devices at an earlier date;

t. Negligently failing to have a protocol for its sales representatives to retain explanted devices for retrieval analysis;

u. Negligently failing to thoroughly and accurately report revisions to the FDA;

v. Negligently violating applicable state and federal laws and regulations; and in all other ways.

715. Exactech knew and/or should have known that it was foreseeable that consumers such as Plaintiff, would suffer injuries as a result of Exactech's failure to exercise reasonable care in the manufacture, design, testing, assembly, inspection, labeling, packaging, storage, supply, marketing, sale, advertising, warning, and distribution of the Devices.

716. As a direct and proximate result of Exactech's negligence and breach of its duties, the Devices implanted into Plaintiff failed.

717. As a direct and proximate result of the failure of Exactech’s Knee Devices, Plaintiff has suffered and will continue to suffer damages and harm including serious personal injuries,

conscious pain and suffering, physical disability, disabilities in activities of daily living, mental anguish, emotional distress, fear, loss of enjoyment of life, loss of income, medical expenses, and financial losses.

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

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

720. Defendants' actions and omissions alleged in this Complaint were intentional, malicious, reckless, wanton, fraudulent, beyond all standards of decency, and without regard for human life or Plaintiffs' rights, thereby warranting the imposition of punitive damages.

FIFTH CAUSE OF ACTION:
BREACH OF EXPRESS WARRANTY

(Against Exactech Defendants and TPG Defendants[16])

721. Plaintiffs hereby incorporate by reference as if fully set forth herein, the factual allegations set forth in the paragraphs above and further allege as follows.

722. Prior to the initial surgeries in which Plaintiff's Exactech Knee Devices were implanted, and at all times relevant to this action, Exactech designed, tested, studied, researched, formulated, manufactured, inspected, labeled, packaged, stored, promoted, advertised, marketed, distributed, and/or sold the Devices for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

723. Exactech expressly warranted the Devices were safe and effective orthopedic devices.

[16] Plaintiffs' claims against TPG Defendants are based on the general concepts of successor liability and piercing the corporate veil and include without limitation any similar doctrines for imposing liability on affiliated companies that may be available under any particular state's governing law.

724. As set forth in specific detail above, Exactech made express representations and warranties about its Devices that include, but are not limited to:

a. the Exactech Devices had a long clinical history and performed better than similar competitors' devices on the market;

b. the Exactech Devices were clinically proven to reduce wear when, in fact, Exactech did not confirm that these statements were clinically accurate;

c. the GXL Hip Device provided "a lifelong implant for patients";

d. the GXL "provides a 59% wear reduction" over their claimed clinically successful standard polyethylene liners;

e. the Optetrak knee system had a 98% survival rate;

f. incidents of loosening of Exactech Devices were not a result of any defect in the Exactech Devices, but instead blamed such incidents on surgical technique or other factors;

g. the Exactech Devices have lower wear propensities than comparable products; and

h. the Exactech Devices have better longevity than comparable products;

725. The express warranties represented by Exactech were a part of the basis for Plaintiffs' use of the Devices, and Plaintiffs and Plaintiffs' surgeon relied on these warranties in deciding to implant the Devices.

726. At the time Exactech manufactured, marketed, sold, and/or distributed the Devices, they knew that the Devices were intended for human use, and that Plaintiffs were foreseeable users of the Devices.

727. At the time of the making of these express warranties, Exactech had knowledge of the purpose for which the Devices were to be used and warranted the same to be in all respects safe, effective, and proper for such purpose.

728. Plaintiff used the Devices for their intended purpose, and in a reasonably foreseeable manner.

729. The Devices manufactured and sold by Exactech did not conform to Exactech's express representations because the Devices failed as a result of accelerated polyethylene wear and caused serious injury to Plaintiff when used as recommended and directed.

730. As a direct and proximate result of the failure of Exactech's Knee Devices, Plaintiff has suffered and will continue to suffer damages and harm including serious personal injuries, conscious pain and suffering, physical disability, disabilities in activities of daily living, mental anguish, emotional distress, fear, loss of enjoyment of life, loss of income, medical expenses, and financial losses.

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

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

733. Defendants' actions and omissions alleged in this Complaint were intentional, malicious, reckless, wanton, fraudulent, beyond all standards of decency, and without regard for human life or Plaintiffs' rights so as to warrant the imposition of punitive damages.

SIXTH CAUSE OF ACTION:
BREACH OF IMPLIED WARRANTY

(Against Exactech Defendants and TPG Defendants[17])

734. Plaintiffs hereby incorporate by reference as if fully set forth herein, the factual allegations set forth in the paragraphs above and further allege as follows.

735. Prior to the initial surgeries in which Plaintiff's Exactech Knee Devices were implanted, and at all times relevant to this action, Exactech designed, tested, studied, researched, formulated, manufactured, inspected, labeled, packaged, stored, promoted, advertised, marketed,

[17] Plaintiffs' claims against TPG Defendants are based on the general concepts of successor liability and piercing the corporate veil and include without limitation any similar doctrines for imposing liability on affiliated companies that may be available under any particular state's governing law.

distributed, and/or sold the Devices for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

736. Exactech impliedly warranted, through its marketing, advertising, distributors, and sales representatives that the Exactech Hip, Knee, and Ankle Devices were of merchantable quality, and fit for the ordinary purposes and uses for which they were sold.

737. In fact, the 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.

738. The Devices manufactured and supplied by Exactech 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 designed, labeled, and manufactured, treated to prevent oxidation, and packaged and stored as to avoid premature degradation of component materials.

739. Plaintiff and/or Plaintiff's physicians reasonably relied upon the skill and judgment of Exactech as to whether the Devices were of merchantable quality and safe for their intended and particular uses and purposes.

740. Contrary to such implied warranties, the Devices were not of merchantable quality or safe for their intended and particular uses and purposes because the Exactech Devices were susceptible to and underwent increased oxidation, resulting in Plaintiff experiencing substantial accelerated 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.

741. As a direct and proximate result of the failure of Exactech's Knee Devices, Plaintiff has suffered and will continue to suffer damages and harm including serious personal injuries, conscious pain and suffering, physical disability, disabilities in activities of daily living, mental anguish, emotional distress, fear, loss of enjoyment of life, loss of income, medical expenses, and financial losses.

742. The injuries, damages, harm, and losses sustained by Plaintiff were caused solely

and wholly by virtue of the following acts, omissions, and conduct of Defendants and were in no way caused and/or contributed to by Plaintiff.

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

744. Exactech's actions and omissions alleged in this Complaint were intentional, malicious, reckless, wanton, fraudulent, beyond all standards of decency, and without regard for human life or Plaintiffs' rights, thereby warranting the imposition of punitive damages.

SEVENTH CAUSE OF ACTION: NEGLIGENT MISREPRESENTATION

(Against Exactech Defendants and TPG Defendants[18])

745. Plaintiffs hereby incorporate by reference as if fully set forth herein, the factual allegations set forth in the paragraphs above and further allege as follows.

746. Prior to the initial surgeries in which Plaintiff's Exactech Knee Devices were implanted, and at all times relevant to this action, Exactech designed, tested, studied, researched, formulated, manufactured, inspected, labeled, packaged, stored, promoted, advertised, marketed, distributed, and/or sold the Devices for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

747. At all relevant times, Exactech possessed superior knowledge about its Exactech Hip, Knee, and Ankle Devices regarding the design, manufacture, storage, packaging, propensities, wear characteristics, longevity, adverse event reports, and failure rates associated with these Devices.

748. Exactech knew that such information was not readily available to Plaintiff or his physicians and that Plaintiff and his physicians relied upon it to accurately provide this information for purposes of deciding which joint replacement device to use and the proper course of medical

[18] Plaintiffs' claims against TPG Defendants are based on the general concepts of successor liability and piercing the corporate veil and include without limitation any similar doctrines for imposing liability on affiliated companies that may be available under any particular state's governing law.

treatment following implantation.

749. In light of its possession of superior knowledge about its Devices, Exactech had a duty to disclose information regarding the safety and efficacy of its products.

750. Prior to and following Plaintiff's implant surgeries, Exactech made negligent misrepresentations and omissions to patients and physicians, including Plaintiff and Plaintiff's surgeons, about Exactech's Hip, Knee, and Ankle Devices. While set forth in greater detail above, such misrepresentations and omissions include, but are not limited to:

a. Exactech's misrepresentation that the Exactech Devices had a long successful clinical history and performed better than similar competitors' devices on the market;

b. Exactech's misrepresentation that the Exactech Devices have lower wear propensities than comparable products;

c. Exactech's misrepresentation that the Exactech Devices have better longevity than comparable products;

d. Exactech's misrepresentation that the GXL liner would last patients for their lifetime;

e. Exactech's misrepresentations that the Optetrak knee system had a 98 % survival rate;

f. Exactech's misrepresentations to surgeons complaining of early revisions that their experience was an anomaly not experienced by other surgeons;

g. Exactech's misrepresentation that the Exactech Devices were clinically proven to reduce wear when, in fact, Exactech did not confirm that these statements were clinically accurate;

h. Exactech's misrepresentation that incidents of loosening of Exactech Devices were not a result of any defect in the Exactech Devices, but instead the result of poor surgical technique or other factors;

i. Exactech's misrepresentation of the success rate of the Exactech Devices;

j. Exactech knew of serious defects and dangers associated with the Exactech Devices, yet Exactech knowingly produced and published deceptive and misleading statements and advertisements regarding the safety and efficacy of the Exactech Devices;

k. Exactech knew, yet failed to disclose, that the Exactech Devices were failing at a high rate;

l. Exactech knew, yet failed to disclose, that other patients experienced problems with the Exactech Devices, including but not limited to, osteolysis, loosening of the components, deterioration of the polyethylene, and reports of significant pain;

m. Exactech knew, yet failed to disclose, that competitor products utilizing highly-crosslinked polyethylene and Vitamin infused highly-crosslinked polyethylene were performing better, had a higher success rate, and lower failure rate than the Exactech Devices;

n. Exactech knew, yet failed to disclose, adequate information about the safety and efficacy of the Exactech Devices;

o. Exactech knew, yet failed to disclose, that they were aware of and/or witnessed revision surgeries in which the Exactech Devices showed accelerated wear, became loose, caused osteolysis, and failed;

p. Exactech knew, yet failed to disclose, the increased rate of wear related adverse events with the Exactech Devices;

q. Exactech knew, yet failed to disclose, the increased incidents of loosening with the Exactech Devices; and

r. Exactech knew, yet failed to disclose, that the Exactech Devices were improperly packaged, as identified in the Recalls.

751. As described above, each of Exactech's representations and omissions about its Hip, Knee, and Ankle Devices was false and misleading.

752. In the exercise of reasonable care, Exactech should have known that each of these representations and omissions was false and misleading.

753. Plaintiff and Plaintiff's surgeons relied upon Exactech's representations and omissions in deciding to use an Exactech Device in their joint replacement surgeries.

754. Each of the representations and omissions stated above were material to Plaintiff and Plaintiff's surgeons' decision to use an Exactech Device in their joint replacement surgery.

755. It was not only foreseeable to Exactech, but also intended that patients and physicians, such as Plaintiff and Plaintiff's surgeons, would receive and rely upon these representations when deciding which device to use for joint replacement surgery.

756. Plaintiff's surgeons exercised reasonable care in relying upon Exactech's representations and omissions in choosing to use Exactech's Devices in Plaintiffs' surgeries.

757. Plaintiff's surgeons also exercised reasonable care in relying upon Exactech's representations and omissions when deciding the best course of medical treatment following implantation of the Exactech's Devices.

758. As a direct and proximate result of Exactech's misrepresentations and omissions, Plaintiff received Exactech's Knee Devices, which subsequently failed.

759. As a direct and proximate result of the failure of Exactech's Knee Devices, Plaintiff has suffered and will continue to suffer damages and harm including serious personal injuries, conscious pain and suffering, physical disability, disabilities in activities of daily living, mental anguish, emotional distress, fear, loss of enjoyment of life, loss of income, medical expenses, and financial losses.

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

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

762. Defendants' actions and omissions alleged in this Complaint were intentional, malicious, reckless, wanton, fraudulent, beyond all standards of decency, and without regard for human life or Plaintiffs' rights, thereby warranting the imposition of punitive damages.

EIGHTH CAUSE OF ACTION: FRAUD

(Against Exactech Defendants and TPG Defendants[19])

763. Plaintiffs hereby incorporate by reference as if fully set forth herein, the factual allegations set forth in the paragraphs above and further allege as follows.

764. Prior to the initial surgeries in which Plaintiff's Exactech Knee Devices were implanted, and at all times relevant to this action, Exactech designed, tested, studied, researched, formulated, manufactured, inspected, labeled, packaged, stored, promoted, advertised, marketed, distributed, and/or sold the Devices for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

765. At all relevant times, Exactech possessed superior knowledge about its Exactech Hip, Knee, and Ankle Devices regarding the design, manufacture, storage, packaging, propensities, wear characteristics, longevity, adverse event reports, and failure rates associated with these Devices.

766. Exactech knew that such information was not readily available to Plaintiff or his physicians and that Plaintiff and his physicians relied upon it to accurately provide this information for purposes of deciding which joint replacement device to use and the proper course of medical treatment following implantation.

767. In light of its possession to superior knowledge about its Devices, Exactech had a duty to disclose information regarding the safety and efficacy of its products.

768. Prior to and following Plaintiff's implant surgeries, Exactech made fraudulent representations and omissions to patients and physicians, including Plaintiff and Plaintiff's

[19] Plaintiffs' claims against TPG Defendants are based on the general concepts of successor liability and piercing the corporate veil and include without limitation any similar doctrines for imposing liability on affiliated companies that may be available under any particular state's governing law.

surgeon, about Exactech's Knee Devices. While set forth in greater detail above, such fraudulent statements, misrepresentations and omissions include, but are not limited to:

a. Exactech's misrepresentation that the Exactech Devices had a long successful clinical history and performed better than similar competitors' devices on the market;

b. Exactech's misrepresentation that the Exactech Devices have lower wear propensities than comparable products;

c. Exactech's misrepresentation that the Exactech Devices have better longevity than comparable products;

d. Exactech's misrepresentation that the Exactech Devices were clinically proven to reduce wear when, in fact, Exactech did not confirm that these statements were clinically accurate;

e. Exactech's misrepresentation that incidents of loosening of Exactech Devices were not a result of any defect in the Exactech Devices, but instead the result of poor surgical technique or other factors;

f. Exactech's misrepresentation of the success rate of the Exactech Devices;

g. Exactech's misrepresentation that the GXL liner would last patients for their lifetime;

h. Exactech's misrepresentations that the Optetrak knee system had a 98 % survival rate;

i. Exactech's misrepresentations to surgeons complaining of early revisions that their experience was an anomaly not experienced by other surgeons;

j. Exactech knew of serious defects and dangers associated with the Exactech Devices, yet Exactech knowingly produced and published deceptive and misleading statements and advertisements regarding the safety and efficacy of the Exactech Devices;

k. Exactech's misrepresentation that components received from suppliers, as

well as those manufactured internally are examined by Exactech personnel to ensure specifications and standards are maintained;

l. Exactech knew, but failed to disclose, that the Exactech hip liners and knee, and ankle inserts were never validated or checked to ensure product specifications to prevent device oxidation;

m. Exactech knew, yet failed to disclose, that the Exactech Devices were failing at a high rate;

n. Exactech knew, yet failed to disclose, that other patients experienced problems with the Exactech Devices, including but not limited to, osteolysis, loosening of the components, deterioration of the polyethylene, and reports of significant pain;

o. Exactech knew, yet failed to disclose, that competitor products utilizing highly-crosslinked polyethylene and Vitamin infused highly-crosslinked polyethylene were performing better, had a higher success rate, and lower failure rate than the Exactech Devices;

p. Exactech knew, yet failed to disclose, adequate information about the safety and efficacy of the Exactech Devices;

q. Exactech knew, yet failed to disclose, that they were aware of and/or witnessed revision surgeries in which the Exactech Devices showed accelerated wear, became loose, caused osteolysis, and failed;

r. Exactech knew, yet failed to disclose, the increased rate of wear related adverse events with the Exactech Devices;

s. Exactech knew, yet failed to disclose, the increased incidents of loosening with the Exactech Devices; and

t. Exactech knew, yet failed to disclose, that the Exactech Devices were improperly packaged, as identified in the Recalls.

769. As described above, each of Exactech's fraudulent representations and omissions

about its Hip, Knee, and Ankle Devices was false and misleading.

770. Exactech made each of these fraudulent representations and omissions knowing that they were false and misleading.

771. Exactech made these fraudulent representations and omissions with the intent of selling more Exactech Hip, Knee, and Ankle Devices and creating demand for Exactech's Devices.

772. Plaintiff and Plaintiff's surgeons relied upon Exactech's fraudulent representations and omissions in deciding to use an Exactech Device in their joint replacement surgeries.

773. Each of the representations and omissions stated above were material to Plaintiff and Plaintiff's surgeons' decision to use an Exactech Device in their joint replacement surgeries.

774. It was not only foreseeable to Exactech, but also intended that patients and physicians, such as Plaintiff and Plaintiff's surgeons, would receive and rely upon these false and fraudulent representations and omissions when deciding which device to use for joint replacement surgery.

775. Plaintiff's surgeons exercised reasonable care in relying upon Exactech's fraudulent representations and omissions in choosing to use Exactech's Devices in Plaintiff's surgeries.

776. Plaintiff's surgeons also exercised reasonable care in relying upon Exactech's fraudulent representations and omissions when deciding the best course of medical treatment following implantation of the Exactech's Devices.

777. As a direct and proximate result of Exactech's fraud, Plaintiffs received Exactech's Knee Devices, which subsequently failed.

778. As a direct and proximate result of the failure of Exactech's Knee Devices, Plaintiff has suffered and will continue to suffer damages and harm including serious personal injuries, conscious pain and suffering, physical disability, disabilities in activities of daily living, mental anguish, emotional distress, fear, loss of enjoyment of life, loss of income, medical expenses, and financial losses.

779. The injuries, damages, harm, and losses sustained by Plaintiff were caused solely

and wholly by virtue of the following acts, omissions, and conduct of Defendants and were in no way caused and/or contributed to by Plaintiff.

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

781. Defendants' actions and omissions alleged in this Complaint were intentional, malicious, reckless, wanton, fraudulent, beyond all standards of decency, and without regard for human life or Plaintiffs' rights, thereby warranting the imposition of punitive damages.

NINTH CAUSE OF ACTION: FRAUDULENT CONCEALMENT

(Against Exactech Defendants and TPG Defendants[20])

782. Plaintiffs hereby incorporate by reference as if fully set forth herein, the factual allegations set forth in the paragraphs above and further allege as follows.

783. Prior to the initial surgeries in which Plaintiff's Exactech Knee Devices were implanted, and at all times relevant to this action, Exactech designed, tested, studied, researched, formulated, manufactured, inspected, labeled, packaged, stored, promoted, advertised, marketed, distributed, and/or sold the Devices for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

784. At all relevant times, Exactech possessed superior knowledge about its Exactech Hip, Knee, and Ankle Devices regarding the design, manufacture, storage, packaging, propensities, wear characteristics, longevity, adverse event reports, and failure rates associated with these Devices.

785. Exactech knew that such information was not readily available to Plainti ff or his physicians and that Plaintiff and his physicians relied upon it to accurately provide this information for purposes of deciding which joint replacement device to use and the proper course of medical

[20] Plaintiffs' claims against TPG Defendants are based on the general concepts of successor liability and piercing the corporate veil and include without limitation any similar doctrines for imposing liability on affiliated companies that may be available under any particular state's governing law.

treatment following implantation.

786. In light of its possession of superior knowledge about its Devices, Exactech had a duty to disclose and not fraudulently conceal information regarding the safety and efficacy of its products.

787. Prior to and following Plaintiff's implant surgeries, Exactech, through its affirmative misrepresentations and omissions, actively and fraudulently concealed from Plaintiff and Plaintiff's healthcare providers the defects in and true and significant risks associated with Exactech's Hip, Knee, and Ankle Devices. While set forth in greater detail above, such fraudulent statements, misrepresentations, and omissions include, but are not limited to:

a. Exactech's misrepresentation that the Exactech Devices had a long successful clinical history and performed better than similar competitors' devices on the market;

b. Exactech's misrepresentation that the Exactech Devices have lower wear propensities than comparable products;

c. Exactech's misrepresentation that the Exactech Devices have better longevity than comparable products;

d. Exactech's misrepresentation that the Exactech Devices were clinically proven to reduce wear when, in fact, Exactech did not confirm that these statements were clinically accurate;

e. Exactech's misrepresentation that incidents of loosening of Exactech Devices were not a result of any defect in the Exactech Devices, but instead the result of poor surgical technique or other factors;

f. Exactech's misrepresentation of the success rate of the Exactech Devices;

g. Exactech's misrepresentation that the GXL liner would last patients for their lifetime;

h. Exactech's misrepresentations that the Optetrak knee system had a 98 % survival rate;

i. Exactech knew of serious defects and dangers associated with the Exactech Devices, yet Exactech knowingly produced and published deceptive and misleading statements and advertisements regarding the safety and efficacy of the Exactech Devices;

j. Exactech's misrepresentation that components received from suppliers, as well as those manufactured internally are examined by Exactech personnel to ensure specifications and standards are maintained;

k. Exactech's fraudulent concealment of the fact that the Exactech hip liners and knee, and ankle inserts were never validated or checked to ensure product specifications to prevent device oxidation;

l. Exactech's fraudulent concealment of the fact the Exactech Devices were failing at a high rate;

m. Exactech's fraudulent concealment of the fact that other patients experienced problems with the Exactech Devices, including but not limited to, osteolysis, loosening of the components, deterioration of the polyethylene, and reports of significant pain;

n. Exactech's fraudulent concealment of the fact that competitor products utilizing highly-crosslinked polyethylene and Vitamin infused highly-crosslinked polyethylene were performing better, had a higher success rate, and lower failure rate than the Exactech Devices;

o. Exactech's fraudulent concealment of adequate information about the safety and efficacy of the Exactech Devices;

p. Exactech's fraudulent concealment of the fact that it was aware of and/or witnessed revision surgeries in which the Exactech Devices showed accelerated wear, became loose, caused osteolysis, and failed;

q. Exactech's fraudulent concealment of the fact that it had knowledge of an increased rate of wear related adverse events with the Exactech Devices;

r. Exactech's fraudulent concealment of the fact that it had knowledge of increased incidents of loosening with the Exactech Devices;

s. Exactech's fraudulent concealment of the fact that that the Exactech Devices were improperly packaged, as identified in the Recalls; and

t. Exactech's fraudulent concealment to any surgeon complaining of early revisions of the fact that other surgeons were also complaining of unexpected early revisions and telling surgeons that their experiences were an anomaly.

788. Exactech fraudulently concealed this material information and made these fraudulent representations and omissions with the intent of selling more Exactech Hip, Knee, and Ankle Devices and creating demand for Exactech's Devices.

789. As described above, each of Exactech's acts, fraudulent representations, and omissions about its Hip, Knee, and Ankle Devices was false and misleading.

790. By concealing this material information and making these fraudulent misrepresentations and omissions, Exactech's marketing, advertisements, promotions, and descriptions of its Hip, Knee, and Ankle Devices were false and misleading.

791. The facts that Exactech fraudulently concealed, misrepresented, and omitted were material to Plaintiff's and Plaintiff's surgeons' decision to use Exactech Devices in their joint replacement surgeries.

792. Indeed, Plaintiff and Plaintiff's surgeons relied upon Exactech's fraudulent misrepresentations and omissions in deciding to use an Exactech Device in their joint replacement surgeries.

793. It was not only foreseeable to Exactech, but also intended that patients and physicians, such as Plaintiff and Plaintiff's surgeons, would receive and rely upon these false and fraudulent representations and omissions when deciding which device to use for joint replacement surgery and the proper course of treatment following implantation.

794. Plaintiff's surgeons exercised reasonable care in relying upon Exactech's fraudulent

representations and omissions in choosing to use Exactech's Devices in Plaintiff's surgeries.

795. Plaintiff's surgeons also exercised reasonable care in relying upon Exactech's fraudulent representations and omissions when deciding the best course of medical treatment following implantation of the Exactech's Devices.

796. As a result of Exactech's fraudulent concealment, omissions, and misrepresentations of material facts, Plaintiff and his healthcare providers were unaware, and could not have reasonably known, learned, or discovered that the Exactech Devices being implanted were defective and unreasonably dangerous.

797. Moreover, as a result of Exactech's fraudulent concealment, omissions, and misrepresentations, following implantation, Plaintiff and his healthcare providers were unaware, and could not have reasonably known, learned, or discovered that any of Plaintiff's symptoms or radiological findings indicative of a potential problem with Plaintiff's joints were the result of defects in the Exactech Devices.

798. As a direct and proximate result of Exactech's fraudulent concealment, omissions, and misrepresentations, Plaintiff received Exactech's Knee Devices, which subsequently failed.

799. As a direct and proximate result of the failure of Exactech's Knee Devices, Plaintiff has suffered and will continue to suffer damages and harm including serious personal injuries, conscious pain and suffering, physical disability, disabilities in activities of daily living, mental anguish, emotional distress, fear, loss of enjoyment of life, loss of income, medical expenses, and financial losses.

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

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

802. Defendants' actions and omissions alleged in this Complaint were intentional,

malicious, reckless, wanton, fraudulent, beyond all standards of decency, and without regard for human life or Plaintiff's rights, thereby warranting the imposition of punitive damages.

TENTH CAUSE OF ACTION:
CONSUMER FRAUD AND DECEPTIVE TRADE PRACTICES
VIOLATIONS OF GBL §§ 349 AND 350

(Against Exactech Defendants and TPG Defendants[21])

803. Plaintiffs hereby incorporate by reference as if fully set forth herein, the factual allegations set forth in the paragraphs above and further allege as follows.

804. The allegations contained in previous paragraphs set forth specific representations the DEFENDANTS have made to consumers, physicians, and other healthcare providers through their advertising and promotional materials (some of which are reproduced above). These representations were made by the DEFENDANTS on an ongoing and repeated basis, and, as specifically relevant here, at various points prior to 2015.

805. The representations made by the DEFENDANTS were materially deceptive in that they asserted that their defective knee 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.

806. In such representations, the DEFENDANTS willfully ignored or avoided the reports, scientific data and studies concluding that their defective knee implants had high failure and revision rates so that it could continue to sell the Opetrak Logic devices and profit from their sales.

807. The DEFENDANTS willfully failed to take protective measures, such as changing

[21] Plaintiffs' claims against TPG Defendants are based on the general concepts of successor liability and piercing the corporate veil and include without limitation any similar doctrines for imposing liability on affiliated companies that may be available under any particular state's governing law.

their products, packaging, guidelines, instructions, and/or warnings, which would have prevented Patients such as BRENDAN LEDDY from being implanted with the defective 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.

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

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

810. The 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 Optetrak 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 his physicians and medical providers, rely upon such concealment, suppression and omission, in connection with the sale, advertisement and promotion of Subject Defective Optetrak devices;

d. Representing that the Subject Defective Optetrak 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.

811. The DEFENDANTS intended for Patients like BRENDAN LEDDY and healthcare providers to rely on their representations and advertisements regarding the Subject Defective Optetrak devices, so that the DEFENDANTS would profit from their sale.

812. The Defendants' deceptive conduct was directed at physicians, healthcare providers, Patients, including Plaintiff, and the public in order to create demand and sell the Optetrak Logic defective devices.

813. Each aspect of the DEFENDANTS' conduct combined to artificially create sales of their Subject Defective Optetrak devices, including the Logic devices and specifically the Defective Implants, and to deceive the public at large and Plaintiff, BRENDAN LEDDY, in particular.

814. As a result of the deceptive trade practices engaged in by the 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.

815. The DEFENDANTS' intentional, deceptive, unconscionable, immoral, and fraudulent representations and material omissions to Plaintiff BRENDAN LEDDY, physicians, and consumers constitute deceptive trade practices.

816. Under New York law, the 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 Optetrak devices.

817. Had the DEFENDANTS not engaged in the deceptive conduct described above, BRENDAN LEDDY would not have been implanted with the defective and dangerous product and would not have incurred related injuries and damages.

818. The DEFENDANTS had actual knowledge of the defective and dangerous condition of the Subject Defective Optetrak devices, including their defective polyethylene plastic tibial inserts, and failed to take any action to cure such defective and dangerous conditions.

819. Plaintiff BRENDAN LEDDY and healthcare providers relied upon the DEFENDANTS misrepresentations and omissions in deciding to purchase and use the Subject Defective Optetrak devices, costs which were passed off to Plaintiff as a patient and consumer.

820. Plaintiff BRENDAN LEDDY and healthcare providers were misled into not objecting to the use of the Subject Defective Optetrak devices as a direct and proximate result of the DEFENDANTS misrepresentations, omissions, and deceptive marketing campaigns.

821. As a direct and proximate result foregoing acts, omissions, and conduct committed by the DEFENDANTS, Plaintiff BRENDAN LEDDY was implanted with the Defective Implants 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.

822. By reason of the foregoing acts, omissions, and conduct committed by the DEFENDANTS, Plaintiff BRENDAN LEDDY 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.

823. By reason of the foregoing acts, omissions and conduct committed by the DEFENDANTS, Plaintiff BRENDAN LEDDY was caused to sustain disabilities in activities of daily living.

824. By reason of the foregoing acts, omissions and conduct committed by the DEFENDANTS, Plaintiff BRENDAN LEDDY has sustained and will sustain medical expenses and related economic losses.

825. The injuries, damages, harm, and losses sustained by Plaintiff BRENDAN LEDDY 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 BRENDAN LEDDY.

826. By reason of the foregoing, Plaintiff BRENDAN LEDDY is entitled to monetary damages from Defendants for his past, present, and future non-economic and economic injuries, harm, and losses in an amount that exceeds the jurisdictional minimum.

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

ELEVENTH CAUSE OF ACTION: LOSS OF CONSORTIUM

(Against Exactech Defendants and TPG Defendants[22])

828. Plaintiffs hereby incorporate by reference as if fully set forth herein, the factual allegations set forth in the paragraphs above and further allege as follows.

829. At all relevant times, Plaintiff PATRICIA LEDDY was and is the lawfully wedded wife of Plaintiff BRENDAN LEDDY, and as such, was and is entitled to the services, consortium and society of BRENDAN LEDDY.

830. As a direct and proximate cause of Exactech's previously described actions, misrepresentations, and omissions and the failure of the Exactech Devices implanted into Plaintiff, Loss of Consortium Plaintiffs have suffered and will continue to suffer the loss of their loved one's support, companionship, services, society, love, affection, and consortium.

831. As a direct and proximate cause of Exactech's previously described actions, misrepresentations, and omissions, and the failure of the Exactech Devices implanted into Plaintiff, Loss of Consortium Plaintiff has suffered and will continue to suffer great emotional pain, distress, and mental anguish.

[22] Loss of Consortium Plaintiffs' claims against TPG Defendants are based on the general concepts of successor liability and piercing the corporate veil and include without limitation any similar doctrines for imposing liability on affiliated companies that may be available under any particular state's governing law.

832. As a direct and proximate result of Exactech's previously described actions, misrepresentations, and omissions, and the failure of the Exactech Devices implanted into Plaintiff, Loss of Consortium Plaintiffs have suffered and will continue suffer to injuries, damages, and economic loss in the future.

833. Defendants' actions and omissions alleged in this Complaint were intentional, malicious, reckless, wanton, fraudulent, beyond all standards of decency, and without regard for human life or the rights of Plaintiffs or Loss of Consortium Plaintiffs, thereby warranting the imposition of punitive damages.

TWELFTH CAUSE OF ACTION: PUNITIVE DAMAGES

(Against Exactech Defendants and TPG Defendants[23])

834. Plaintiffs hereby incorporate by reference as if fully set forth herein, the factual allegations set forth in in the paragraphs above and further allege as follows.

835. Defendants' actions and omissions alleged in this Complaint were intentional, malicious, reckless, wanton, fraudulent, beyond all standards of decency, and without regard for human life or Plaintiff's rights. These actions include, but are not limited to:

a. Intentionally and recklessly designing, manufacturing, and selling Exactech Hip, Knee, and Ankle Devices Defendants knew to be defective due to their susceptibility to oxidation, accelerated wear, and failure;

b. Intentionally and recklessly failing to rotate and test inventory to remove oxidized and otherwise compromised Exactech Hip, Knee, and Ankle Devices from the market prior to implantation;

c. Intentionally and recklessly failing to confirm Exactech Hip, Knee, and Ankle Devices were properly packaged and stored for seventeen years;

[23] Plaintiffs' claims against TPG Defendants are based on the general concepts of successor liability and piercing the corporate veil and include without limitation any similar doctrines for imposing liability on affiliated companies that may be available under any particular state's governing law.

d. Intentionally and recklessly failing to investigate, report, and follow up on reports of failure associated with Exactech Hip, Knee, and Ankle Devices; and

e. Fraudulently misrepresenting, omitting, and concealing facts regarding the failure rates, wear characteristics, defects, and substantial injuries caused by the Exactech Hip, Knee, and Ankle Devices.

836. As a direct and proximate result of the failure of Exactech's Knee Devices, Plaintiff has suffered and will continue to suffer damages and harm including serious personal injuries, conscious pain and suffering, physical disability, disabilities in activities of daily living, mental anguish, emotional distress, fear, loss of enjoyment of life, loss of income, medical expenses, and financial losses.

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

838. Plaintiffs are thus entitled to punitive damages.

839. Plaintiffs demand judgment against Defendants and request punitive damages and all other such relief as the Court deems equitable and just.

PRAYER FOR RELIEF

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

a. Compensatory damages in excess of the jurisdictional amount, including but not limited to compensation for injury, pain, suffering, mental anguish, emotional distress, loss of enjoyment of life, and other non-economic damages in an amount to be determined in a trial of this action;

b. Economic damages that include, but are not limited to, medical expenses, out-of-pocket expenses, lost wages, and diminished earning capacity in an amount to be determined in a trial of this action;

c. Punitive and/or exemplary damages in an amount to be determined in a trial of this action on Counts I, II, III, IV, IV, VI, VII, VIII, IX, X, XI, XII;

d. Attorneys' fees, expenses, and costs in this action;

e. Pre-judgment and post-judgment interest; and

f. Any and all further relief that this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury.

Dated: February 6, 2023

Respectfully Submitted,

/s/ Ilana S. Wolk

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