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

IN RE: EXACTECH POLYETHYLENE ORTHOPEDIC PRODUCTS LIABILITY LITIGATION	**MDL No. 3044 (NGG) (MMH)** **Case No.: 1:22-md-03044-NGG-MMH** **District Judge Nicholas G. Garaufis** **Magistrate Judge Marcia M. Henry**

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THIS DOCUMENT RELATES TO: ALL CASES

EXACTECH DEFENDANTS' MASTER LONG FORM ANSWER AND ADDITIONAL DEFENSES

Defendants Exactech, Inc. and Exactech U.S., Inc. (collectively, the "Exactech Defendants"), by and through their counsel, respond to Plaintiffs' Master Personal Injury Complaint ("Complaint"), and state their additional defenses as follows:

PRELIMINARY STATEMENT

Exactech Defendants' Master Long Form Answer and Additional Defenses does not waive any affirmative defense that could be asserted or constitute an admission of any claims. As ordered, the Exactech Defendants reserve the right to later move to dismiss counts alleged in the Master Complaint (at the appropriate time in any individual Plaintiff's action), later assert additional affirmative defenses in individual actions, file an Amended Answer to address specifically any individual Complaints, or otherwise challenge the sufficiency of any claim or cause of action in any Complaint under the applicable state's law. The Exactech Defendants have not admitted the allegations set forth in the Master Complaint and Short Form Complaints, nor conceded or waived the right to dispute the legal validity of the claims alleged therein. *See* Case Management Order No. 1, Doc. 87.

GENERAL DENIAL

The Exactech Defendants note that a significant portion of the allegations are not proper allegations against the Exactech Defendants and instead constitute information or issues that, even if relevant, are properly addressed by expert witnesses in the areas of engineering, medicine, and regulation, or by the Court, to the extent they are issues or questions of law. The Exactech Defendants deny each and every allegation in the Complaint unless expressly admitted or otherwise answered herein. Further, the section headings and footnotes from the Complaint are included only for purposes of organization and ease of reference. The Exactech Defendants do not admit, and instead specifically deny, any averments in the headings and footnotes.

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.

ANSWER: The Exactech Defendants admit that the Plaintiffs have brought lawsuits alleging product liability claims involving the alleged implantation of hip, knee, and ankle joint replacement systems. The Exactech Defendants deny the remaining allegations contained in Paragraph 1 of the Complaint and decline to adopt Plaintiffs' characterizations.

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").

ANSWER: The Exactech Defendants admit that this litigation concerns the alleged implantation of Exactech hip, knee, and ankle joint replacement systems (hereinafter, these products generally are referred to as "Devices," a term that does not denote the exact components specifically implanted in Plaintiffs). The Exactech Defendants deny the remaining allegations contained in Paragraph 2 of the Complaint.

3. While each of these Devices is distinct, common among them is Exactech's use of ultra-high molecular weight polyethylene ("UHMWPE") in the inserts or liner components.

ANSWER: The Exactech Defendants admit that these Devices contain ultra-high molecular weight polyethylene ("UHMWPE") in the inserts or liner components. The Exactech Defendants deny the remaining allegations contained in Paragraph 3 of the Complaint.

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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 4 of the Complaint.

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, degradation, pitting, and delamination. Additionally, Exactech failed to properly design, manufacture, test, surveil clinical history, and report to regulatory authorities and clinicians failures of its defective femoral components of its Optetrak and Truliant knee systems. *See* E.B. GAUSDEN, ET. AL., *Mid-term Survivorship of Primary Total Knee Arthroplasty with a Specific Implant*, BONE JOINT J., 105-B(3): 277-283, Mar. 2023. Femoral components that improperly loosen and do not adhere create micromotion and increase risk of higher volumetric polyethylene wear.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 5 of the Complaint.

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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 6 of the Complaint.

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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 7 of the Complaint.

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.

ANSWER: The Exactech Defendants admit that Exactech, Inc. engaged in voluntary actions classified by FDA as voluntary recalls of GXL Liners, Optetrak knee implants, and Vantage ankle implants. The Exactech Defendants deny the remaining allegations contained in Paragraph 8 of the Complaint.

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.

ANSWER: The Exactech Defendants admit that Exactech, Inc. engaged in voluntary actions classified by FDA as voluntary recalls of GXL Liners on the indicated dates reflected in Exhibit A. The Exactech Defendants deny the remaining allegations contained in Paragraph 9 of the Complaint and decline to adopt Plaintiffs' characterizations.

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.

ANSWER: The Exactech Defendants admit that Exactech, Inc. engaged in voluntary actions classified by FDA as voluntary recalls of certain Knee Devices and Ankle Devices. The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 10 of the Complaint regarding surgeons' actions. The Exactech Defendants deny the remaining allegations contained in Paragraph 10 of the Complaint and decline to adopt Plaintiffs' characterizations.

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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 11 of the Complaint.

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.

ANSWER: Paragraph 12 contains scientific and medical opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 12 can be construed as containing allegations against the Exactech Defendants requiring a response, the

Exactech Defendants deny the allegations contained in Paragraph 12 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

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.

ANSWER: The Exactech Defendants admit that in November 2021 the FDA conducted an inspection of Exactech, Inc. and issued an FDA Form-483. With regard to the FDA's findings in connection with that inspection, the Exactech Defendants admit that the cited FDA Form 483 document contains those findings and that document speaks for itself. The Exactech Defendants deny the remaining allegations contained in Paragraph 13 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 14 of the Complaint.

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

ANSWER: Paragraph 15 of the Complaint contains rhetorical statements and legal conclusions that are not allegations against the Exactech Defendants to which response is required. To the extent Paragraph 15 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations contained in Paragraph 15 of the Complaint.

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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 16 of the Complaint.

PARTIES

I. PLAINTIFFS

17. Plaintiffs are individuals who underwent joint replacement surgeries in which they received one or more defective Exactech Hip, Knee, or Ankle Devices that ultimately failed, causing them to suffer serious personal injuries, including pain, traumatic revision surgery, impaired mobility, physical disability, permanent and substantial physical deformities, loss of use of a limb, amputation, death, medical expense, loss of the enjoyment of life, loss of wages, loss of consortium, and/or other medical conditions.

ANSWER: The Exactech Defendants deny any allegation in Paragraph 17 of the Complaint regarding "failure" or "cause" and deny that Plaintiffs were injured or damaged to the extent claims. The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 17 of the Complaint.

II. EXACTECH DEFENDANTS

18. 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. Exactech, Inc. is a wholly owned subsidiary of Defendant Osteon Holdings, Inc.

ANSWER: The Exactech Defendants admit that Exactech, Inc. is a corporation organized under the laws of the State of Florida with its principal place of business in Gainesville, Florida. The Exactech Defendants deny the remaining allegations contained in Paragraph 18 of the Complaint.

19. 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.

ANSWER: The Exactech Defendants admit that, until February 2023, Exactech U.S., Inc. was a Florida corporation organized under the laws of the State of Florida with its principal place of business in Gainesville, Florida. The Exactech Defendants deny the remaining allegations contained in Paragraph 19 of the Complaint.

20. 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.

ANSWER: The Exactech Defendants admit that Exactech, Inc. generally designs, manufactures, tests, develops, packages, markets, and distributes orthopedic joint implants, including the Devices, throughout the United States. The Exactech Defendants further admit that Exactech U.S., Inc. participated generally in the sale of the Devices in the United States. The Exactech Defendants deny the remaining allegations contained in Paragraph 20 of the Complaint.

21. 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.

ANSWER: The Exactech Defendants admit that Exactech, Inc. derived revenue from the sale of its products throughout the United States, including the State of New York. The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 21 of the Complaint.

22. 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.

ANSWER: The Exactech Defendants admit that Exactech, Inc. designed, manufactured, marketed, and participated in the sale of the Devices for implantation into patients by orthopedic surgeons throughout the United States and derived revenue from the sale of those medical devices. The Exactech Defendants further admit that Exactech U.S., Inc. participated in the sale of certain

medical devices throughout the United States from which entity(ies) within the Exactech, Inc. corporate family derive revenue. The Exactech Defendants deny the remaining allegations contained in Paragraph 22 of the Complaint.

23. At all times relevant to this action, Exactech Defendants were responsible for placing the Exactech Devices implanted into Plaintiffs 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.

ANSWER: The Exactech Defendants admit that Exactech, Inc. marketed and participated in the sale of the Devices for implantation into patients by orthopedic surgeons throughout the United States. The Exactech Defendants further admit that Exactech U.S., Inc. participated in the sale of the Devices generally. The Exactech Defendants deny the remaining allegations contained in Paragraph 23 of the Complaint.

III. TPG DEFENDANTS

24. Defendant TPG, Inc. 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. TPG, Inc. was formerly known as both TPG Capital, LP and TPG Partners, LLC (hereinafter collectively referred to as "TPG").

ANSWER: Paragraph 24 of the Complaint contains allegations regarding a defendant other than the Exactech Defendants and therefore does not call for a response from the Exactech Defendants. The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 24 of the Complaint.

25. Upon information and belief, TPG Capital, LP converted to TPG, Inc. in or around December 2021.

ANSWER: Paragraph 25 of the Complaint contains allegations regarding a defendant other than the Exactech Defendants and therefore does not call for a response from the Exactech Defendants. The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 25 of the Complaint.

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

ANSWER: Paragraph 26 of the Complaint contains allegations regarding a defendant other than the Exactech Defendants and therefore does not call for a response from the Exactech Defendants. The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 26 of the Complaint.

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

ANSWER: Paragraph 27 of the Complaint contains allegations regarding a defendant other than the Exactech Defendants and therefore does not call for a response from the Exactech Defendants. The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 27 of the Complaint.

28. TPG, Inc. is an alternative asset manager that works with companies in many sectors, including the medical device sector.

ANSWER: Paragraph 28 of the Complaint contains allegations regarding a defendant other than the Exactech Defendants and therefore does not call for a response from the Exactech Defendants. The Exactech Defendants admit that Exactech is in the medical device sector and is a portfolio company of TPG. The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 28 of the Complaint.

29. The healthcare sector is one of TPG, Inc.'s most active sectors.

ANSWER: The Exactech Defendants admit that in February 2018, the stock of Exactech was acquired for a price reflecting a total transaction value of approximately $737 million. The Exactech Defendants deny any remaining allegations contained in Paragraph 30 of the Complaint.

30. As set forth in further detail below, in February 2018, TPG, Inc.'s predecessor entity - TPG Capital, LP - paid over $737 million to merge with Exactech ("2018 Merger").

ANSWER: The Exactech Defendants admit that in February 2018, the stock of Exactech was acquired for a price reflecting a total transaction value of approximately $737 million. The Exactech Defendants deny any remaining allegations contained in Paragraph 30 of the Complaint.

31. TPG, Inc. 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."

ANSWER: Paragraph 31 of the Complaint contains allegations regarding a defendant other than the Exactech Defendants and therefore does not call for a response from the Exactech Defendants. The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 31 of the Complaint.

32. Defendant Osteon Holdings, Inc. is a Delaware corporation that has its principal place of business in Delaware, and is an indirect wholly owned subsidiary or indirect beneficially owned affiliate of TPG, Inc. Osteon Holdings, Inc. is a citizen of Delaware. Osteon Holdings, Inc. was formerly known as Osteon Holdings, LP.

ANSWER: Paragraph 32 of the Complaint contains allegations regarding a defendant other than the Exactech Defendants and therefore does not call for a response from the Exactech Defendants. The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 32 of the Complaint.

33. Osteon Holdings, LP converted to Osteon Holdings, Inc. in or around February 2018.

ANSWER: Paragraph 33 of the Complaint contains allegations regarding a defendant other than the Exactech Defendants and therefore does not call for a response from the Exactech Defendants. The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 33 of the Complaint.

34. Defendant Osteon Merger Sub, Inc. is a Texas corporation that has its principal place of business in Florida and is a wholly owned subsidiary of Osteon Holdings, Inc. Osteon Merger Sub, Inc. is a citizen of Florida and Texas.

ANSWER: Paragraph 34 of the Complaint contains allegations regarding a defendant other than the Exactech Defendants and therefore does not call for a response from the Exactech Defendants. The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 34 of the Complaint.

35. Defendant Osteon Intermediate Holdings II, Inc., is a Delaware corporation that has its principal place of business in Delaware 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.

ANSWER: Paragraph 35 of the Complaint contains allegations regarding a defendant other than the Exactech Defendants and therefore does not call for a response from the Exactech Defendants. The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 35 of the Complaint.

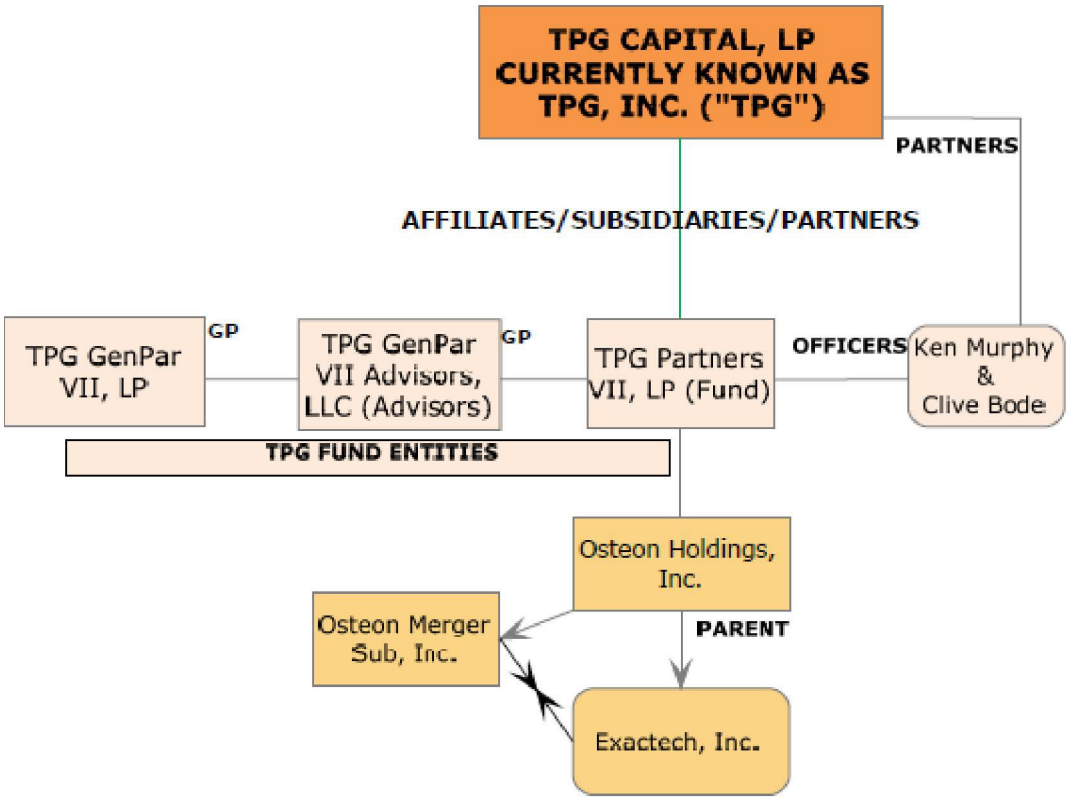
36. At all relevant times, Defendant Osteon Holdings, Inc. (formerly known as Osteon Holdings, LP), Defendant Osteon Merger Sub, Inc., and Defendant Osteon Intermediate Holdings II, Inc. (hereinafter collectively known as "Osteon") have been controlled by TPG, Inc. or its predecessor entities.

ANSWER: Paragraph 36 of the Complaint contains allegations regarding a defendant other than the Exactech Defendants and therefore does not call for a response from the Exactech Defendants. The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 36 of the Complaint.

37. Defendants TPG, Inc., Osteon Holdings, Inc., Osteon Merger Sub, Inc., and Osteon Intermediate Holdings II, Inc. are hereinafter collectively referred to as "TPG Defendants."

ANSWER: Paragraph 37 of the Complaint contains allegations regarding a defendant other than the Exactech Defendants and therefore does not call for a response from the Exactech Defendants. The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 37 of the Complaint.

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



ANSWER: The Exactech Defendants admit that Exactech, Inc. merged with Osteon Merger Sub, Inc. and Exactech Inc. became a subsidiary of Osteon Holdings, Inc. The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 38 of the Complaint.

39. The TPG Defendants, through and in concert with related entities TPG Partners VII, LP, TPG Genpar VII, LP, TPG Genpar VII Advisors, LLC (collectively TPG Fund Entities), exercised control over the merger with Exactech and subsequent operations of Exactech for their direct benefit and they used Exactech to engage in improper conduct as outlined herein and caused harm to Plaintiffs through such improper conduct.

ANSWER: Paragraph 39 of the Complaint contains rhetorical statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The Exactech Defendants deny the allegations contained in Paragraph 39 of the Complaint.

40. The TPG Defendants used Exactech as an agent, alter ego, and mere instrumentality such that the TPG Defendants maintained control over Exactech. Moreover, Exactech and the TPG Defendants should be held jointly and severally liable.

ANSWER: Paragraph 40 contains Plaintiffs' characterizations of its claims and/or legal conclusions, to which no response is required. To the extent Paragraph 40 may be deemed to require a response, the Exactech Defendants deny the allegations in Paragraph 40 of the Complaint.

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

ANSWER: Paragraph 41 of the Complaint contains rhetorical statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 41 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations.

JURISDICTION AND VENUE

42. 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.

ANSWER: Paragraph 42 of the Complaint contains legal conclusions to which no response is required. To the extent Paragraph 42 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 42 of the Complaint.

43. 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.

ANSWER: Paragraph 43 of the Complaint contains Plaintiffs'legal conclusions to which no response is required. To the extent Paragraph 43 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that Exactech Defendants participated in the sale of the Devices throughout the United States. The Exactech Defendants further admit that Exactech, Inc. has worked with surgeons and professionals at the Hospital for Special Surgery in New York at various times over the years regarding innovations in medical device technology and procedures. The Exactech Defendants deny the remaining allegations contained in Paragraph 43 of the Complaint and decline to adopt Plaintiffs' characterizations.

44. 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, the TPG Defendants transacted, solicited, and conducted business in the State of New York and in each Plaintiff's forum state through TPG, Inc.'s New York office, the NASDAQ Stock Market Exchange on which TPG, Inc. is listed, and the TPG Defendants' employees and agents, and derived substantial revenue from such business in those states, including New York. Indeed, TPG, Inc.'s Officers in New York are also Officers of Defendant Osteon Holdings, Inc. and the TPG Fund Entities that funded Osteon Holdings, Inc. and Osteon Merger Sub, Inc. that merged into Exactech.

ANSWER: Paragraph 44 of the Complaint contains Plaintiffs' characterizations and legal conclusions to which no response is required. To the extent Paragraph 44 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that Osteon Merger Sub, Inc. merged into Exactech. The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of any remaining allegations contained in Paragraph 44 of the Complaint.

45. 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.

ANSWER: Paragraph 45 of the Complaint contains legal conclusions to which no response is required. To the extent Paragraph 45 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that Exactech Defendants participated in the sale of the Devices throughout the United States. The Exactech Defendants deny the remaining allegations contained in Paragraph 45 of the Complaint and decline to adopt Plaintiffs' characterizations.

46. 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.

ANSWER: Paragraph 46 of the Complaint contains legal conclusions to which no response is required. The Order speaks for itself. To the extent Paragraph 46 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations and therefore deny them.

47. 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.

ANSWER: Paragraph 47 of the Complaint contains legal conclusions to which no response is required. To the extent Paragraph 47 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations and therefore deny that venue properly lies with respect to every lawsuit presently consolidated or which may be consolidated in this consolidated proceeding.

FACTUAL ALLEGATIONS

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

48. 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.

ANSWER: Paragraph 48 of the Complaint contains rhetorical statements about Plaintiffs' Complaint to which no response is required. To the extent Paragraph 48 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations and decline to adopt Plaintiff's characterizations.

49. 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.

ANSWER: The Exactech Defendants admit that Dr. William Petty was the CEO of Exactech from inception until March 2014, and Dr. William Petty then became Executive Chairman. The Exactech Defendants deny any remaining allegations in Paragraph 49 of the Complaint.

50. 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.

ANSWER: The Exactech Defendants admit that, to their knowledge, Betty Petty served in various roles at Exactech at different times, including the indicated roles. The Exactech Defendants deny the remaining allegations in Paragraph 50 of the Complaint.

51. 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.

ANSWER: The Exactech Defendants admit that, to their knowledge, Gary Miller, Ph.D. is a biomechanical engineer who previously served as Executive Vice President of Research and Development at Exactech, Inc. The Exactech Defendants deny the remaining allegations in Paragraph 51 of the Complaint.

52. 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... ."[1]

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote, in part, the Exactech website, and admit that David Petty is the son of William Petty and Betty Petty and was the first non-founding employee of the company. The cited webpage speaks for itself. The Exactech Defendants deny the remaining allegations contained in Paragraph 52 of the Complaint.

53. 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.

ANSWER: The Exactech Defendants admit the allegations in Paragraph 53 of the Complaint.

54. 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.

ANSWER: The Exactech Defendants admit that Mr. Phillips was employed by Exactech since the 1990s and served in various roles, including Treasurer and Chief Financial Officer, until

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

his departure from the company in 2020. The Exactech Defendants deny the remaining allegations in Paragraph 54 of the Complaint.

55. 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.

ANSWER: The Exactech Defendants admit that Mr. Thompson joined Exactech in 2004 and served as Vice President, Strategic Initiatives prior to and after the acquisition of Exactech completed in 2018. The Exactech Defendants deny the remaining allegations in Paragraph 55 of the Complaint.

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

ANSWER: The Exactech Defendants admit that Donna Edwards has been at Exactech since 2001 and served as Exactech's Vice President, Legal and General Counsel prior to the 2018 Merger. The Exactech Defendants further admit that, following the 2018 Merger, Ms. Edwards served in several roles. The Exactech Defendants further admit that, in 2019, she served as the Vice President, Legal and from 2020 to 2022, Ms. Edwards served as the Senior Vice President, Legal, and Corporate Secretary. The Exactech Defendants further admit that, currently, Ms. Edwards serves as General Counsel, Senior Vice President, Legal and Corporate Secretary. The Exactech Defendants deny the remaining allegations contained in Paragraph 56 of the Complaint.

57. 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.

ANSWER: The Exactech Defendants admit that Mr. Roche served as a Director of Engineering prior to the 2018 acquisition of Exactech and serves as Senior Vice President,

Extremities. The Exactech Defendants deny the remaining allegations in Paragraph 57 of the Complaint.

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

ANSWER: The Exactech Defendants admit that Mr. Szabo served as a Vice President of Marketing prior to the 2018 acquisition of Exactech. The Exactech Defendants deny any remaining allegations in Paragraph 58 of the Complaint.

59. Michael LaGatta was a full-time employee of TPG and many of its subsidiaries and affiliates from approximately 2011 until 2022. For example, Mr. LaGatta has signed agreements on behalf of a number of TPG's subsidiaries and affiliates, including, but not limited to:

a. TPG Global, LLC - Vice President
b. TPG Holdings, LP - Vice President
c. TPG Partner Holdings, LP - Vice President
d. TPG Group Advisors (Cayman), Inc. - Vice President
e. Osteon Holdings, LP ("Parent") - Vice President
f. Osteon Merger Sub, Inc. - Vice President

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the allegations in Paragraph 59 of the Complaint.

60. 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.

ANSWER: The Exactech Defendants admit that Mr. Binder serves as Chairman and was appointed Chief Executive Officer in March of 2022 and has served as an advisor to TPG Capital. The Exactech Defendants deny the remaining allegations in Paragraph 60 of the Complaint.

61. 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 since at least 2017.

ANSWER: The Exactech Defendants admit that Mr. Hann has served as Exactech's Senior Vice President, Business Development since 2018 and served as a consultant to TPG Capital. The Exactech Defendants deny the remaining allegations in Paragraph 61 of the Complaint.

62. 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 Board Members. Prior to assuming his role as Chief Financial Officer and Treasurer of Exactech, Inc., Mr. Bolukbasi worked for TPG as a private equity operations executive, 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.

ANSWER: The Exactech Defendants admit that Mr. Bolukbasi was employed by Exactech as Chief Financial Officer from 2020 to 2022 and that he was relieved of his duties upon the advice and consent of the Exactech Board of Directors. The Exactech Defendants admit that Mr. Bolukbasi was employed by TPG Global, LLC. The Exactech Defendants further admit that Mr. Bolukbasi acted as an advisor to TPG Capital. The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 62 of the Complaint and therefore deny them.

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

ANSWER: The Exactech Defendants admit that Mr. Garrison serves on the Board of Directors of Exactech and is a Principal of TPG Global, LLC, which he joined in 2008. The Exactech Defendants deny any remaining allegations in Paragraph 63 of the Complaint.

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

ANSWER: The Exactech Defendants admit that Mr. Schilling serves on the Board of Directors of Exactech and is Partner, Head of Operations, with TPG Global, LLC, which he joined in 2011. The Exactech Defendants deny the remaining allegations in Paragraph 64 of the Complaint.

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

ANSWER: The Exactech Defendants admit that Mr. Sisitsky serves on the Exactech Board of Directors and is President, Co-Managing Partner with TPG Global, LLC, which he joined in 2003. The Exactech Defendants deny the remaining allegations in Paragraph 65 of the Complaint.

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

ANSWER: The Exactech Defendants admit that Ms. Golz serves on the Exactech Board of Directors.

67. 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.

ANSWER: The Exactech Defendants admit that Mr. Johnson joined Exactech and served as the Vice President of Marketing, Extremities from 2002 to 2016. The Exactech Defendants admit the allegations in sentence two of Paragraph 67, with the exception of the allegation that Mr. Johnson led a team of orthopedic surgeons, to the extent that refers to Exactech's customers. The Exactech Defendants admit that Mr. Johnson became Exactech's President and Chief Executive Officer in January of 2020 and that Mr. Binder was named Chief Executive Officer in March of 2022. The Exactech Defendants deny any remaining allegations in Paragraph 67 of the Complaint.

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

68. 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.

ANSWER: The Exactech Defendants admit that Exactech, Inc. generally designs, manufactures and sells certain orthopedic implant devices, related surgical instrumentation, and certain biologic services to physicians throughout the United States. The Exactech Defendants

further admit that Exactech U.S., Inc. participated generally in the sale of the Devices in the United Staes. The Exactech Defendants deny the remaining allegations contained in Paragraph 68 of the Complaint.

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

ANSWER: The Exactech Defendants admit that, until February 2023, Exactech U.S., Inc. operated as a subsidiary of Exactech, Inc. The Exactech Defendants deny the remaining allegations contained in Paragraph 69 of the Complaint.

70. 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.

ANSWER: The Exactech Defendants admit that Plaintiffs have accurately set forth a partial quote from certain Exactech marketing materials. The Exactech Defendants deny the remaining allegations contained in Paragraph 70 of the Complaint.

71. 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.

ANSWER: The Exactech Defendants admit the allegations in Paragraph 71 of the Complaint.

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

ANSWER: The Exactech Defendants admit that its initial product offering was in the field of hip reconstruction and that Dr. William Petty and Dr. Gary Miller, in their roles at the company, participated in the design of hip reconstruction devices. The Exactech Defendants deny any remaining allegations in Paragraph 72 of the Complaint.

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

ANSWER: The Exactech Defendants admit that Exactech, Inc. transacted approximately $2.1 million in sales in 1991. The Exactech Defendants deny the remaining allegations in Paragraph 73 of the Complaint.

74. 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.

ANSWER: The Exactech Defendants admit that Exactech, Inc. has worked with surgeons and professionals at the Hospital for Special Surgery in New York at various time over the years regarding innovations in medical device technology and procedures. The Exactech Defendants further admit that the Hospital for Special Surgery held patents for certain joint arthroplasty designs. The Exactech Defendants deny the remaining allegations in Paragraph 74 of the Complaint.

75. 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.

ANSWER: The Exactech Defendants admit the allegations in Paragraph 75 of the Complaint.

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

ANSWER: The Exactech Defendants admit that Exactech, Inc. went public with an IPO on the NASDAQ in 1996 that resulted in the raising of capital used in part to support commercialization of the Optetrak knee. The Exactech Defendants deny the remaining allegations in Paragraph 76 of the Complaint.

77. 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.

ANSWER: The Exactech Defendants admit that in 2005, Exactech introduced the Connexion GXL polyethylene for its AcuMatch A-Series acetabular system. The Exactech Defendants deny the remaining allegations in Paragraph 77 of the Complaint.

78. 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.

ANSWER: The Exactech Defendants admit that in 2009, Exactech, Inc. introduced the Optetrak Logic as the next generation of its Optetrak knee system. The Exactech Defendants further admit that Exactech's sales of its knee product lines were approximately $75 million in 2009. The Exactech Defendants deny any remaining allegations in Paragraph 78 of the Complaint.

79. 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.

ANSWER: The Exactech Defendants admit that Exactech, Inc. has contracted with and continues to contract with third-party vendors for the manufacture of certain components parts, that Exactech, Inc. manufactures certain device components parts itself, and that Exactech, Inc. designed and packaged its medical devices and performed quality assurance activities. The Exactech Defendants deny the remaining allegations in Paragraph 79 of the Complaint.

80. 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."[2]

(Emphasis added).

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote, in part, a 2010 press release regarding the company's acquisition of Brighton Partners. The cited press release speaks for itself. The Exactech Defendants deny the remaining allegations contained in Paragraph 80 of the Complaint.

81. 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 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.

[2] 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).

ANSWER: The Exactech Defendants admit the allegations contained in Paragraph 81 of the Complaint.

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

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 82, due to a lack of specificity as to which components, suppliers, and business partners are being referenced, and in the absence of more specificity, therefore deny them.

83. 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.

ANSWER: The Exactech Defendants admit that Exactech, Inc. manufactured and packaged certain medical devices at its facility in Gainesville, Florida and that it received certain component parts and raw materials from suppliers at that location. The Exactech Defendants further admit that Exactech, Inc. employed quality control policies and procedures that governed the manufacture and packaging of Exactech, Inc.'s products. The Exactech Defendants deny the remaining allegations in Paragraph 83 of the Complaint.

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

ANSWER: The Exactech Defendants admit that Exactech, Inc. introduced and began marketing the Vantage Total Ankle System in 2016. The Exactech Defendants deny the remaining allegations in Paragraph 84 of the Complaint.

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

ANSWER: The Exactech Defendants admit that Exactech, Inc. began selling the Truliant knee system in 2017, and that the Truliant knee system evolved from design elements of the Optetrak knee system. The Exactech Defendants deny the remaining allegations in Paragraph 85 of the Complaint.

86. Later that year, Exactech began discussions about merging with the TPG Defendants.

ANSWER: The Exactech Defendants admit that in 2017, certain individuals at Exactech, Inc. had discussions with certain individuals at TPG Partners VII, LP regarding a potential acquisition of the company. The Exactech Defendants deny the remaining allegations in Paragraph 86 of the Complaint.

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

ANSWER: The Exactech Defendants admit that Exactech, Inc. maintains an inventory of its products. The Exactech Defendants deny the remaining allegations in Paragraph 87 of the Complaint.

88. 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.

ANSWER: The Exactech Defendants admit that inventories of its products are provided to Exactech's distributors which they possess until they are implanted or returned to Exactech. The Exactech Defendants deny any remaining allegations in Paragraph 88 of the Complaint.

89. 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.

ANSWER: The Exactech Defendants admit that independent sales agents make available to surgeons various sizes of orthopedic implants before or during a surgical procedure to meet the

needs of surgeons and patients. The Exactech Defendants deny the remaining allegations in Paragraph 89.

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

ANSWER: The Exactech Defendants admit that inventory generally can constitute an asset. The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 90, including due to the vagueness of the allegations.

91. 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."

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote a portion of Exactech's past 10K Annual Reports, which speak for themselves. The Exactech Defendants deny the remaining allegations in Paragraph 91 of the Complaint.

III. TPG DEFENDANTS' CONTROL OF EXACTECH

A. TPG Defendants' Control over Exactech

92. 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, LP ("Parent") (now Defendant Osteon Holdings, Inc.) and Defendant Osteon Merger Sub, Inc., a corporation and wholly owned subsidiary of Parent.

ANSWER: The Exactech Defendants admit that on October 22, 2017, Exactech, Inc. submitted a Form 8-K filing to the SEC reporting that it had entered into an Agreement and Plan of Merger with Osteon Holdings, L.P. and Osteon Merger Sub, Inc., a Florida corporation and wholly owned subsidiary of Osteon Holdings, L.P. The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 92 of the Complaint.

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

ANSWER: The Exactech Defendants admit that the October 22, 2017 Form 8-K filing describes the parties to the Agreement and Plan of Merger and discusses the issue of financing. The Exactech Defendants deny any remaining allegations in Paragraph 93 of the Complaint.

94. 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.

ANSWER: The Exactech Defendants admit that the Agreement and Plan of Merger attached to the October 22, 2017 Form 8-K filing provided that Exactech, Inc. and Osteon Merger Sub, Inc. would be merged and Exactech, Inc. would continue as the surviving company. The Exactech Defendants deny any remaining allegations in Paragraph 94 of the Complaint.

95. 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, LP, to purchase certain equity interests of Parent ("Letter Agreement").

ANSWER: The Exactech Defendants admit the allegations in Paragraph 95 of the Complaint.

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

ANSWER: The Exactech Defendants admit the allegations in Paragraph 96 of the Complaint.

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

ANSWER: Paragraph 97 of the Complaint contains allegations directed at parties other than the Exactech Defendants and therefore does not require a response from the Exactech Defendants. To the extent Paragraph 97 contains allegations requiring a response from the

Exactech Defendants, the Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations.

98. TPG Capital, LP (now Defendant TPG, Inc.) negotiated the terms of the merger of Exactech, as it controlled Osteon Holdings, LP (now Defendant Osteon Holdings Inc.) and Defendant Osteon Merger Sub, Inc.

ANSWER: Paragraph 98 of the Complaint contains allegations directed at parties other than the Exactech Defendants and therefore does not require a response from the Exactech Defendants. To the extent Paragraph 98 contains allegations requiring a response from the Exactech Defendants, the Exactech Defendants admit that Partners VII, LP negotiated the terms of Exactech's merger with Osteon Merger Sub, Inc. The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations and therefore deny them.

99. TPG Capital LP (now Defendant TPG, Inc.) also organized and directed the financing of the merger of Exactech through TPG Partners VII, LP, which served as the financing entity for the merger and is controlled by TPG, Inc.

ANSWER: Paragraph 99 of the Complaint contains allegations directed at parties other than the Exactech Defendants and therefore does not require a response from the Exactech Defendants. To the extent Paragraph 99 contains allegations requiring a response from the Exactech Defendants, the Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations and therefore deny them.

B. TPG's Control over Its Affiliates

100. Osteon Holdings, LP (the predecessor entity of Defendant Osteon Holdings Inc.) and Defendant Osteon Merger Sub, Inc. are referred to as "Affiliates" of TPG Capital, LP (now Defendant TPG, Inc.) in SEC filings related to the Merger.

ANSWER: The Exactech Defendants admit that Osteon Holdings, L.P. and Osteon Merger Sub, Inc. are referred to as "Affiliates" of TPG Capital, L.P. in SEC filings related to the

Merger. The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 100 of the Complaint.

101. Specifically, Exactech, Inc. reported to the SEC that "Parent [Osteon Holdings LP, the predecessor entity of Defendant Osteon Holdings Inc.] and Merger Sub [Defendant, Osteon Merger Sub, Inc] are affiliates of global private equity firm TPG Capital LP." Exactech, Inc., Current Report (Form 8-K) (Oct. 22, 2017).

ANSWER: The Exactech Defendants admit that Exactech reported to the SEC that Osteon Holdings, L.P. and Osteon Merger Sub, Inc. are referred to as "Affiliates" of TPG Capital, L.P. in SEC filings. The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 101 of the Complaint.

102. 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.

ANSWER: To the extent Paragraph 102 quotes selected statements from a press release related to an amendment to a merger agreement between Exactech, Inc. and entities affiliated with TPG Capital, the Exactech Defendants refer to the contents therein and deny any description that

is inconsistent therewith. The Exactech Defendants deny any remaining allegations in Paragraph 102 of the Complaint.

103. 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.

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote select portions of a Section 8-K filing pertaining to Exactech, Inc. dated February 13, 2018. The Exactech Defendants admit to the content stated verbatim in that filing and deny any remaining allegations in Paragraph 103 of the Complaint.

104. 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).

ANSWER: Paragraph 104 contains legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited regulation speaks for itself. To the extent Paragraph 104 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that the Securities Act of 1933 defines the word "affiliate" and deny the remaining allegations, including because they decline to adopt Plaintiffs' characterizations.

105. Osteon Holdings, LP (predecessor entity of Defendant Osteon Holdings, Inc.) and Defendant Osteon Merger Sub, Inc. were the corporate vehicles used by TPG Capital LP (now Defendant TPG, Inc.) to consummate the merger with Exactech, Inc.

ANSWER: The Exactech Defendants admit that Osteon Holdings, L.P. and Osteon Merger Sub, Inc. were two entities involved in Osteon's acquisition of Exactech, Inc. and deny

any remaining allegations in Paragraph 105 of the Complaint, including due to the vagueness of the allegations.

106. Both of these entities were affiliates of TPG Capital, LP (now Defendant TPG, Inc.) and, therefore, controlled by TPG Capital, LP (now Defendant TPG, Inc.) under the definition of "Affiliate" as set forth in the Securities Act of 1933.

ANSWER: Paragraph 106 contains legal conclusions and allegations against other defendants that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 106 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that certain documents filed with the SEC identify Osteon Holdings, L.P. and Osteon Merger Sub, Inc. as "Affiliates" of TPG Capital, L.P. The Exactech Defendants lack knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 106 of the Complaint and therefore deny them.

107. Since Defendant Osteon Merger Sub, Inc. was "merged with and into Exactech, Inc.," Exactech, Inc. is considered an affiliate controlled by TPG Capital, LP (now Defendant TPG, Inc.), pursuant to the merger transaction. TPG Capital, LP (now Defendant TPG, Inc.) 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.

ANSWER: Paragraph 107 contains Plaintiffs' characterization of their claims and/or legal conclusions. To the extent Paragraph 107 may be deemed to require a response, the Exactech Defendants deny the allegations contained in Paragraph 107 of the Complaint.

C. Conversion of Osteon Holdings, LP to Osteon Holdings, Inc.

108. 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, LP. Osteon Holdings, LP was the "Parent" to the Merger.

ANSWER: To the extent Paragraph 108 describes the terms of a Rollover and Voting Agreement executed between Osteon Holdings, L.P. and William Petty, M.D., Betty Petty, David Petty, and Prima Investments, Limited Partnership on or about October 22, 2017, the Exactech

Defendants refer to the contents therein and deny any description that is inconsistent therewith. The Exactech Defendants deny any remaining allegations in Paragraph 108 of the Complaint.

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

ANSWER: The Exactech Defendants admit the allegations in Paragraph 109 of the Complaint.

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

ANSWER: To the extent Paragraph 110 describes the terms of Amendment No. 1 to a Rollover and Voting Agreement executed on or about December 3, 2017, the Exactech Defendants refer to the contents therein and deny any description that is inconsistent therewith. The Exactech Defendants deny any remaining allegations in Paragraph 110 of the Complaint.

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

ANSWER: To the extent Paragraph 111 describes the terms of a Rollover and Voting Agreement executed between Osteon Holdings, L.P. and William Petty, M.D., Betty Petty, David Petty, and Prima Investments, Limited Partnership on or about October 22, 2017, the Exactech Defendants refer to the contents therein and deny any description that is inconsistent therewith. The Exactech Defendants deny any remaining allegations in Paragraph 111 of the Complaint.

112. Osteon Holdings, LP was a limited partnership. Under basic tenets of corporate law, Limited Partnerships do not have stock or stockholders. A Limited Partnership has a general

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

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.

ANSWER: Paragraph 112 contains legal conclusions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 112 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that Osteon Holdings, L.P. was a limited partnership and deny the remaining allegations contained in Paragraph 112 of the Complaint.

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

ANSWER: The Exactech Defendants admit that on or about February 14, 2018, an Amendment No. 2 to the Rule 13E-3 Transaction Statement was signed and filed with the Securities and Exchange Commission. The Exactech Defendants deny any remaining allegations in Paragraph 113 of the Complaint.

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

ANSWER: The Exactech Defendants admit that prior agreements associated with the transaction referred to Osteon Holdings, L.P. as "Parent." The Exactech Defendants deny any remaining allegations in Paragraph 114 of the Complaint.

115. In the Final Amendment, the Parent is no longer referred to as Osteon Holdings, LP. Instead, the Final Amendment refers to the Parent as Osteon Holdings Inc.

ANSWER: The Exactech Defendants admit that Amendment No. 2 to the Rule 13E-3 Transaction Statement refers to Osteon Holdings, Inc. as "Parent."

116. There is no disclosure explaining why the original Parent company, Osteon Holdings, LP was converted to Osteon Holdings, Inc.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 116 of the Complaint, including because of the vagueness of the term "disclosure."

D. TPG Capital, LP's (now Defendant TPG, Inc.) Control over Rollover & Voting Agreement Negotiations with Exactech

117. 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 LP]," an affiliate of TPG Capital, LP (now Defendant TPG, Inc.). *See* Exactech, Inc., Proxy Statement (Form DEF 14A), at 34 (Jan. 16, 2018).

ANSWER: To the extent Paragraph 117 quotes or describes select portions of a Proxy Statement dated January 16, 2018, the Exactech Defendants refer to the contents therein and deny any description that is inconsistent therewith. The Exactech Defendants deny any remaining allegations in Paragraph 117 of the Complaint.

118. "As a condition to receiving new equity securities in [Osteon Holdings, LP], 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 Capital, LP (now Defendant TPG, Inc.)]." *Id.* at 96.

ANSWER: To the extent Paragraph 118 quotes select portions of a Proxy Statement dated January 16, 2018, the Exactech Defendants refer to the contents therein and deny any description that is inconsistent therewith. The Exactech Defendants deny any remaining allegations in Paragraph 118 of the Complaint.

119. "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.

ANSWER: The Exactech Defendants deny the allegations in Paragraph 119 of the Complaint due to Plaintiffs' failure to accurately convey the content of the quoted Proxy Statement.

120. As a result of these discussions, Osteon Holdings, LP 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.

ANSWER: The Exactech Defendants admit that Osteon Holdings, L.P. and the Exactech founding shareholders and other officers executed a Rollover Agreement dated October 22, 2017, as amended on December 3, 2017. The Exactech Defendants deny any remaining allegations in Paragraph 120 of the Complaint.

121. 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, LP "immediately prior to an initial public offering" to shares in an anticipated Initial Public Offering ("IPO") involving TPG Capital, LP, its partners, and affiliates.

ANSWER: The Exactech Defendants admit that Amendment No. 1 to the Rollover and Voting Agreement includes a paragraph on automatic conversion, which provision speaks for itself. The Exactech Defendants deny any remaining allegations in Paragraph 121 of the Complaint.

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

ANSWER: Paragraph 122 contains allegations directed and pertaining to other defendants to which the Exactech Defendants need not respond. To the extent Paragraph 122 could be construed as containing allegations against the Exactech Defendants, the Exactech Defendants acknowledge that TPG, Inc. announced pricing of its initial public offering on January 12, 2022 with the expectation that shares would begin trading on January 13, 2022 and deny any remaining allegations in Paragraph 122 of the Complaint.

123. Osteon Holdings, LP, a TPG controlled affiliate and party to the Rollover Agreement, had no authority to commit future TPG, Inc. IPO shares through an automatic conversion to Osteon Holdings, LP shareholders. As stated before, Osteon Holdings, LP was converted to Osteon Holdings, Inc.

ANSWER: Paragraph 123 contains allegations directed and pertaining to other defendants to which the Exactech Defendants need not respond. To the extent Paragraph 123 could be construed as containing allegations against the Exactech Defendants, the Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 123 of the Complaint. TPG Capital, LP (now Defendant TPG, Inc.), 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.

ANSWER: Paragraph 124 contains allegations directed and pertaining to other defendants to which the Exactech Defendants need not respond. To the extent Paragraph 124 could be construed as containing allegations against the Exactech Defendants, the Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 124 of the Complaint.

125. TPG Capital, LP (now Defendant TPG, Inc.) officers are also officers of Osteon Holdings, LP (now Osteon Holdings, Inc.). 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 (now Defendant TPG, Inc.) controlled Osteon Holdings, LP (now Osteon Holdings, Inc.) and the negotiations related to the Exactech merger through its common officers, general counsel, and outside counsel.

ANSWER: Paragraph 125 contains Plaintiffs' characterizations, legal conclusions, and allegations directed and pertaining to other defendants to which the Exactech Defendants need not respond. To the extent Paragraph 125 could be construed as containing allegations against the Exactech Defendants, the Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 125 of the Complaint.

E. TPG's Control over the Management Agreement

126. 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.

ANSWER: To the extent Paragraph 126 describes Amendment No. 1 to the Rollover and Voting Agreement, the Exactech Defendants refer to the contents therein and deny any description that is inconsistent therewith. The Exactech Defendants admit individuals employed by TPG Global, LLC serve on Exactech's Board. The Exactech Defendants deny any remaining allegations in Paragraph 126 of the Complaint.

127. TPG requiring Exactech to use TPG's management agreement demonstrates that TPG has control over the management of Exactech.

ANSWER: The Exactech Defendants deny the allegations in Paragraph 127 of the Complaint.

128. 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.

ANSWER: To the extent Paragraph 128 describes selected statements from Amendment No. 1 to the Rollover and Voting Agreement, the Exactech Defendants refer to the contents therein and deny any description that is inconsistent therewith. The Exactech Defendants deny any remaining allegations in Paragraph 128 of the Complaint.

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

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 129 of the Complaint.

F. Co-Mingling Liability

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

ANSWER: The Exactech Defendants admit that the Merger Agreement contains provisions related to liabilities and that the agreement speaks for itself. The Exactech Defendants deny the remaining allegations in Paragraph 130 of the Complaint.

131. 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.

ANSWER: The Exactech Defendants admit that the Merger Agreement contains provisions related to liabilities and that the agreement speaks for itself. The Exactech Defendants deny the remaining allegations in Paragraph 131 of the Complaint.

132. 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 Defendant Osteon Holdings, Inc.'s prior written consent.

ANSWER: The Exactech Defendants deny the allegations in Paragraph 132 of the Complaint.

133. Defendants Osteon Holdings, Inc., Osteon Merger Sub, Inc., and non Defendant TPG Partners VII, LP 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.

ANSWER: The Exactech Defendants admit that Osteon Merger Sub, Inc. and non-Defendant TPG Partners VII, L.P. are named as affiliates and grouped together as "The TPG Parties" in the Final Amendment of the SEC Rule 13E-3 Transaction Statement that Osteon merger Sub, Inc. and TPG Partners VII, L.P. filed with Exactech on February 14, 2018. The Exactech Defendants deny the allegations in Paragraph 133 of the Complaint.

134. 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, LP.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 134 of the Complaint, including because of a lack of specificity as to the document being referenced.

135. "The TPG Parties," as described in the Final Amendment of the SEC Rule 13E-3 Transaction Statement, should be grouped together for purposes of liability under the Merger Agreement.

ANSWER: The Exactech Defendants deny the allegations in Paragraph 135 of the Complaint.

136. 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.

ANSWER: The Exactech Defendants deny the allegations in Paragraph 136 of the Complaint.

G. TPG's Post-Merger Control of Exactech

137. TPG is not a passive investor in Exactech.

ANSWER: The Exactech Defendants admit that TPG Partners VII, LP is an investor in Exactech. The Exactech Defendants deny the allegations in Paragraph 137 of the Complaint.

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

ANSWER: The Exactech Defendants deny the allegations in Paragraph 138 of the Complaint, including because of the vagueness of the allegation.

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

ANSWER: Paragraph 139 of the Complaint contains allegations directed at parties other than the Exactech Defendants and therefore does not require a response from the Exactech Defendants. To the extent Paragraph 139 contains allegations requiring a response from the Exactech Defendants, the Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations.

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

ANSWER: Paragraph 140 of the Complaint contains allegations directed at parties other than the Exactech Defendants and therefore does not require a response from the Exactech Defendants. To the extent Paragraph 140 contains allegations requiring a response from the Exactech Defendants, the Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations.

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

ANSWER: Paragraph 141 contains rhetorical statements that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 141 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 141 of the Complaint.

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

ANSWER: Paragraph 142 of the Complaint contains allegations directed at parties other than the Exactech Defendants and therefore does not require a response from the Exactech Defendants. To the extent Paragraph 142 contains allegations requiring a response from the Exactech Defendants, the Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations.

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

ANSWER: Paragraph 143 of the Complaint contains allegations directed at parties other than the Exactech Defendants and therefore does not require a response from the Exactech Defendants. To the extent Paragraph 143 contains allegations requiring a response from the Exactech Defendants, the Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations.

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

ANSWER: Paragraph 144 of the Complaint contains allegations directed at parties other than the Exactech Defendants and therefore does not require a response from the Exactech Defendants. To the extent Paragraph 144 contains allegations requiring a response from the Exactech Defendants, the Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations.

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

ANSWER: Paragraph 145 of the Complaint contains allegations directed at parties other than the Exactech Defendants and therefore does not require a response from the Exactech Defendants. To the extent Paragraph 145 contains allegations requiring a response from the Exactech Defendants, the Exactech Defendants deny the allegations in Paragraph 145.

146. 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.

ANSWER: To the extent Paragraph 146 describes selected statements from an Exactech proxy statement, the Exactech Defendants refer to the contents therein and deny any description that is inconsistent therewith.

147. Jeffrey R. Binder and Daniel Hann both advised TPG Capital on its merger with Exactech.

ANSWER: Paragraph 147 of the Complaint contains allegations directed at parties other than the Exactech Defendants and therefore does not require a response from the Exactech Defendants. To the extent Paragraph 147 contains allegations requiring a response from the Exactech Defendants, the Exactech Defendants admit that Mr. Binder and Mr. Hann were involved in Exactech's merger with Osteon Merger Sub, Inc. The Exactech Defendants deny the remaining allegations in Paragraph 147 of the Complaint.

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

ANSWER: The Exactech Defendants admit the allegations in Paragraph 148 of the Complaint.

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

ANSWER: The Exactech Defendants admit the allegations in Paragraph 149 of the Complaint.

150. 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.

ANSWER: To the extent Paragraph 150 describes selected statements from a proxy statement related to the transaction, the Exactech Defendants refer to the contents therein and deny any description that is inconsistent therewith. The Exactech Defendants admit to the content regarding the 2017 communications between Mr. Binch and Mr. Sisitsky contained in the proxy statement. (See Proxy Statement, p. 29.)

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

ANSWER: The Exactech Defendants admit that Kerem Bolukbasi was employed by TPG Global, LLC and Kendall Garrison, John Schilling, and Todd Sisitsky are employed by TPG Global, LLC. The Exactech Defendants admit that Mr. Bolukbasi, Mr. Garrison, Mr. Schilling, and Mr. Sisitsky became officers or directors of Exactech following Exactech's merger with Osteon Merger Sub, Inc. The Exactech Defendants deny the remaining allegations in Paragraph 151.

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

ANSWER: The Exactech Defendants deny the allegations in Paragraph 152.

153. 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.

ANSWER: The Exactech Defendants admit that Osteon Intermediate Holdings II, Inc. is the insured on a certificate of insurance associated with Exactech, Inc., which insurance includes products liability. The Exactech Defendants deny any remaining allegations in Paragraph 153 of the Complaint.

154. 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.

ANSWER: The Exactech Defendants admit that Mr. Binder, Mr. Hann, Mr. Bolukbasi, Mr. Garrison, Mr. Schilling, and Mr. Sisitsky have held leadership positions with Exactech, which positions include officer and/or director positions. The Exactech Defendants deny any remaining allegations in Paragraph 154, including due to the vagueness of the phrase "TPG Advisors."

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

ANSWER: The Exactech Defendants admit that three individuals (Mr. Garrison, Mr. Schilling, and Mr. Sisitsky) associated with TPG Global, LLC serve on Exactech's Board of Directors. The Exactech Defendants deny any remaining allegations in Paragraph 155 of the Complaint.

156. 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, LP. 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."

ANSWER: The Exactech Defendants deny the allegations in Paragraph 156 of the Complaint.

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

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

ANSWER: The Exactech Defendants deny the allegations in Paragraph 157 of the Complaint.

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

ANSWER: The Exactech Defendants admit that three members of Exactech's Board of Directors work for TPG Global, LLC. The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegation that "TPG Officers and Directors are also Officers and Directors of Osteon Holdings." The Exactech Defendants deny the remaining allegations in Paragraph 158 of the Complaint.

159. Upon information and belief, in 2017 or 2018, during due diligence prior to the acquisition of Exactech or shortly after the acquisition of 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.

ANSWER: Paragraph 159 contains allegations directed at parties other than the Exactech Defendants and therefore does not require a response from the Exactech Defendants. To the extent Paragraph 159 contains allegations requiring a response from the Exactech Defendants, the Exactech Defendants deny the allegations in Paragraph 159 of the Complaint and decline to adopt Plaintiffs' characterizations.

160. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 160 of the Complaint and decline to adopt Plaintiffs' characterizations.

161. 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.

ANSWER: The Exactech Defendants deny the allegations in Paragraph 161 of the Complaint.

162. 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.

ANSWER: The Exactech Defendants deny the allegations in Paragraph 162 of the Complaint, including because of the vagueness of the phrase "clinical evidence of early onset failures."

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

ANSWER: The Exactech Defendants admit that Exactech, Inc. issued a Class 2 voluntary recall of certain knee products in August 2021. The Exactech Defendants deny the remaining allegations contained in Paragraph 163 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

164. 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."[4]

ANSWER: The Exactech Defendants deny the allegations in Paragraph 164 of the Complaint.

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

ANSWER: The Exactech Defendants deny the allegations in Paragraph 165 of the Complaint.

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

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

ANSWER: The Exactech Defendants deny the allegations in Paragraph 166 of the Complaint.

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

ANSWER: The Exactech Defendants admit that Ms. Golz is a member of Exactech's Board of Directors. To the extent Paragraph 167 quotes and describes a press release which the Exactech Defendants did not create, from a non-party entity iRobot, the Exactech Defendants refer to the contents therein and deny any description that is inconsistent therewith. The Exactech Defendants deny any remaining allegations in Paragraph 167 of the Complaint.

168. 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.

ANSWER: The Exactech Defendants deny the allegations in Paragraph 168 of the Complaint.

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

A. FDA's Regulatory Process for Medical Devices

169. 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.

ANSWER: Paragraph 169 contains regulatory opinions and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited or applicable regulations speak for themselves. To the extent Paragraph 169 can be construed as

containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that medical devices are classified into Class I, II, and III, admit only to those duties imposed upon them by applicable law, admit that 510(k) clearance or PMA is necessary to market certain medical devices, and deny the remaining allegations in Paragraph 169 and decline to adopt Plaintiffs' characterizations.

170. 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.

ANSWER: Paragraph 170 contains regulatory opinions and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 170 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that a PMA application requires data related to the safety and efficacy of the product. The Exactech Defendants deny the remaining allegations contained in Paragraph 170 of the Complaint.

171. 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.

ANSWER: Paragraph 171 contains regulatory opinions and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 171 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that demonstration of substantial equivalence is a common component of the 510(k) process to determine the safety and efficacy of a medical device and deny the remaining allegations in Paragraph 171, including because they decline to adopt Plaintiffs' characterizations.

172. 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.

ANSWER: Paragraph 172 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 172 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 172 of the Complaint and therefore deny them, including because they decline to adopt Plaintiffs' characterizations.

173. 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.

ANSWER: Paragraph 173 contains regulatory opinions and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 173 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that a company may market a device after it receives 510(k) clearance and permission from FDA and deny the remaining allegations contained in Paragraph 173 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

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

ANSWER: The Exactech Defendants admit the allegations contained in Paragraph 174 of the Complaint.

175. 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.

ANSWER: Paragraph 175 contains rhetorical statements that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 175 can be

construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants lack information or knowledge sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 175 of the Complaint.

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

ANSWER: Paragraph 176 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 176 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit only to those duties imposed upon them by applicable law and deny the remaining allegations contained in Paragraph 176 of the Complaint.

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

177. 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).

ANSWER: The Exactech Defendants admit that Plaintiffs have quoted a portion of an unidentified Annual Report. The Exactech Defendants deny the remaining allegations contained in Paragraph 177 since the quote is incomplete and taken out of context.

178. 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.

ANSWER: The Exactech Defendants admit that Plaintiffs have quoted a portion of an unidentified Annual Report. The Exactech Defendants deny the remaining allegations contained in Paragraph 178 since the quote is incomplete and taken out of context, and deny the allegation regarding "lip service."

179. 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.

ANSWER: Paragraph 179 contains regulatory statement and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited statute speaks for itself. To the extent Paragraph 179 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the Devices are adulterated, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

180. 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.

ANSWER: Paragraph 180 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited statute speaks for itself. To the extent Paragraph 180 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the Devices are misbranded or dangerous, deny that its labeling is false or misleading, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

181. 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).

ANSWER: Paragraph 181 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited statute speaks for itself. To the extent Paragraph 181 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that federal law imposes medical device reporting requirements, admit that they comply with those requirements, admit only to those duties imposed upon them by applicable law, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

182. 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.

ANSWER: Paragraph 182 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 182 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that the FDA may promulgate quality and manufacturing regulations, admit that they comply with those requirements, admit only to those duties imposed upon them by applicable law, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

183. 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.

ANSWER: Paragraph 183 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited regulation speaks for itself. To the extent Paragraph 183 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that the FDA may promulgate quality and manufacturing regulations, admit that they comply with those requirements, admit only to those duties imposed upon them by applicable law, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

184. 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.

ANSWER: Paragraph 184 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited statute and regulation speak for themselves. To the extent Paragraph 184 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the Devices are adulterated, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

185. 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).

ANSWER: Paragraph 185 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited regulation speaks for itself. To the extent Paragraph 185 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that the

FDA has promulgated quality system regulations, admit that the Exactech Defendants comply with those requirements, admit only to those duties imposed upon them by applicable law, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

186. 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.

ANSWER: Paragraph 186 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited regulation speaks for itself. To the extent Paragraph 186 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that the FDA has promulgated quality system regulations, admit that the Exactech Defendants comply with those requirements, admit only to those duties imposed upon them by applicable law, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

187. 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.

ANSWER: Paragraph 187 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited regulation speaks for itself. To the extent Paragraph 187 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that the FDA has promulgated quality and manufacturing regulations, admit that the Exactech Defendants comply with those requirements, admit only to those duties imposed upon them by applicable law, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

188. 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.

ANSWER: Paragraph 188 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited regulation speaks for itself. To the extent Paragraph 188 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that the FDA has promulgated quality and manufacturing regulations, admit that the Exactech Defendants comply with those requirements, admit only to those duties imposed upon them by applicable law, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

189. 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.

ANSWER: Paragraph 189 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited regulation speaks for itself. To the extent Paragraph 189 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that the FDA has promulgated quality and manufacturing regulations, admit that the Exactech Defendants comply with those requirements, admit only to those duties imposed upon them by applicable law, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

190. 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.

ANSWER: Paragraph 190 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited regulation speaks for itself. To the extent Paragraph 190 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that the FDA has promulgated quality and manufacturing regulations, admit that the Exactech Defendants

comply with those requirements, admit only to those duties imposed upon them by applicable law, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

191. 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.

ANSWER: Paragraph 191 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited regulation speaks for itself. To the extent Paragraph 191 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that the FDA has promulgated quality and manufacturing regulations, admit that the Exactech Defendants comply with those requirements, admit only to those duties imposed upon them by applicable law, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

192. 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.

ANSWER: Paragraph 192 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited regulation speaks for itself. To the extent Paragraph 192 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that the FDA has promulgated quality and manufacturing regulations, admit that the Exactech Defendants comply with those requirements, admit only to those duties imposed upon them by applicable law, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

193. 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.

ANSWER: Paragraph 193 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited regulation speaks for itself. To the extent Paragraph 193 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that the FDA has promulgated quality and manufacturing regulations, admit that the Exactech Defendants comply with those requirements, admit only to those duties imposed upon them by applicable law, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

194. 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.

ANSWER: Paragraph 194 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited regulation speaks for itself. To the extent Paragraph 194 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that the FDA has promulgated quality and manufacturing regulations, admit that the Exactech Defendants comply with those requirements, admit only to those duties imposed upon them by applicable law, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

195. 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.

ANSWER: Paragraph 195 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited regulation speaks for itself. To the extent Paragraph 195 can be construed as containing allegations

against the Exactech Defendants requiring a response, the Exactech Defendants admit that the FDA has promulgated quality and manufacturing regulations, admit that the Exactech Defendants comply with those requirements, admit only to those duties imposed upon them by applicable law, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

196. 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.

ANSWER: Paragraph 196 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 196 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit only to those duties imposed upon them by applicable law, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

197. 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.

ANSWER: Paragraph 197 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited regulation speaks for itself. To the extent Paragraph 197 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit only to those duties imposed upon them by applicable law, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

198. 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.

ANSWER: Paragraph 198 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited regulation speaks for itself. To the extent Paragraph 198 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that the FDA has promulgated quality and manufacturing regulations, admit that the Exactech Defendants comply with those requirements, admit only to those duties imposed upon them by applicable law, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

199. 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.

ANSWER: Paragraph 199 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited regulation speaks for itself. To the extent Paragraph 199 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that the FDA has promulgated quality and manufacturing regulations, admit that the Exactech Defendants comply with those requirements, admit only to those duties imposed upon them by applicable law, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

200. 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.

ANSWER: Paragraph 200 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited

regulation speaks for itself. To the extent Paragraph 200 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that the FDA has promulgated quality and manufacturing regulations, admit that the Exactech Defendants comply with those requirements, admit only to those duties imposed upon them by applicable law, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

201. 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.

ANSWER: Paragraph 201 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited regulation speaks for itself. To the extent Paragraph 201 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that the FDA has promulgated quality and manufacturing regulations, admit that the Exactech Defendants comply with those requirements, admit only to those duties imposed upon them by applicable law, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

202. 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.

ANSWER: Paragraph 202 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited regulation speaks for itself. To the extent Paragraph 202 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that the FDA has promulgated quality system regulations, admit that the Exactech Defendants comply with those requirements, admit only to those duties imposed upon them by applicable law, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

203. 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.

ANSWER: Paragraph 203 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited regulation speaks for itself. To the extent Paragraph 203 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that the FDA has promulgated quality and manufacturing regulations, admit that the Exactech Defendants comply with those requirements, admit only to those duties imposed upon them by applicable law, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

204. 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).

ANSWER: Paragraph 204 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited regulations speak for themselves. To the extent Paragraph 204 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that the FDA has promulgated quality and manufacturing regulations, admit that the Exactech Defendants comply with those requirements, admit only to those duties imposed upon them by applicable law, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

205. 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.

ANSWER: Paragraph 205 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited regulation speaks for itself. To the extent Paragraph 205 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that the FDA has promulgated quality and manufacturing regulations, admit that the Exactech Defendants comply with those requirements, admit only to those duties imposed upon them by applicable law, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

206. 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.

ANSWER: Paragraph 206 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited regulation speaks for itself. To the extent Paragraph 206 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that the FDA has promulgated quality and manufacturing regulations, admit that the Exactech Defendants comply with those requirements, admit only to those duties imposed upon them by applicable law, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

207. 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.

ANSWER: Paragraph 207 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited regulation speaks for itself. To the extent Paragraph 207 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that the FDA has promulgated quality and manufacturing regulations, admit that the Exactech Defendants comply with those requirements, admit only to those duties imposed upon them by applicable law, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

208. 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.

ANSWER: Paragraph 208 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited regulation speaks for itself. To the extent Paragraph 208 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that the FDA has promulgated quality and manufacturing regulations, admit that the Exactech Defendants comply with those requirements, admit only to those duties imposed upon them by applicable law, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

209. 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.

ANSWER: Paragraph 209 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited regulation speaks for itself. To the extent Paragraph 209 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that the FDA has promulgated quality and manufacturing regulations, admit that the Exactech Defendants comply with those requirements, admit only to those duties imposed upon them by applicable law, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

210. 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.

ANSWER: Paragraph 210 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited regulation speaks for itself. To the extent Paragraph 210 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that the FDA has promulgated quality and manufacturing regulations, admit that the Exactech Defendants comply with those requirements, admit only to those duties imposed upon them by applicable law, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

211. 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.

ANSWER: Paragraph 211 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited

regulation speaks for itself. To the extent Paragraph 211 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that the FDA has promulgated quality and manufacturing regulations, admit that the Exactech Defendants comply with those requirements, admit only to those duties imposed upon them by applicable law, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

212. 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.

ANSWER: Paragraph 212 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited regulation speaks for itself. To the extent Paragraph 212 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that the FDA has promulgated quality and manufacturing regulations, admit that the Exactech Defendants comply with those requirements, admit only to those duties imposed upon them by applicable law, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

213. 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.

ANSWER: Paragraph 213 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited regulation speaks for itself. To the extent Paragraph 213 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that the FDA has promulgated complaint handling requirements, admit that the Exactech Defendants

comply with those requirements, admit only to those duties imposed upon them by applicable law, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

214. 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.

ANSWER: Paragraph 214 contains regulatory statements and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. The cited regulation speaks for itself. To the extent Paragraph 214 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that the FDA has promulgated complaint handling requirements, admit that the Exactech Defendants comply with those requirements, admit only to those duties imposed upon them by applicable law, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

215. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 215 of the Complaint.

C. Industry Standards for Medical Device Packaging

216. 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.

ANSWER: Paragraph 216 contains regulatory opinions and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 216 can be construed as containing allegations against the Exactech Defendants

requiring a response, the Exactech Defendants admit only to those duties imposed upon them by applicable law, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

217. 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.

ANSWER: Paragraph 217 contains regulatory opinions and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 217 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations due to the vagueness of the "industry standard(s) and regulatory authorities" referenced and because they decline to adopt Plaintiffs' characterizations. To the extent this allegation intends to state the contents of unidentified industry standards or regulations, those standards and regulations speak for themselves.

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

ANSWER: Paragraph 218 contains regulatory and scientific opinions and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 218 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that storage conditions of some medical device components can affect them and deny any remaining allegations, including because of the vagueness of the allegations (including failure to identify the devices referenced) and because the Exactech Defendants decline to adopt Plaintiffs' characterizations.

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

ANSWER: Paragraph 219 contains regulatory opinions and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. To the extent

Paragraph 219 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit to those duties and requirements established by applicable law and regulation, admit that health risks to patients should be considered and addressed and that Exactech did so, and deny any remaining allegations in Paragraph 219, including because they decline to adopt Plaintiffs' characterizations.

220. 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.

ANSWER: Paragraph 220 contains regulatory opinions and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 220 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit to those requirements and duties established applicable regulations and law but deny any remaining allegations in Paragraph 220 due to their vagueness (including the failure to identify any standards or regulations they intend to reference) and decline to adopt Plaintiffs' characterizations.

221. 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.

ANSWER: Paragraph 221 contains scientific and regulatory opinions and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 221 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that many factors are considered with respect to medical device packaging, admit that the Exactech Defendants properly considered them, and deny any remaining allegations, including because they decline to adopt Plaintiffs' characterizations.

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

ANSWER: Paragraph 222 contains regulatory opinions and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 222 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that many factors are considered with respect to medical device packaging, admit that the Exactech Defendants properly considered those factors, deny any remaining allegations, and decline to adopt Plaintiffs' characterizations.

223. 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.

ANSWER: Paragraph 223 contains scientific and regulatory opinions and/or legal conclusions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 223 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they are vague and contain no references to standards or regulations as to the bases for the allegations and because the Exactech Defendants decline to adopt Plaintiffs' characterizations.

224. 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.

ANSWER: Paragraph 224 contains regulatory opinions and legal conclusions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 224 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they are vague and contain no references to standards or regulations as to the bases for the allegations and because the Exactech Defendants decline to adopt Plaintiffs' characterizations.

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

225. 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.

ANSWER: The Exactech Defendants generally admit that individuals within the company understand the impact of packaging on Exactech, Inc.'s medical devices. The Exactech Defendants deny the remaining allegations contained in Paragraph 225 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

226. 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.

ANSWER: The Exactech Defendants generally admit that individuals within the company understand the potential risks involved with oxidation of certain medical devices, and admit that certain of Exactech, Inc.'s medical devices had a shelf life of between 5 and 8 years. The Exactech Defendants deny the remaining allegations contained in Paragraph 226 of the Complaint.

227. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 227 of the Complaint.

228. 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.

ANSWER: The Exactech Defendants admit that Exactech, Inc. maintained processes and procedures regarding its packaging process, and that certain individuals at Exactech, Inc. were

aware of the oxidation process in connection with certain medical devices. The Exactech Defendants deny the remaining allegations in Paragraph 228 of the Complaint.

229. 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.

ANSWER: The Exactech Defendants admit that in approximately 2007, Exactech, Inc. developed protocol, PR-2006-043 and test report TR-2007-042. The Exactech Defendants further admit that Plaintiffs have attempted to quote, in part, an FDA 483 Inspection document, which speaks for itself. The Exactech Defendants deny the remaining allegations in Paragraph 229, including because they decline to adopt Plaintiffs' characterizations.

230. 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.*

ANSWER: The Exactech Defendants admit that Plaintiffs have provided a partial quote from an FDA document, but deny the allegations in Paragraph 230 since the partial quote does not accurately or fully describe the referenced protocol and test report.

231. 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*.

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote, in part, a statement from the FDA 483 observation dated November 17, 2021. The document speaks

for itself. The Exactech Defendants deny the remaining allegations contained in Paragraph 231 of the Complaint including Plaintiffs' characterization of the document.

232. 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.

ANSWER: The Exactech Defendants deny the allegations in Paragraph 232 of the Complaint.

233. 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*.

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote, in part, a statement from the FDA 483 observation dated November 17, 2021. The document speaks for itself. The Exactech Defendants deny the remaining allegations contained in Paragraph 233 of the Complaint including Plaintiffs' characterization of the document.

234. 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.

ANSWER: The Exactech Defendants deny the allegations in Paragraph 234 of the Complaint.

235. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 235 of the Complaint.

236. 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.

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote, in part, a statement from the FDA 483 observation dated November 17, 2021. The document speaks for itself. The Exactech Defendants deny the remaining allegations contained in Paragraph 236 of the Complaint including Plaintiffs' characterization of the document.

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

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote, in part, a statement from the FDA 483 observation dated November 17, 2021. The document speaks for itself. The Exactech Defendants deny the remaining allegations contained in Paragraph 237 of the Complaint.

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

ANSWER: The Exactech Defendants admit that it expanded the original voluntary recall activities related to Exactech, Inc.'s hip, ankle, and knee products. The Exactech Defendants deny the remaining allegations in Paragraph 238 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

239. 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.

ANSWER: The Exactech Defendants admit that certain packaging specifications for certain Exactech, Inc. polyethylene liners and inserts specified a vacuum bag consisting of layers of low-density polyethylene, nylon, and a secondary barrier layer containing ethylene vinyl alcohol

("EVOH"). The Exactech Defendants deny the remaining allegations contained in Paragraph 239 of the Complaint.

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

ANSWER: The Exactech Defendants deny the allegations of Paragraph 240 of the Complaint.

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

ANSWER: The Exactech Defendants admit that the Exactech Defendants purchased vacuum bags from Hillman Supply, Inc. The Exactech Defendants deny the remaining allegations contained in Paragraph 241 of the Complaint.

242. 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.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 242 of the Complaint and therefore deny them.

243. 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.

ANSWER: The Exactech Defendants admit that certain of Exactech, Inc.'s medical devices were manufactured with a packaging non-conformity due to the failure of Hillman Supply to provide packaging material that met Exactech, Inc.'s packaging specification, and that Exactech, Inc. was unaware of this packaging non-conformity until 2021. The Exactech Defendants deny the remaining allegations in Paragraph 243 of the Complaint.

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

244. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 244 of the Complaint.

i. Exactech's Finned Tibial Trays

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

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 245 of the Complaint due to the vagueness of what Plaintiffs mean by "largest," and therefore deny them.

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

ANSWER: The Exactech Defendants admit that the total sales reported by the company for 2007 match the figures contained in Paragraph 246 of the Complaint.

247. 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).

ANSWER: The Exactech Defendants admit that originally the Finned Tibial Tray and the Trapezoid Tray were two tibia options available for use with the Optetrak product line, and state that both were used commonly in index total knee replacement procedures. The Exactech Defendants deny the remaining allegations contained in Paragraph 247 of the Complaint, including because of the use of the term "defective" and because they decline to adopt Plaintiffs' characterizations.

248. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 248 of the Complaint.

249. Exactech's Finned Tibia Tray was defective.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 249 of the Complaint.

250. 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.

ANSWER: The Exactech Defendants admit that Mr. O'Neill and Dr. Moody made Exactech aware of some revisions in Dr. Moody's patients who had received finned tibial trays. The Exactech Defendants deny the allegations contained in Paragraph 250 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

251. 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.

ANSWER: The Exactech Defendants admit that Mr. O'Neill and Dr. Moody made Exactech aware of revisions in Dr. Moody's patients who had received finned tibial trays and that Exactech employees investigated. The Exactech Defendants deny the remaining allegations in Paragraph 251 of the Complaint, including because the allegations are vague and they decline to adopt Plaintiffs' characterizations.

252. 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.

ANSWER: The Exactech Defendants deny the allegations in Paragraph 252 of the Complaint.

253. 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.

ANSWER: The Exactech Defendants admit that it received reports that some surgeons' patients who had finned tibial trays experienced tibial loosening and revision surgeries during the time period stated. The Exactech Defendants deny the remaining allegations in Paragraph 253 of the Complaint.

254. 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.

ANSWER: The Exactech Defendants admit that it engaged Dr. Gradisar to perform an audit of patient outcomes, the results of which speak for themselves. The Exactech Defendants deny the remaining allegations in Paragraph 254 of the Complaint.

255. 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.

ANSWER: The Exactech Defendants admit that Dr. Gradisar reviewed knee revisions performed at Summa Health between January 1, 2007, and March 31, 2008. The Exactech Defendants deny the remaining allegations in Paragraph 255 of the Complaint.

256. 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.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 256 of the Complaint and therefore deny them.

257. 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.

ANSWER: The Exactech Defendants deny the allegations in Paragraph 257 of the Complaint.

258. 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.

ANSWER: The Exactech Defendants admit that Dr. Gradisar performed an audit, the results of which speak for themselves. The Exactech Defendants deny the remaining allegations in Paragraph 258 of the Complaint.

259. 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..."

ANSWER: The Exactech Defendants admit that Dr. Gradisar performed an audit, the results of which speak for themselves. The Exactech Defendants admit that Plaintiffs attempt to quote a document related to the audit, which document speaks for itself. The Exactech Defendants deny the remaining allegations in Paragraph 259 of the Complaint.

260. 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.

ANSWER: The Exactech Defendants admit that Dr. Gradisar performed an audit, the results of which speak for themselves. The Exactech Defendants admit that Plaintiffs attempt to quote a document related to the audit, which document speaks for itself. The Exactech Defendants deny the remaining allegations in Paragraph 260 of the Complaint, including any allegation premised on the existence of a flaw or defect in the finned tibial tray.

261. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 261 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

262. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 262 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

263. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 263 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

264. 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."

ANSWER: The Exactech Defendants admit that Plaintiffs attempt to quote a memorandum document, which document would speak for itself. The Exactech Defendants deny the remaining allegations contained in Paragraph 264 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

265. 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.[5] Such a high revision rate is generally recognized as very unacceptable.

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to relay information contained in a study by Thelu, et al., which study speaks for itself. The Exactech Defendants deny any remaining allegations in Paragraph 265 of the Complaint.

266. 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."[6]

ANSWER: The Exactech Defendants admit that individuals affiliated with Exactech responded to the Thelu article, which response speaks for itself and the contents of which the Exactech Defendants admit to be accurate. The Exactech Defendants deny any remaining allegations in Paragraph 266 of the Complaint.

267. 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.

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[5] 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).

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

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 267 of the Complaint.

268. 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).

ANSWER: The Exactech Defendants admit that the referenced qui tam lawsuit was filed in Alabama in 2018, and that the allegations in the complaint in that lawsuit speak for themselves. The Exactech Defendants deny the allegations set forth in the qui tam lawsuit, and deny the remaining allegations contained in Paragraph 268 of the Complaint.

269. 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.

ANSWER: The Exactech Defendants admit that Plaintiffs have quoted from a portion of an affidavit of Laurent Angibaud, which speaks for itself. The Exactech Defendants deny the remaining allegations in Paragraph 269 of the Complaint.

270. 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.

ANSWER: The Exactech Defendants admit that Dr. Petty was aware of three physicians who had aseptic loosening issues – Drs. McCloud, Moody, and Lemak – and that Dr. Petty concluded that those issues related to their technique. The Exactech Defendants deny the remaining allegations in Paragraph 270 of the Complaint.

271. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 271 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

272. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 272 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

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

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 273 of the Complaint and decline to adopt Plaintiffs' characterizations.

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

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

ANSWER: The Exactech Defendants deny the allegations in Paragraph 274 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

275. 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.

ANSWER: The Exactech Defendants admit that on March 10, 2017 the FDA conducted an inspection of Exactech, Inc. and issued an FDA Form-483 in which it made the observations listed in subparts a through g of Paragraph 275. The Exactech Defendants deny the remaining allegations contained in Paragraph 275 of the Complaint.

276. 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.

ANSWER: The Exactech Defendants admit that FDA Establishment Inspection Report 1038671 contained findings regarding Exactech, Inc.'s complaint handling procedures. The Exactech Defendants deny the remaining allegations contained in Paragraph 276 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

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

ANSWER: The Exactech Defendants admit that following the March 2017 inspection, the FDA issued a 483 observation notice to Exactech, Inc. which speaks for itself. The Exactech Defendants deny the remaining allegations in Paragraph 277 of the Complaint.

278. 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.

ANSWER: The Exactech Defendants admit that FDA Establishment Inspection Report 1038671 contained findings regarding Exactech, Inc.'s complaint handling procedures. The Exactech Defendants deny the remaining allegations contained in Paragraph 278 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

279. 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.

ANSWER: The Exactech Defendants admit that FDA Establishment Inspection Report 1038671 contained findings regarding Exactech, Inc.'s complaint handling procedures. The Exactech Defendants deny the remaining allegations contained in Paragraph 279 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

280. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 280 of the Complaint.

281. 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.

ANSWER: The Exactech Defendants admit that Paragraph 283 contains a partial quote from an FDA document. The Exactech Defendants deny the remaining allegations contained in Paragraph 281 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

282. 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.

ANSWER: The Exactech Defendants admit that Paragraph 282 contains a partial quote from an FDA document. The Exactech Defendants deny the remaining allegations contained in Paragraph 282 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

283. 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).

ANSWER: The Exactech Defendants deny the allegations in Paragraph 283 of the Complaint.

284. 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).

ANSWER: The Exactech Defendants admit that on January 31, 2020 the FDA conducted an inspection of Exactech, Inc. and issued an FDA Form-483 in which it made the observations listed in subparts a through e of Paragraph 284. The Exactech Defendants deny the remaining allegations contained in Paragraph 284 of the Complaint.

285. 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.

ANSWER: The Exactech Defendants admit that on November 17, 2021 the FDA conducted an inspection of Exactech, Inc. and issued an FDA Form-483 in which it made the observations listed in subparts a through d of Paragraph 285. The Exactech Defendants deny the remaining allegations contained in Paragraph 285 of the Complaint.

286. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 286 of the Complaint.

V. EXACTECH DEVICES AT ISSUE

A. Exactech's Total Hip Replacement Systems

i. Total Hip Replacement Surgery

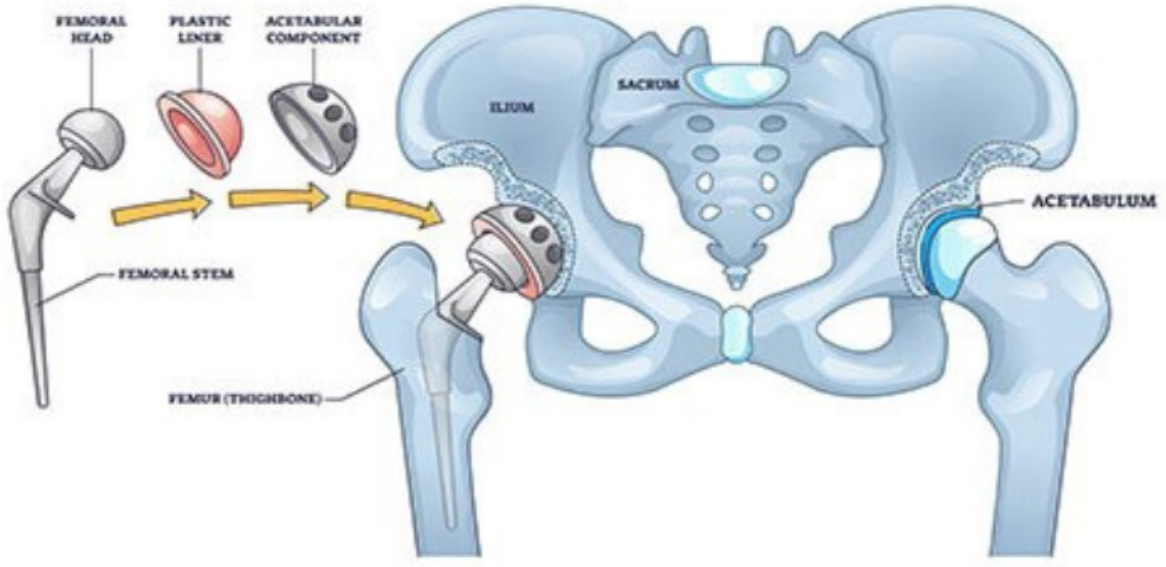
287. Total hip replacement ("THR") or total hip arthroplasty ("THA") involves the implantation of a hip implant prothesis where the natural bone and cartilage have become diseased because of osteoarthritis, osteonecrosis, or due to trauma to the hip joint.

ANSWER: Paragraph 287 contains medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 287 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

288. 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.

ANSWER: Paragraph 288 contains medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent



Paragraph 288 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

289. 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.

ANSWER: Paragraph 289 contains scientific and medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 289 can be construed as containing allegations against the Exactech Defendants that require a response, the Exactech Defendants admit that ultra-high molecular weight polyethylene remains a material of choice for many surgeons and is the predominant bearing surface material in total joint replacement surgeries today. The Exactech Defendants deny the remaining allegations in Paragraph 289 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

290. 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.

ANSWER: Paragraph 290 contains scientific and medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 290 can be construed as containing allegations against the Exactech Defendants that require a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

291. 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.

ANSWER: Paragraph 291 contains scientific and medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 291 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

292. 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.

ANSWER: Paragraph 292 contains scientific and medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 292 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

293. 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.

ANSWER: Paragraph 293 contains scientific and medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 293 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because the allegations are vague and they decline to adopt Plaintiffs' characterizations.

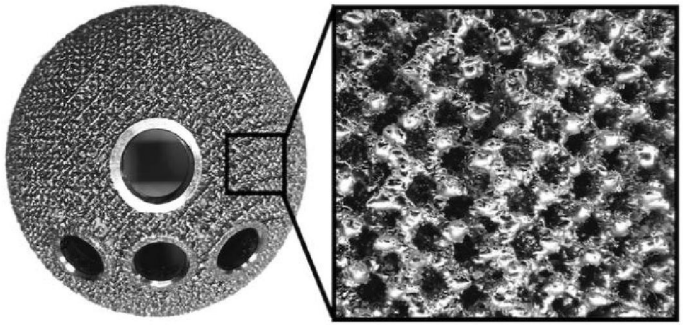
294. Dr. Charnley's design of the hip device focused on low-friction with the use of UHMWPE, a highly polished stainless steel femoral head that was small in diameter (22mm) relative to the natural femoral head to reduce the surface area, and minimizing the surface roughness of the UHMWPE.

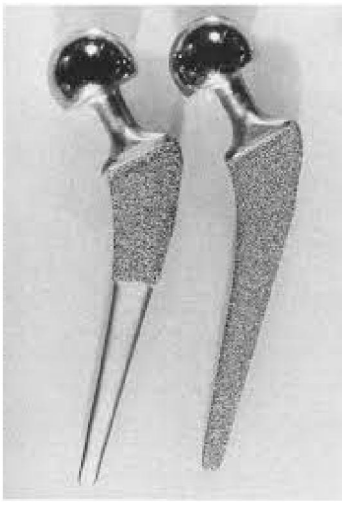
ANSWER: Paragraph 294 contains scientific and medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 294 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

295. 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.

ANSWER: Paragraph 295 contains scientific and medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 295 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

296. 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.





ANSWER: Paragraph 296 contains scientific and medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 296 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

297. 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.

ANSWER: Paragraph 297 contains scientific and medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 297 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

298. 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.

ANSWER: Paragraph 298 contains scientific and medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 298 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

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

299. 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").

ANSWER: Paragraph 299 contains scientific and medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 299 can be construed as containing allegations against the Exactech Defendants that require a response, the Exactech Defendants deny the allegations, including because the allegations are vague and they decline to adopt Plaintiffs' characterizations.

300. 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.

ANSWER: Paragraph 300 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 300 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because the allegations are vague and they decline to adopt Plaintiffs' characterizations.

301. 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.

ANSWER: Paragraph 301 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 301 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because the allegations are vague and they decline to adopt Plaintiffs' characterizations.

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

ANSWER: Paragraph 302 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 302 can be construed as containing allegations against the Exactech Defendants

requiring a response, the Exactech Defendants deny the allegations, including because the allegations are vague and they decline to adopt Plaintiffs' characterizations.

303. 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.

ANSWER: Paragraph 303 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 303 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because the allegations are vague and they decline to adopt Plaintiffs' characterizations.

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

ANSWER: Paragraph 304 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 304 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because the allegations are vague and they decline to adopt Plaintiffs' characterizations.

305. 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.

ANSWER: Paragraph 305 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 305 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because the allegations are vague and they decline to adopt Plaintiffs' characterizations.

306. 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.

ANSWER: Paragraph 306 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 306 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

307. 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.

ANSWER: Paragraph 307 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 307 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

308. 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.

ANSWER: Paragraph 308 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 308 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because the allegations are vague and they decline to adopt Plaintiffs' characterizations.

309. 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.

ANSWER: Paragraph 309 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 309 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because the allegations are vague and they decline to adopt Plaintiffs' characterizations.

310. 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.

ANSWER: Paragraph 310 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 310 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because the allegations are vague and they decline to adopt Plaintiffs' characterizations.

311. 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.

ANSWER: Paragraph 311 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 311 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because the allegations are vague and they decline to adopt Plaintiffs' characterizations.

312. 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.

ANSWER: Paragraph 312 contains scientific and medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 312 can be construed as containing allegations against the Exactech Defendants

requiring a response, the Exactech Defendants deny the allegations, including because the allegations are vague and they decline to adopt Plaintiffs' characterizations.

313. 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.

ANSWER: Paragraph 313 contains medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 313 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because the allegations are vague and they decline to adopt Plaintiffs' characterizations.

314. 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.

ANSWER: Paragraph 314 contains medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 314 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because the allegations are vague and they decline to adopt Plaintiffs' characterizations.

315. 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.

ANSWER: Paragraph 315 contains medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 315 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

316. 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).

ANSWER: Paragraph 316 contains medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 316 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

317. 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.

ANSWER: Paragraph 317 contains medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 317 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

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

ANSWER: Paragraph 318 contains medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 318 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

319. 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.

ANSWER: Paragraph 319 contains medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent

Paragraph 319 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because the allegations are vague and they decline to adopt Plaintiffs' characterizations.

320. 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.

ANSWER: Paragraph 320 contains medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 320 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

321. 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.

ANSWER: Paragraph 321 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 321 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

322. 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."

ANSWER: The Exactech Defendants admit that Exactech, Inc. developed a highly crosslinked polyethylene hip liner infused with Vitamin E in 2018 and admit that Paragraph 322

contains a partial quote from an Exactech document. The Exactech Defendants deny the remaining allegations in Paragraph 322 of the Complaint.

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

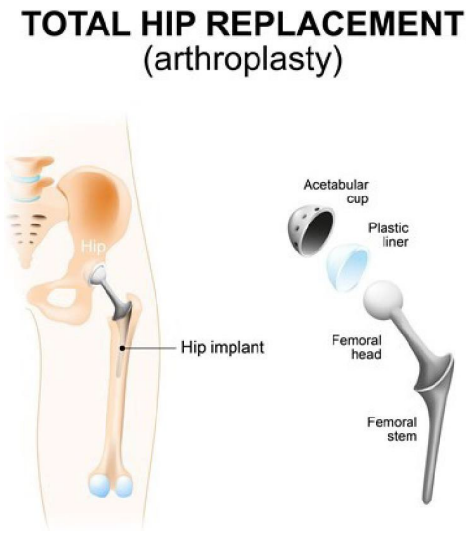
323. Throughout the relevant period, Exactech designed, developed, tested, assembled, manufactured, packaged, labeled, distributed, marketed, supplied, warranted, and/or sold the subject defective total hip replacement systems and components for use in THAs under the trade names: Connexion GXL, Novation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

ANSWER: The Exactech Defendants admit that Exactech, Inc. designed, manufactured, packaged, marketed, labeled, and sold the Devices. The Exactech Defendants further admit that Exactech U.S., Inc. generally participated in the sale of the Devices in the United States. The Exactech Defendants deny the remaining allegations contained in Paragraph 323 of the Complaint.

324. 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."

ANSWER: The Exactech Defendants admit the allegations contained in Paragraph 324 of the Complaint.

325. 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.



ANSWER: The Exactech Defendants admit that a prosthetic hip replacement system typically consists of the four components identified in Paragraph 325 but can also consist of other components made of other materials. The Exactech Defendants deny the remaining allegations in Paragraph 325.

326. The acetabular liners in Exactech's Hip Devices are made of UHMWPE. 57 Case 1:22-md-03044-NGG-MMH Document 164 Filed 03/22/23 Page 58 of 147 PageID #: 1916

ANSWER: The Exactech Defendants admit that until 2018, certain of Exactech, Inc.'s products were made of UHMWPE. The Exactech Defendants deny the remaining allegations contained in Paragraph 326 of the Complaint.

327. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 327 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

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

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 328 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

329. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 329 of the Complaint.

iv. Exactech Total Hip Systems 510(k)

330. 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.

ANSWER: The Exactech Defendants admit the allegations in Paragraph 330 of the Complaint.

331. 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.

ANSWER: The Exactech Defendants deny the allegations in Paragraph 331 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

332. 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).

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote, in part, the Exactech website. The cited webpage speaks for itself. The Exactech Defendants deny the remaining allegations contained in Paragraph 332 of the Complaint.

333. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 333 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

334. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 334 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

335. 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

ANSWER: The Exactech Defendants admit that the Novation Crown Cup and liners are modifications of the previously cleared AcuMatch A-Series predicates. The Exactech Defendants further admit that the design features of the Novation Crown Cup and liners include, among other things, No-Hole and Cluster Hole design options; shells manufactured from titanium (Ti) alloy with plasma coating and an additional hydroxylapitite (HA) coating option; and sphere and taper inner diameter geometry. The Exactech Defendants deny the remaining allegations contained in Paragraph 335 of the Complaint.

336. 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.

ANSWER: The Exactech Defendants admit that the Novation GXL liners have the same polyethylene material as the GXL materials used with the AcuMatch and MCS hip implant systems. The Exactech Defendants deny any remaining allegations in Paragraph 336 of the Complaint.

337. 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.

ANSWER: The Exactech Defendants admit that in 2010, Exactech, Inc. submitted a Special 510(k) application (510(k) number K100269) for proposed modifications to the Novation Crown Cup and Liners, which were previously cleared under 510(k) number K070479. The Exactech Defendants further admit that the Special 510(k) application (K100269) identified proposed additions to product scope, hemispherical overall height, elimination of the constrained liner feature, and a modified cup thickness for the Cups, and proposed additions in scope of the product, hemispherical overall height, modified inner diameter (ID) chamifer, and a modified liner thickness for the Liners. The Exactech Defendants further admit that the proposed modifications in the Special 510(k) application (K100269) were cleared by the FDA in or around May of 2010. The Exactech Defendants deny the remaining allegations contained in Paragraph 337 of the Complaint. including because they decline to adopt Plaintiffs' characterizations.

338. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 338 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

339. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 339 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

340. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 340 of the Complaint, including because it declines to adopt Plaintiffs' characterizations.

341. 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.

ANSWER: The Exactech Defendants admit that Exactech, Inc. submitted a 510(k) application for the Exactech Novation and AcuMatch XLE liners, which are Vitamin E infused and highly crosslinked. The Exactech Defendants deny the remaining allegations in Paragraph 341 of the Complaint.

342. 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.

ANSWER: The Exactech Defendants admit the allegations contained in Paragraph 342 of the Complaint.

343. 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.

ANSWER: The Exactech Defendants admit that the XLE liners are blended with Vitamin E prior to consolidation and crosslinking, imparted with an irradiation dose of 100 KiloGray (kGy) prior to final gamma sterilization, and undergo an annealing process to quench free radicals. The Exactech Defendants further admit that the XLE liners are considered highly crosslinked. The Exactech Defendants deny the remaining allegations contained in Paragraph 343 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

344. 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 hereto as Exhibit A.

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote, in part, Exhibit A attached to the Complaint. The cited document speaks for itself. The Exactech Defendants admit that Exactech, Inc. began the process of transitioning the GXL liner from the US market when the XLE liner was introduced in 2019. The Exactech Defendants deny the remaining allegations contained in Paragraph 344 of the Complaint, including because the decline to adopt Plaintiffs' characterizations.

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

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 345 of the Complaint.

346. 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."

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 346 of the Complaint.

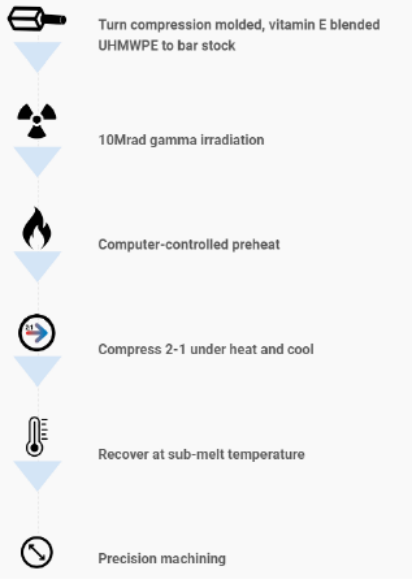
347. Exactech failed to inform the medical community of its "transition" to XLE Liners because it wanted to sell off its remaining inventory.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 347 of the Complaint.

348. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 348 of the Complaint, including because the decline to adopt Plaintiffs' characterizations.

349. 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).

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote, in part, the Exactech website. The cited webpage speaks for itself. The Exactech Defendants deny the remaining allegations contained in Paragraph 349 of the Complaint.

350. 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 hereto as Exhibit A.

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote, in part, the Exactech website. The cited webpage speaks for itself. The Exactech Defendants deny the remaining allegations contained in Paragraph 349 of the Complaint.

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

ANSWER: The Exactech Defendants admit that in the FAQ's, Exactech, Inc. refers to XLE liners as compatible replacements for GXL liners. The Exactech Defendants deny the remaining allegations in Paragraph 351 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

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

352. 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.

ANSWER: The Exactech Defendants admit that Exactech, Inc. marketed and sold the Devices in the United States, including the State of New York, and in other parts of the world. The Exactech Defendants further admit that Exactech U.S., Inc. generally participated in the sale of the Devices in the United States. The Exactech Defendants deny the remaining allegations contained in Paragraph 352 of the Complaint.

353. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 353 of the Complaint.

354. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 354 of the Complaint, and in each of its subparts.

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

355. 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 hereto as Exhibit A.

ANSWER: The Exactech Defendants admit that on June 24, 2021, Exactech, Inc. published Frequently Asked Questions regarding its GXL acetabular polyethylene liner for its US Sales Agents and surgeon customers, but deny that Plaintiffs have accurately quoted or summarized the information contained in that document.

356. 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.

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote, in part, Exhibit A attached to the Complaint. The cited document speaks for itself. The Exactech Defendants deny the remaining allegations contained in Paragraph 356 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

357. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 357 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

358. 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.

ANSWER: The Exactech Defendants admit that in the FAQ's, Exactech, Inc. refers to XLE liners as compatible replacements for GXL liners. The Exactech Defendants deny the remaining allegations in Paragraph 358 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

359. 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.

ANSWER: The Exactech Defendants admit that Exactech, Inc.'s Frequently Asked Questions regarding its Connexion GXL liners state that bench testing reveals that the XLE liners

outperforms the Connexion GXL liner in both volumetric wear and edge loading assessments. The Exactech Defendants deny the remaining allegations contained in Paragraph 359 of the Complaint.

360. 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.

ANSWER: The Exactech Defendants admit the allegations contained in Paragraph 360 of the Complaint.

361. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 361 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

362. 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 hereto as Exhibit B.

ANSWER: The Exactech Defendants admit that Plaintiffs have attached Exhibit B to the Complaint, which is captioned "Urgent Dear Healthcare Professional Communication" dated June 28, 2021 and which relates to Connexion GXL liners. The Exactech Defendants further admit that the Frequently Asked Questions document for Surgeons referenced in this Paragraph is dated June 24, 2021, and the Urgent Dear Healthcare Professional Communication letter referenced in this Paragraph is dated June 28, 2021. The Exactech Defendants further admit that both documents were intended to inform surgeons about recent observations made by Exactech regarding the clinical performance of the Connexion GXL acetabular liners in certain populations of patients. The cited document speaks for itself. The Exactech Defendants deny the remaining allegations contained in Paragraph 362 of the Complaint.

363. 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."[7];

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."[8]; 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 ... ."[9]

ANSWER: The Exactech Defendants deny the allegations in Paragraph 363 of the Complaint, including its subparts, including because they decline to adopt Plaintiffs' characterizations.

364. 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, June 28, 2021 Hip DHCP Letter at 1.

[7] W. CHRISTIAN THOMAS, ET AL., *Early Polyethylene Failure in a Modern Total Hip Prosthesis: A Note of Caution,* 35 J. ARTHROPLASTY 1297 (2020).

[8] CYNTHIA A KAHLENBERG, ET AL., "*Early Failure of a Modern Moderately Cross-Linked Polyethylene Acetabular Liner,*" 6 ARTHROPLASTY TODAY 224, 226 (2020)

[9] RAMANKANTH R. YAKKANTI, ET AL., *Unexpected Wear of a Moderately Crosslinked Polyethylene in Total Hip Arthroplasty*, ARTIC. PRESS, 2021.

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote, in part, from the June 28, 2021 "Urgent Dear Healthcare Professional Communication" regarding Connexion GXL liners. The cited document speaks for itself. The Exactech Defendants deny the remaining allegations contained in Paragraph 364 of the Complaint.

365. 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*.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 365 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

366. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 366 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

367. 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 hereto as Exhibit C.

ANSWER: The Exactech Defendants admit that on June 29, 2021, Exactech, Inc. voluntarily initiated a market notification regarding its GXL hip liners that was categorized as a Class 2 Recall. The Exactech Defendants deny the remaining allegations contained in Paragraph 367 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

368. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 368 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

369. 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.

ANSWER: To the extent this allegation relates to the June 28, 2021 communication, the Exactech Defendants admit the allegations on Paragraph 369 of the Complaint.

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

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the allegations contained in Paragraph 370 of the Complaint and therefore deny them.

371. 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.

ANSWER: The Exactech Defendants admit that Exactech was transitioning the GXL Liners out of the US market and had introduced its XLE liners and deny the remaining allegations contained in Paragraph 371 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

372. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 372 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

373. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 373 of the Complaint.

374. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 374 of the Complaint.

375. 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;

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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).

ANSWER: The Exactech Defendants admit that in November 2021 the FDA conducted an inspection of Exactech, Inc. and issued an FDA Form-483 in which it made the observations listed in subparts a through e of Paragraph 375. The Exactech Defendants deny the remaining allegations in Paragraph 375 of the Complaint.

376. 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 hereto as Exhibit D.[10]

ANSWER: The Exactech Defendants admit that on August 11, 2022, Exactech voluntarily took steps to expand the June 2021 GXL voluntary actions classified as a Class 2 Recall to include the non-conforming packaging as an additional potential risk factor and to recall the liners outlined above from the field. The Exactech Defendants deny the remaining allegations in Paragraph 376 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

377. That same day, Exactech sent an Urgent Dear Healthcare Professional Communication (August 11, 2022 Hip DHCP Letter) to Surgeons, Hospitals, and Healthcare Professionals, attached hereto as Exhibit E.

ANSWER: The Exactech Defendants admit that Exactech, Inc. sent an "Urgent Dear Healthcare Professional Communication" dated August 11, 2022 to surgeons, hospitals and healthcare professionals. The Exactech Defendants deny the remaining allegations in Paragraph 377.

378. 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.

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote, in part, Exhibit E to the Complaint. The cited document speaks for itself. The Exactech Defendants deny the remaining allegations in Paragraph 378 of the Complaint.

379. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 379 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

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

380. 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.

ANSWER: The Exactech Defendants admit that XLE liners were not included in the scope of the August 2022 Class 2 voluntary recall activities. The Exactech Defendants deny the remaining allegations in Paragraph 380 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

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

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote, in part, Exhibit E to the Complaint. The cited document speaks for itself. The Exactech Defendants deny the remaining allegations in Paragraph 381 of the Complaint, including that that Exactech, Inc.'s Urgent Dear Healthcare Professional Communication contained any bolded language as indicated in Paragraph 381.

382. 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.

ANSWER: The Exactech Defendants admit that it expanded the original voluntary recall activities related to Exactech, Inc.'s GXL hip liners to include GXL liners and conventional liners manufactured since 2004. The Exactech Defendants deny the remaining allegations in Paragraph 382 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

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

ANSWER: The Exactech Defendants admit that the June 28, 2021 "Urgent Dear Healthcare Professional Communication" does not refer to devices implanted between 2015 and 2021. The Exactech Defendants deny the remaining allegations in Paragraph 383 of the Complaint.

384. 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 at 3.

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote, in part, Exhibit E to the Complaint. The cited document speaks for itself. The Exactech Defendants deny the remaining allegations in Paragraph 384 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

385. 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*.

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote, in part, Exhibit E to the Complaint. The cited document speaks for itself. The Exactech Defendants deny the remaining allegations in Paragraph 385 of the Complaint.

386. 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.

ANSWER: The Exactech Defendants admit the allegations in Paragraph 386 of the Complaint.

387. 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.

ANSWER: The Exactech Defendants admit the allegations in Paragraph 387 of the Complaint.

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

ANSWER: The Exactech Defendants deny the allegations in Paragraph 388 of the Complaint.

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

ANSWER: The Exactech Defendants admit that packaging of Exactech, Inc.'s components is an important part of the manufacturing process. The Exactech Defendants deny the remaining allegations in Paragraph 389 of the Complaint.

390. 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.

ANSWER: The Exactech Defendants deny the allegations in Paragraph 390 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

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

ANSWER: The Exactech Defendants deny the allegations in Paragraph 391 of the Complaint.

392. 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.

ANSWER: The Exactech Defendants deny the allegations in Paragraph 392 of the Complaint.

393. 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.

ANSWER: The Exactech Defendants deny the allegations in Paragraph 393 of the Complaint.

394. 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.

ANSWER: The Exactech Defendants deny the allegations in Paragraph 394 of the Complaint.

395. 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.

ANSWER: The Exactech Defendants deny the allegations in Paragraph 395 of the Complaint.

396. Nonetheless, Exactech risked patients' safety in hopes that the defects would not result in high failure rates.

ANSWER: The Exactech Defendants deny the allegations in Paragraph 396 of the Complaint.

397. 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.

ANSWER: The Exactech Defendants deny the allegations in Paragraph 397 of the Complaint.

398. 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.*

ANSWER: The Exactech Defendants deny the allegations in Paragraph 398 of the Complaint.

399. 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.

ANSWER: The Exactech Defendants deny the allegations in Paragraph 399 of the Complaint.

400. 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.

ANSWER: The Exactech Defendants deny the allegations in Paragraph 400 of the Complaint.

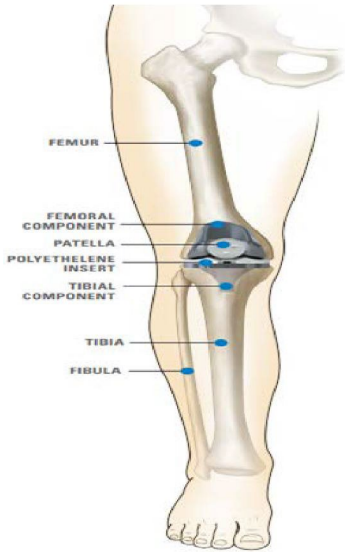
401. Patients implanted with Exactech GXL Liners that failed due to accelerated wear have suffered significant and continuing pain and personal injuries as well as substantial medical bills and expenses.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 401 and therefore deny them, including due to a lack of specificity as to which patients are being referenced.

B. Exactech's Total Knee Arthroplasty Systems

i. Total Knee Arthroplasty

402. 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.



ANSWER: Paragraph 402 contains scientific and medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 402 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

403. 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.

ANSWER: Paragraph 403 contains scientific and medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 403 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that disease and injury can impact the function of the knee. The Exactech Defendants deny the remaining allegations of Paragraph 403, including because they decline to adopt Plaintiffs' characterizations.

404. 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.

ANSWER: Paragraph 404 contains scientific and medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 404 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

405. 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.

ANSWER: Paragraph 405 contains scientific and medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 405 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

406. 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.

ANSWER: Paragraph 406 contains scientific and medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 406 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

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

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

ANSWER: Paragraph 407 contains scientific and medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 407 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

408. 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.

ANSWER: Paragraph 408 contains scientific and medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 408 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

409. 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.

ANSWER: Paragraph 409 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 409 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

410. 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.

ANSWER: Paragraph 410 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 410 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

411. 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.

ANSWER: Paragraph 411 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 411 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

412. 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").

ANSWER: Paragraph 412 contains scientific and medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 412 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because the allegations are vague and they decline to adopt Plaintiffs' characterizations.

413. 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.

ANSWER: Paragraph 413 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 413 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because the allegations are vague and they decline to adopt Plaintiffs' characterizations.

414. 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.

ANSWER: Paragraph 414 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 414 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because the allegations are vague and they decline to adopt Plaintiffs' characterizations.

415. 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.

ANSWER: Paragraph 415 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 415 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because the allegations are vague and they decline to adopt Plaintiffs' characterizations.

416. 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.

ANSWER: Paragraph 416 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 416 can be construed as containing allegations against the Exactech Defendants

requiring a response, the Exactech Defendants deny the allegations, including because the allegations are vague and they decline to adopt Plaintiffs' characterizations.

417. 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.

ANSWER: Paragraph 417 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 417 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

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

ANSWER: Paragraph 418 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 418 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because the allegations are vague and they decline to adopt Plaintiffs' characterizations.

419. 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.

ANSWER: Paragraph 419 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 419 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because the allegations are vague and they decline to adopt Plaintiffs' characterizations.

420. 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.

ANSWER: Paragraph 420 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 420 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because the allegations are vague and they decline to adopt Plaintiffs' characterizations.

421. 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.

ANSWER: Paragraph 421 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 421 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because the allegations are vague and they decline to adopt Plaintiffs' characterizations.

422. 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.

ANSWER: Paragraph 422 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 422 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

423. 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.

ANSWER: Paragraph 423 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 423 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because the allegations are vague and they decline to adopt Plaintiffs' characterizations.

424. 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.

ANSWER: Paragraph 424 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 424 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because the allegations are vague and they decline to adopt Plaintiffs' characterizations.

425. 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.

ANSWER: Paragraph 425 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 425 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because the allegations are vague and they decline to adopt Plaintiffs' characterizations.

426. 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.

ANSWER: Paragraph 426 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent

Paragraph 426 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because the allegations are vague and they decline to adopt Plaintiffs' characterizations.

427. 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.

ANSWER: Paragraph 427 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 427 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because the allegations are vague and they decline to adopt Plaintiffs' characterizations.

428. 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.

ANSWER: Paragraph 428 contains scientific and medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 428 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because the allegations are vague and they decline to adopt Plaintiffs' characterizations.

429. 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.

ANSWER: Paragraph 429 contains scientific and medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 429 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because the allegations are vague and they decline to adopt Plaintiffs' characterizations.

430. 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).

ANSWER: Paragraph 430 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 430 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because the allegations are vague and they decline to adopt Plaintiffs' characterizations.

431. 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.

ANSWER: Paragraph 431 contains medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 431 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations..

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

ANSWER: Paragraph 432 contains medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 432 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

433. 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.

ANSWER: Paragraph 433 contains medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 433 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

434. 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.

ANSWER: Paragraph 434 contains medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 434 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

435. 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.

ANSWER: Paragraph 435 contains medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 435 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

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

436. 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").

ANSWER: The Exactech Defendants admit that Exactech, Inc. designed, manufactured, marketed, labeled, and participated in the sale of certain orthopedic products for implantation into patients by orthopedic surgeons throughout the United States. The Exactech Defendants further admit that Exactech U.S., Inc. participated in the sale of the Devices generally. The Exactech Defendants deny the remaining allegations contained in Paragraph 436 of the Complaint.

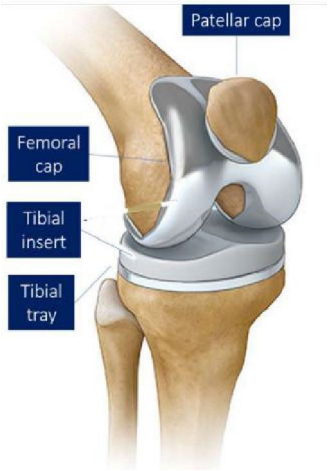
437. The Optetrak was introduced in 1994, the Optetrak Logic in 2009, and the Truliant in 2017. The Optetrak knee systems were initially built upon technology licensed from the Hospital for Special Surgery (HSS). The Exactech Knee Devices feature a mix of polyethylene and metal-based components.

ANSWER: The Exactech Defendants admit the allegations in Paragraph 437 of the Complaint.

438. 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.

ANSWER: The Exactech Defendants admit the allegations contained in Paragraph 438 of the Complaint.

439. 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.



ANSWER: The Exactech Defendants admit that a total knee replacement system typically consists of the four components identified in Paragraph 439 but can also consist of other components made of other materials. The Exactech Defendants deny the remaining allegations in Paragraph 439 of the Complaint.

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

ANSWER: The Exactech Defendants admit that until 2018, certain of Exactech, Inc.'s products were made of UHMWPE. The Exactech Defendants deny the remaining allegations contained in Paragraph 440 of the Complaint.

441. 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.

ANSWER: The Exactech Defendants admit the Exactech, Inc. marketing brochure referred to above mentions various aspects of the manufacturing, packaging and sterilization processes, and further admit that the referenced document speaks for itself. The Exactech Defendants deny the remaining allegations in Paragraph 441 of the Complaint.

442. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 442 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

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

ANSWER: The Exactech Defendants admit the allegations of Paragraph 443 of the Complaint.

444. 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.

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote a select portion of an Exactech brochure, which speaks for itself. The Exactech Defendants deny the remaining allegations of Paragraph 444 of the Complaint.

445. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 445 of the Complaint.

446. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 446 of the Complaint.

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

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 447 of the Complaint.

448. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 448 of the Complaint.

iv. Exactech Total Knee Systems 510(k)

449. 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.

ANSWER: The Exactech Defendants admit the allegations of Paragraph 449 of the Complaint.

450. 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.

ANSWER: The Exactech Defendants admit that between 1994 and 2018, Exactech, Inc. received multiple FDA clearance letters through the 510(k) process to market Exactech, Inc.'s knee products in the United States. The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 450 of the Complaint due to the vagueness of the allegations.

451. 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.

ANSWER: The Exactech Defendants deny the allegations of Paragraph 451 of the Complaint.

452. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 452 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

453. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 453 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

454. 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.

ANSWER: The Exactech Defendants admit that on November 4, 2022, Exactech, Inc. announced FDA 510(k) clearance of the TriVerse primary knee replacement system using highly cross-linked (HXLPE) vitamin E-stabilized polyethylene and that the system would launch in the second quarter of 2023. The Exactech Defendants admit that Plaintiffs have attempted to paraphrase data contained on the Summary of Safety and Effectiveness for K222380, which document speaks for itself. The Exactech Defendants deny the remaining allegations contained in Paragraph 454 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

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

455. 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.

ANSWER: The Exactech Defendants admit that Exactech, Inc. designed, manufactured, packaged, marketed, labeled, and sold the Devices. The Exactech Defendants further admit that Exactech U.S., Inc. generally participated in the sale of the Devices in the United States. The Exactech Defendants deny the remaining allegations contained in Paragraph 455 of the Complaint.

456. 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.

ANSWER: The Exactech Defendants admit that Exactech, Inc. used brochures and videos to promote its knee devices. The Exactech Defendants deny the remaining allegations in Paragraph 456 of the Complaint.

457. Exactech distributes and otherwise directly provides Orthopedic Surgeons instructions for use (IFU) and instructions for implantation of the Exactech Knee Devices.

ANSWER: The Exactech Defendants admit that Exactech, Inc. provides instructions for use with its devices as required by FDA regulations and also makes available Operative Technique guides for its products. The Exactech Defendants deny the remaining allegations in Paragraph 457 of the Complaint.

458. 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."

ANSWER: The Exactech Defendants admit that certain Exactech, Inc. promotional materials contain the partial quote cited in Paragraph 458. The Exactech Defendants deny the remaining allegations in Paragraph 458 of the Complaint.

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

ANSWER: The Exactech Defendants admit that Exactech, Inc. generally represented to surgeons and others that its UHMWPE tibial inserts are designed to resist oxidation, reduce wear, and improve longevity of knee prostheses. The Exactech Defendants deny the remaining allegations in Paragraph 459 of the Complaint.

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

ANSWER: The Exactech Defendants admit that Exactech, Inc. generally represented to surgeons and others that its UHMWPE tibial inserts have a long clinical history of excellent wear characteristics. The Exactech Defendants deny the remaining allegations in Paragraph 460 of the Complaint.

461. 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 ..."

ANSWER: The Exactech Defendants admit that Exactech, Inc. generally represented to surgeons and others that its comprehensive knee systems address concerns for contact stress, patellar tracking, polyethylene wear, joint stability and bone preservation. The Exactech Defendants deny the remaining allegations in Paragraph 461 of the Complaint.

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

ANSWER: The Exactech Defendants admit that Exactech, Inc. generally represented to surgeons and others that its Knee Devices have excellent long-term clinical outcomes. The Exactech Defendants deny the remaining allegations in Paragraph 462 of the Complaint.

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

ANSWER: The Exactech Defendants admit that Exactech, Inc. generally represented to surgeons and others that surgeons and patients can have confidence in the performance and longevity of its Knee Devices. The Exactech Defendants deny the remaining allegations in Paragraph 463 of the Complaint.

464. 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."

ANSWER: The Exactech Defendants admit that Exactech, Inc. generally represented that its products are designed to improve patient outcomes. The Exactech Defendants deny the remaining allegations in Paragraph 464 of the Complaint, including for the reason that they did not provide an express warranty with their products.

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

ANSWER: The Exactech Defendants admit that Exactech, Inc. generally represented to surgeons and others that the Optetrak knee system had excellent long-term clinical outcomes and admit that Plaintiffs have quoted in part from an Exactech promotional document detailing published clinical data. The Exactech Defendants deny the remaining allegations in Paragraph 465 of the Complaint.

466. 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.

ANSWER: The Exactech Defendants deny the allegations in Paragraph 466 of the Complaint, including the premise that consultants were compensated in exchange for product promotion.

467. 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.

ANSWER: The Exactech Defendants admit that Exactech, Inc. contracted with Raymond P. Robinson and Dr. Gradisar and that compensation and reimbursements were paid to both of them, and that such payment information is available through Open Payments Data, which data

speaks for itself. The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 467 of the Complaint.

468. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 468 of the Complaint.

469. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 469 of the Complaint.

470. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 470 of the Complaint.

471. 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.

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote an Exactech design rationale, a document which speaks for itself, but deny the allegations contained in Paragraph 471 of the Complaint, including because the Exactech Defendants did not offer an express warranty.

472. 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, 712-0121 Rev. D, © 2010.

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote an Exactech brochure, a document which speaks for itself, but deny the allegations contained in Paragraph 472 of the Complaint, including because the Exactech Defendants did not offer an express warranty.

473. 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.

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote an Exactech design rationale, a document which speaks for itself, but deny the allegations contained in Paragraph 473 of the Complaint, including because the Exactech Defendants did not offer an express warranty.

474. 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, 71201-21 Rev. D, © 2010.

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote an Exactech brochure, a document which speaks for itself, but deny the remaining allegations contained in Paragraph 474 of the Complaint.

475. 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.*

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote an Exactech brochure, a document which speaks for itself, but deny the remaining allegations contained in Paragraph 475 of the Complaint, including because the Exactech Defendants did not offer an express warranty.

476. 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).

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote, in part, from the Exactech website regarding Exactech, Inc.'s knee insert components. The cited portion of the website speaks for itself. The Exactech Defendants deny the remaining allegations contained in Paragraph 476 of the Complaint.

477. 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*.

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote, in part, from the Exactech website regarding Exactech, Inc.'s knee insert components. The cited portion of the website speaks for itself. The Exactech Defendants deny the remaining allegations contained in Paragraph 477 of the Complaint.

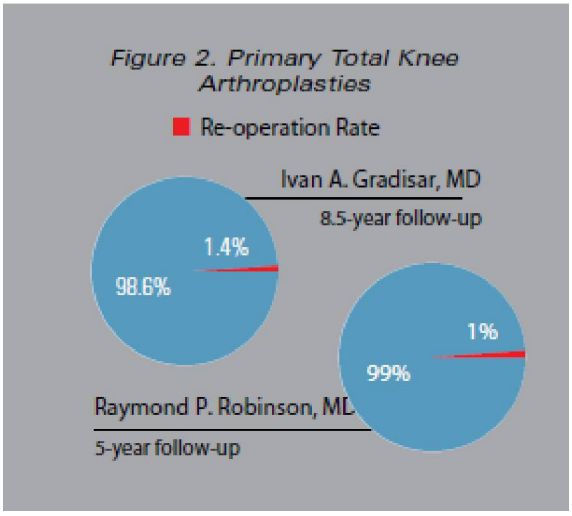
478. Exactech compares its wear rates to competitors and states: "Comparative laboratory testing published by various manufacturers and researchers shows that Exactech's net compression molded polyethylene has demonstrated approximately 6X less wear than extruded UHMWPE. This is achieved without sacrificing other important mechanical properties." *Id*.

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote, in part, from the Exactech website regarding Exactech, Inc.'s knee insert components. The cited

portion of the website speaks for itself. The Exactech Defendants deny the remaining allegations contained in Paragraph 478 of the Complaint.

479. 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)*.



ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote Exactech brochures, documents which speak for themselves, but deny the remaining allegations contained in Paragraph 479 of the Complaint, including because the Exactech Defendants did not offer an express warranty.

480. 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

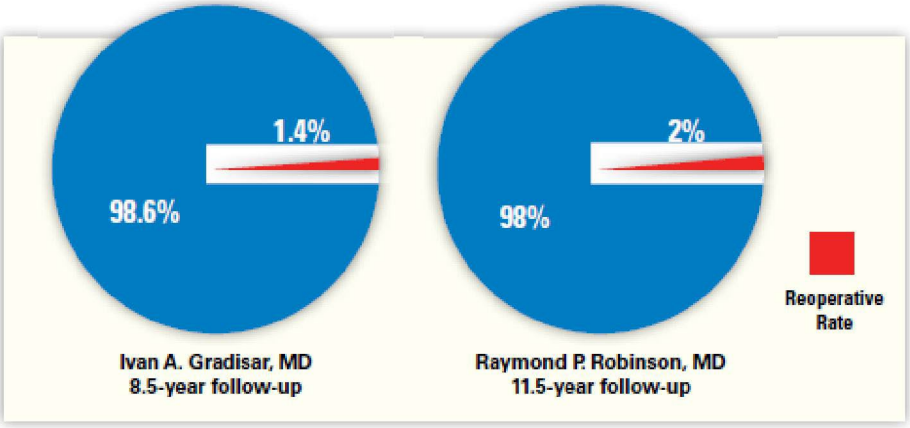
between April 27, 1996 and November 11, 1996. *See* ROBINSON, *Five-Year Follow-up of Primary Optetrak Posterior Stabilized Total Knee Arthroplasties in Osteoarthritis,* J. OF ARTHROPLASTY, *Vol. 20 No. 7* (2005).

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to summarize, in part, the publication by Dr. Raymond P. Robinson. The cited publication speaks for itself. The Exactech Defendants deny the remaining allegations contained in Paragraph 480 of the Complaint.

481. 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.

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote an Exactech design rationale and Exactech brochure, documents which speak for themselves, but deny the remaining allegations contained in Paragraph 481 of the Complaint, including because the Exactech Defendants did not offer an express warranty.

482. 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.

ANSWER: The Exactech Defendants deny the allegations in Paragraph 482 of the Complaint.

483. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 483 of the Complaint.

484. 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 instances we had unacceptable rates of tibial loosening (meaning the component loses its fixation within the bone and the patient must have a revision procedure)."

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 484 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

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

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 485 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

486. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 486 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

487. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 487 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

488. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 488 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

489. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 489 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

490. 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, Feb. 7, 2022 Knee and Ankle DHCP Letter at 2.

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote, in part, from a "Dear Health Care Professional" letter dated February 7, 2022 regarding Optetrak knee components. The cited document speaks for itself. The Exactech Defendants deny the remaining allegations contained in Paragraph 490 of the Complaint.

491. 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 at 2. Exactech then cited to "statistically significant increased cumulative revision rates" in the United Kingdom Registry and the New Zealand Registry. *Id.*

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote, in part, from a "Dear Health Care Professional" letter dated February 7, 2022 regarding Optetrak knee components. The cited document speaks for itself. The Exactech Defendants deny the remaining allegations contained in Paragraph 491 of the Complaint.

492. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 492 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

493. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 493 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

494. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 494 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

495. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 495 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

496. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 496 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

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

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

ANSWER: The Exactech Defendants admit that on August 30, 2021, Exactech, Inc. engaged in voluntary actions classified by the FDA as voluntary recalls of certain Optetrak knee components. The Exactech Defendants deny the remaining allegations in Paragraph 497 of the Complaint.

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

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote, in part, from the August 30, 2021 voluntary recall notification. The document speaks for itself. The Exactech Defendants deny the remaining allegations contained in Paragraph 498 of the Complaint.

499. 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, Aug. 30, 2021 FDA Recall Notification.

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote, in part, Exhibit G to the Complaint. The cited document speaks for itself. The Exactech Defendants

deny the remaining allegations contained in Paragraph 499 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

500. 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.

ANSWER: The Exactech Defendants admit that Exactech, Inc. sent notice of the August 2021 voluntary recall to its distributors and sales agents. The Exactech Defendants deny the remaining allegation in Paragraph 500 of the Complaint including because they decline to accept Plaintiffs' representations.

501. 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 hereto as Exhibit H.

ANSWER: The Exactech Defendants admit the allegations contained in Paragraph 501 of the Complaint.

502. 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.

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote, in part, Exhibit H to the Complaint. The cited document speaks for itself. The Exactech Defendants deny the remaining allegations contained in Paragraph 502 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

503. 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*.

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote, in part, Exhibit H to the Complaint. The cited document speaks for itself. The Exactech Defendants deny the remaining allegations contained in Paragraph 503 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

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

ANSWER: The Exactech Defendants deny the allegations in Paragraph 504 of the Complaint.

505. 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).

ANSWER: The Exactech Defendants admit that in November 2021, the FDA conducted an inspection of Exactech, Inc. and issued an FDA Form-483 in which it made the observations listed in subparts a through e of Paragraph 505. The Exactech Defendants deny the remaining allegations in Paragraph 505 of the Complaint.

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

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 506 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

507. 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 hereto.

ANSWER: The Exactech Defendants admit that on February 7, 2022, Exactech, Inc. issued an Urgent Medical Device Correction to surgeons and healthcare professionals. The cited document speaks for itself. The Exactech Defendants deny the remaining allegations contained in Paragraph 507 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

508. 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).

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote, in part, Exhibit F to the Complaint. The cited document speaks for itself. The Exactech Defendants deny the remaining allegations contained in Paragraph 508 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

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

ANSWER: The Exactech Defendants deny the allegations in Paragraph 509 of the Complaint.

510. 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.

ANSWER: The Exactech Defendants deny the allegations in Paragraph 510 of the Complaint.

511. 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.

ANSWER: The Exactech Defendants deny the allegations in Paragraph 511 of the Complaint.

512. 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.

ANSWER: The Exactech Defendants admit that certain Exactech, Inc. knee devices were packaged in vacuum bags that did not conform to Exactech, Inc.'s packaging specifications. The

Exactech Defendants deny the remaining allegations in Paragraph 512 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

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

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 513 of the Complaint.

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

ANSWER: The Exactech Defendants admit that packaging of Exactech, Inc.'s components is an important part of the manufacturing process. The Exactech Defendants deny the remaining allegations in Paragraph 514 of the Complaint.

515. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 515 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

516. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 516 of the Complaint.

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

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 517 of the Complaint.

518. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 518 of the Complaint.

519. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 519 of the Complaint.

520. 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*.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 520 of the Complaint.

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

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 521 of the Complaint.

524. Because

522. 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. In a March 2023 article in THE BONE & JOINT JOURNAL, a report of a study conducted at the Hospital for Special Surgery provided that surgeons at that facility saw "an increase in revision of Optetrak TKAs for aseptic loosening, early and severe polyethylene wear, osteolysis, as well as component loosening related to cement debonding." *See* E.B. GAUSDEN, ET. AL., *Mid-term Survivorship of Primary Total Knee Arthroplasty with a Specific Implant*, BONE JOINT J., 105B(3): 277-278, Mar. 2023.

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote, in part, an article. The cited document speaks for itself. The Exactech Defendants deny the remaining allegations contained in Paragraph 522 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

523. 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.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 523 and therefore deny them, including due to a lack of specificity as to which patients are being referenced.

C. Exactech's Total Ankle Replacement System

i. Total Ankle Replacement Surgery

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

ANSWER: Paragraph 524 contains medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 524 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

525. 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.

ANSWER: Paragraph 525 contains medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent

Paragraph 525 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that total ankle replacement can contain the components identified in Paragraph 525 and deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

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

ANSWER: Paragraph 526 contains scientific and medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 526 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

527. 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.

ANSWER: Paragraph 527 contains medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 527 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

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

ANSWER: Paragraph 528 contains scientific and medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 528 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

529. 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.

ANSWER: Paragraph 529 contains scientific and medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 529 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

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

ANSWER: Paragraph 530 contains scientific and medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 530 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

531. 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.

ANSWER: Paragraph 531 contains rhetorical scientific and medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 531 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

532. 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).

ANSWER: Paragraph 532 contains rhetorical scientific and medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 532 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

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

ANSWER: Paragraph 533 contains medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 533 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

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

534. 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.

ANSWER: Paragraph 534 contains scientific and medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 534 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

535. 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.

ANSWER: Paragraph 535 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent

Paragraph 535 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

536. 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.

ANSWER: Paragraph 536 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 536 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

537. 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.

ANSWER: Paragraph 537 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 537 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

538. 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.

ANSWER: Paragraph 538 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 538 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

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

ANSWER: Paragraph 539 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 539 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

540. 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.

ANSWER: Paragraph 540 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 540 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

541. 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.

ANSWER: Paragraph 541 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 541 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

542. 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.

ANSWER: Paragraph 542 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 542 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

543. 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.

ANSWER: Paragraph 543 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 543 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

544. 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.

ANSWER: Paragraph 544 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 544 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

545. 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.

ANSWER: Paragraph 545 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent

Paragraph 545 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

546. 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.

ANSWER: Paragraph 546 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 546 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

547. 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.

ANSWER: Paragraph 547 contains scientific statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 547 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

548. 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.

ANSWER: Paragraph 548 contains medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 548 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

549. 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.

ANSWER: Paragraph 549 contains medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 549 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

550. 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.

ANSWER: Paragraph 550 contains medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 550 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

551. 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).

ANSWER: Paragraph 551 contains medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 551 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

552. 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.

ANSWER: Paragraph 552 contains medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 552 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

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

ANSWER: Paragraph 553 contains medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 553 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

554. 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.

ANSWER: Paragraph 554 contains medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 554 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

555. 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.

ANSWER: Paragraph 555 contains medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 555 can be construed as containing allegations against the Exactech Defendants

requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

556. 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.

ANSWER: Paragraph 556 contains scientific and medical statements and opinions that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 556 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations, including because they decline to adopt Plaintiffs' characterizations.

iii. Exactech's Vantage Total Ankle System

557. 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").

ANSWER: The Exactech Defendants admit that Exactech, Inc. designed, manufactured, packaged, marketed, labeled, and sold the Devices. The Exactech Defendants further admit that Exactech U.S., Inc. generally participated in the sale of the Devices in the United States. The Exactech Defendants deny the remaining allegations contained in Paragraph 557 of the Complaint.

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

ANSWER: The Exactech Defendants admit that Exactech, Inc. introduced and began marketing the Vantage Total Ankle System in 2016. The Exactech Defendants deny the remaining allegations in Paragraph 558 of the Complaint.

559. 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.

ANSWER: Exactech admits that the allegations in Paragraph 559 contain a partial statement of the indicated use for the Devices. The Exactech Defendant deny the remaining allegations in Paragraph 559 of the Complaint.

560. 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.

ANSWER: The Exactech Defendants admit the allegations in Paragraph 560 of the Complaint.

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

ANSWER: The Exactech Defendants admit the allegations contained in Paragraph 561 of the Complaint.

562. 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.

ANSWER: The Exactech Defendants admit that there are similarities between the design and manufacturing processes for the polyethylene inserts utilized by Exactech, Inc. in its Vantage® Total Ankle System and Exactech, Inc.'s knee replacement products. The Exactech Defendants deny the remaining allegations contained in Paragraph 562 of the Complaint.

563. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 563 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

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

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 564 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

565. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 565 of the Complaint.

iv. Exactech Vantage Total Ankle System 510(k)

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

ANSWER: The Exactech Defendants admit the allegations contained in Paragraph 566 of the Complaint.

567. 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).

ANSWER: The Exactech Defendants admit the allegations contained in Paragraph 567 of the Complaint.

568. 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.

ANSWER: The Exactech Defendants admit the allegations contained in Paragraph 568 of the Complaint.

569. 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.

ANSWER: The Exactech Defendants admit the allegations contained in Paragraph 569 of the Complaint.

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

570. 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.

ANSWER: The Exactech Defendants admit that Exactech, Inc. marketed and sold the Devices in the United States, including the State of New York, and in other parts of the world. The Exactech Defendants further admit that Exactech U.S., Inc. generally participated in the sale of the Devices in the United States. The Exactech Defendants deny the remaining allegations contained in Paragraph 570 of the Complaint.

571. 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)).

ANSWER: The Exactech Defendants admit the allegations contained in Paragraphs 571 of the Complaint.

572. 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."

ANSWER: The Exactech Defendants generally admit that Exactech, Inc. used brochures and video to promote its Vantage Total Ankle System, and that Plaintiffs have cited two such brochures. The Exactech Defendant deny the remaining allegations in Paragraph 572 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

573. 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."

ANSWER: The Exactech Defendants admit that Exactech, Inc. provides instructions for use with its devices as required by FDA regulations and also makes available Operative Technique

guides for its products. The Exactech Defendants deny the remaining allegations in Paragraph 573 of the Complaint.

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

ANSWER: The Exactech Defendants admit that Exactech, Inc. generally represented to surgeons and others that its Vantage Total Ankle System was safe and effective for use in certain patients under appropriate circumstances. The Exactech Defendants deny the remaining allegations in Paragraph 574 of the Complaint.

575. 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."

ANSWER: The Exactech Defendants admit that Plaintiffs have accurately set forth a partial quote from an Exactech, Inc. Vantage Total Ankle System product brochure, which speaks for itself. The Exactech Defendants deny the remaining allegations contained in Paragraph 575 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

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

ANSWER: The Exactech Defendants deny the allegations in Paragraph 576 of the Complaint, including because they decline to adopt Plaintiff's characterizations of "boast[ing]."

577. 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.

ANSWER: The Exactech Defendants deny the allegations in Paragraph 577 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

578. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 578 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

579. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 579 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

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

580. 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.

ANSWER: The Exactech Defendants admit that on August 30, 2021, Exactech, Inc. engaged in voluntary actions classified by the FDA as voluntary recalls of certain Vantage Total Ankle System components. The Exactech Defendants deny the remaining allegations in Paragraph 580 of the Complaint.

581. 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.

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote, in part, Exhibit G to the Complaint. The cited document speaks for itself. The Exactech Defendants deny the remaining allegations contained in Paragraph 581 of the Complaint.

582. 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").

ANSWER: The Exactech Defendants admit the voluntary Class 2 recall initiated in August 2021 was related to vacuum bags that did not conform to Exactech, Inc.'s packaging

specifications. The Exactech Defendants deny the remaining allegations in Paragraph 582 including because they decline to accept Plaintiffs' characterizations.

583. 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, Aug. 30, 2021 FDA Recall Notification.

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote, in part, Exhibit G to the Complaint. The cited document speaks for itself. The Exactech Defendants deny the remaining allegations contained in Paragraph 583 of the Complaint.

584. 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.

ANSWER: The Exactech Defendants admit that Exactech, Inc. sent notice of the August 2021 voluntary recall to its distributors and sales agents. The Exactech Defendants deny the remaining allegation in Paragraph 584 of the Complaint including because they decline to accept Plaintiffs' representations.

585. 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 hereto as Exhibit H.

ANSWER: The Exactech Defendants admit the allegations contained in Paragraph 585 of the Complaint.

586. 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.

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote, in part, Exhibit G to the Complaint. The cited document speaks for itself. The Exactech Defendants deny the remaining allegations contained in Paragraph 586 of the Complaint.

587. 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*.

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote, in part, Exhibit H to the Complaint. The cited document speaks for itself. The Exactech Defendants deny the remaining allegations contained in Paragraph 587 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

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

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 588 of the Complaint.

589. 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).

ANSWER: The Exactech Defendants admit that in November 2021, the FDA conducted an inspection of Exactech, Inc. and issued an FDA Form-483 in which it made the observations listed in subparts a through e of Paragraph 589. The Exactech Defendants deny the remaining allegations in Paragraph 589 of the Complaint.

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

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 590 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

591. 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 hereto.

ANSWER: The Exactech Defendants admit that on February 7, 2022, Exactech, Inc. issued an Urgent Medical Device Correction to surgeons and healthcare professionals. The cited document speaks for itself. The Exactech Defendants deny the remaining allegations contained in Paragraph 591 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

592. 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).

ANSWER: The Exactech Defendants admit that Plaintiffs have attempted to quote, in part, Exhibit F to the Complaint. The cited document speaks for itself. The Exactech Defendants deny the remaining allegations contained in Paragraph 592 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

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

ANSWER: The Exactech Defendants deny the allegations in Paragraph 593 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

594. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 594 of the Complaint.

595. 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.

ANSWER: The Exactech Defendants admit that certain Exactech, Inc. ankle devices were packaged in vacuum bags that did not conform to Exactech, Inc.'s packaging specifications. The Exactech Defendants deny the remaining allegations in Paragraph 595 of the Complaint, including because they decline to adopt Plaintiffs' characterizations.

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

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 596 of the Complaint.

597. 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.

ANSWER: The Exactech Defendants admit that packaging of Exactech, Inc.'s components is an important part of the manufacturing process. The Exactech Defendants deny the remaining allegations in Paragraph 597 of the Complaint.

598. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 598 of the Complaint.

599. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 599 of the Complaint.

600. 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*.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 600 of the Complaint.

601. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 601 of the Complaint.

602. 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.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 602 of the Complaint and therefore deny them, including due to a lack of specificity as to which patients are being referenced.

VI. SUMMARY OF EXACTECH'S ACTS AND OMISSIONS

603. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 603 of the Complaint.

604. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 604 of the Complaint.

605. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 605 of the Complaint.

606. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 606 of the Complaint.

607. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 607 of the Complaint and in each of its subparts.

608. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 608 of the Complaint.

609. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 609 of the Complaint.

610. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 610 of the Complaint.

611. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 611 of the Complaint.

612. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 612 of the Complaint.

613. As a direct, proximate, and legal consequence of Exactech's conduct and the defective nature of the Exactech Devices as described herein, Plaintiffs have 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 613 of the Complaint.

614. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 614 of the Complaint.

VII. TOLLING OF THE STATUTES OF LIMITATIONS

A. Latent Injury

615. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 615 of the Complaint.

616. 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).

ANSWER: Paragraph 616 of the Complaint contains rhetorical statements that are not allegations against the Exactech Defendants to which a response is required. The cited document speaks for itself. To the extent Paragraph 616 can be construed as containing allegations against

the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations contained in Paragraph 616 of the Complaint.

617. 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.

ANSWER: Paragraph 617 of the Complaint contains rhetorical statements that are not allegations against the Exactech Defendants to which a response is required. To the extent Paragraph 617 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants deny the allegations contained in Paragraph 617 of the Complaint.

618. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 618 of the Complaint.

619. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 619 of the Complaint.

B. Fraudulent Concealment

620. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 620 of the Complaint.

621. 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.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of any allegations regarding reliance by Plaintiffs and/or their healthcare providers and therefore deny the allegations contained in Paragraph 621 of the Complaint.

622. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 622 of the Complaint.

623. 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.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of any allegations regarding reliance by Plaintiffs and/or their healthcare providers and therefore deny the allegations contained in Paragraph 623 of the Complaint.

624. 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.

ANSWER: The Exactech Defendants deny the allegations in Paragraph 624 of the Complaint and decline to adopt Plaintiffs' characterizations.

625. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 625 of the Complaint.

626. 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.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 626 of the Complaint regarding the knowledge of Plaintiffs and their healthcare providers. The Exactech Defendants deny the remaining allegations contained in Paragraph 626 of the Complaint.

627. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 627 of the Complaint.

628. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 628 of the Complaint.

629. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 629 of the Complaint.

630. 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.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 630 of the Complaint regarding the knowledge

of Plaintiffs and their healthcare providers. The Exactech Defendants deny the remaining allegations contained in Paragraph 630 of the Complaint.

631. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 631 of the Complaint.

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

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 632 of the Complaint.

633. Further, the limitations period should be tolled under principles of equitable tolling.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 633 of the Complaint.

CAUSES OF ACTION

FIRST CAUSE OF ACTION: STRICT LIABILITY – MANUFACTURING DEFECT

(Against Exactech Defendants and TPG Defendants[11])

634. Plaintiffs hereby incorporate by reference as if fully set forth herein, the factual allegations set forth in paragraphs 1 to 634 and further allege as follows.

ANSWER: The Exactech Defendants incorporate by reference their Answers to Paragraphs 1 through 633 above as their answer to this paragraph, as if fully set forth herein.

635. Prior to the initial surgeries in which Plaintiffs' Exactech Hip, Knee, and Ankle Devices were implanted, and at all times relevant to this action, Exactech designed, tested, studied, researched, formulated, manufactured, inspected, labeled, packaged, stored, promoted, advertised,

[11] 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.

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 Plaintiffs.

ANSWER: The Exactech Defendants further admit that Exactech, Inc. generally designs, manufactures, tests, develops, packages, markets, and distributes orthopedic joint implants, including the Devices, throughout the United States. The Exactech Defendants further admit that Exactech U.S., Inc. participated generally in the sale of the Devices in the United States. The Exactech Defendants deny the remaining allegations contained in Paragraph 63 of the Complaint.

636. The Exactech Hip, Knee, and Ankle Devices implanted into Plaintiffs 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 636 of the Complaint.

637. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 637 of the Complaint, including each subpart.

638. As a result of these manufacturing defects, Exactech's Hip, Knee, and Ankle Devices were unreasonably dangerous.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 638 of the Complaint.

639. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 639 of the Complaint.

640. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 640 of the Complaint.

641. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 641 of the Complaint.

642. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 642 of the Complaint.

643. Plaintiffs were implanted with Exactech Hip, Knee, and/or Ankle Devices that contained the manufacturing defects set forth above.

ANSWER: The Exactech Defendants admit that certain patients were implanted with Exactech hip, knee and ankle devices. The Exactech Defendants deny the remaining allegations in Paragraph 643 of the Complaint.

644. These defects existed when the Exactech Hip, Knee, and Ankle Devices left Exactech's control.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 644 of the Complaint.

645. 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 Plaintiffs.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 645 of the Complaint and therefore deny them.

646. Plaintiffs' 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.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 646 of the Complaint and therefore deny them.

647. As a result of the manufacturing defects in Exactech's Hip, Knee, and Ankle Devices implanted into Plaintiffs, the Devices failed.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 647 of the Complaint.

648. The manufacturing defects in Exactech's Hip, Knee, and Ankle Devices implanted into Plaintiffs were a substantial factor in causing Plaintiffs' injuries.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 648 of the Complaint.

649. Plaintiffs could not, by the exercise of reasonable care, have discovered these manufacturing defects, perceived their dangers, or avoided injury.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 649 of the Complaint.

650. As a direct and proximate result of the failure of Exactech's Hip, Knee, and Ankle Devices, Plaintiffs suffered serious physical injury, harm, damages, and economic loss, and will continue to suffer such harm, damages, and economic loss in the future.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 650 of the Complaint.

651. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 651 of the Complaint.

SECOND CAUSE OF ACTION: STRICT LIABILITY – DESIGN DEFECT

(Against Exactech Defendants and TPG Defendants[12])

652. Plaintiffs hereby incorporate by reference as if fully set forth herein, the factual allegations set forth in paragraphs 1 to 634 and further allege as follows.

ANSWER: The Exactech Defendants incorporate by reference their Answers to Paragraphs 1 through 651 above as their answer to this paragraph, as if fully set forth herein.

653. Prior to the initial surgeries in which Plaintiffs' Exactech Hip, Knee, and Ankle 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 Plaintiffs.

[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.

ANSWER: The Exactech Defendants admit that Exactech, Inc. designed, manufactured, marketed, labeled, and participated in the sale of the Devices for implantation into patients by orthopedic surgeons throughout the United States. The Exactech Defendants further admit that Exactech U.S., Inc. participated in the sale of the Devices generally. The Exactech Defendants deny the remaining allegations contained in Paragraph 653 of the Complaint.

654. The Exactech Hip, Knee, and Ankle Devices implanted into Plaintiffs and the Devices' corresponding packaging were defective in their design.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 654 of the Complaint.

655. 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 Plaintiffs, 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 655 of the Complaint.

656. As a result of these design defects, Exactech's Hip, Knee, and Ankle Devices were unreasonably dangerous.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 656 of the Complaint.

657. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 657 of the Complaint.

658. As alleged herein, Exactech knew or had reason to know that the Devices caused an increased risk of harm to the 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. Exactech has not and cannot identify product benefits which outweigh these increased risks.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 658 of the Complaint.

659. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 659 of the Complaint.

660. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 660 of the Complaint.

661. Safer feasible alternative designs that would have avoided Plaintiffs' 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 661 of the Complaint.

662. Plaintiffs were implanted with Exactech Hip, Knee, and/or Ankle Devices that contained the design defects set forth above.

ANSWER: The Exactech Defendants admit that certain patients were implanted with Exactech hip, knee and ankle devices. The Exactech Defendants deny the remaining allegations in Paragraph 662 of the Complaint.

663. These defects existed when the Exactech Hip, Knee, and Ankle Devices left Exactech's control.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 663 of the Complaint.

664. 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 Plaintiffs.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 664 of the Complaint and therefore deny them.

665. Plaintiffs' 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.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 665 of the Complaint and therefore deny them.

666. As a result of the design defects in Exactech's Hip, Knee, and Ankle Devices implanted into Plaintiffs, the Devices failed.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 666 of the Complaint.

667. The design defects in Exactech's Hip, Knee, and Ankle Devices implanted into Plaintiffs were a substantial factor in causing Plaintiffs' injuries.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 667 of the Complaint.

668. 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.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 668 of the Complaint and therefore deny them.

669. Plaintiffs could not, by the exercise of reasonable care, have discovered these design defects, perceived their dangers, or avoided injury.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 669 of the Complaint.

670. As a direct and proximate result of the failure of Exactech's Hip, Knee, and Ankle Devices, Plaintiffs suffered serious physical injury, harm, damages, and economic loss, and will continue to suffer such harm, damages, and economic loss in the future.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 670 of the Complaint.

671. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 671 of the Complaint.

THIRD CAUSE OF ACTION:
STRICT LIABILITY – DEFECT DUE TO INADEQUATE WARNINGS OR INSTRUCTIONS

(Against Exactech Defendants and TPG Defendants[13])

672. Plaintiffs hereby incorporate by reference as if fully set forth herein, the factual allegations set forth in paragraphs 1 to 634 and further allege as follows.

ANSWER: The Exactech Defendants incorporate by reference their Answers to Paragraphs 1 through 671 above as their answer to this paragraph, as if fully set forth herein.

673. Prior to the initial surgeries in which Plaintiffs' Exactech Hip, Knee, and Ankle 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 Plaintiffs.

[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.

ANSWER: The Exactech Defendants admit that Exactech, Inc. designed, manufactured, marketed, labeled, and participated in the sale of the Devices for implantation into patients by orthopedic surgeons throughout the United States. The Exactech Defendants further admit that Exactech U.S., Inc. participated in the sale of the Devices generally. The Exactech Defendants deny the remaining allegations contained in Paragraph 673 of the Complaint.

674. The Exactech Hip, Knee, and Ankle Devices implanted into Plaintiffs and the Devices' corresponding packaging were defective due to inadequate warnings and instructions.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 674 of the Complaint.

675. The Devices were defective due to inadequate and improper warnings and 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 675 of the Complaint.

676. Likewise, the Devices were defective due to inadequate post-sale warnings and instructions, because following Plaintiffs' 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 676 of the Complaint.

677. As a result of these warning defects, Exactech's Hip, Knee, and Ankle Devices were unreasonably dangerous.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 677 of the Complaint.

678. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 678 of the Complaint.

679. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 679 of the Complaint.

680. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 680 of the Complaint.

681. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 681 of the Complaint.

682. Plaintiffs were implanted with Exactech Hip, Knee, and/or Ankle Devices that contained the warning defects set forth above.

ANSWER: The Exactech Defendants admit that certain patients were implanted with Exactech hip, knee and ankle devices. The Exactech Defendants deny the remaining allegations in Paragraph 682 of the Complaint.

683. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 683 of the Complaint.

684. 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 Plaintiffs.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 684 of the Complaint and therefore deny them.

685. Plaintiffs' 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.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 685 of the Complaint and therefore deny them.

686. As a result of the warning defects in Exactech's Hip, Knee, and Ankle Devices implanted into Plaintiffs, the Devices failed.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 686 of the Complaint.

687. As a result of the warning defects in Exactech's Hip, Knee, and Ankle Devices, Plaintiffs' and Plaintiffs' surgeons lacked critical information to mitigate harm after the Devices failed.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 687 of the Complaint.

688. The warning defects in Exactech's Hip, Knee, and Ankle Devices implanted into Plaintiffs were a substantial factor in causing Plaintiffs' injuries.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 688 of the Complaint.

689. 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 proper and intended use.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 689 of the Complaint and therefore deny them.

690. Plaintiffs could not, by the exercise of reasonable care, have discovered these defects, perceived their dangers, or avoided injury.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 690 of the Complaint.

691. Indeed, Plaintiffs and their 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.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 691 of the Complaint and therefore deny them.

692. Had Exactech provided adequate warnings and instructions prior to or following the sale of the Devices implanted into Plaintiffs, Plaintiffs and their surgeons would have heeded those warnings and avoided or, in the alternative, mitigated the injuries suffered by Plaintiffs.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs' and their surgeons' actions contained in Paragraph 692 of the Complaint and therefore deny them. The Exactech Defendants deny the remaining allegations contained in Paragraph 692 of the Complaint.

693. As a direct and proximate result of these warning defects and the failure of Exactech's Hip, Knee, and Ankle Devices, Plaintiffs suffered serious physical injury, harm, damages, and economic loss, and will continue to suffer such harm, damages, and economic loss in the future.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 693 of the Complaint.

694. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 694 of the Complaint.

FOURTH CAUSE OF ACTION:
NEGLIGENCE

(Against Exactech Defendants and TPG Defendants[14])

695. Plaintiffs hereby incorporate by reference as if fully set forth herein, the factual allegations set forth in paragraphs 1 to 634 and further allege as follows.

ANSWER: The Exactech Defendants incorporate by reference their Answers to Paragraphs 1 through 694 above as their answer to this paragraph, as if fully set forth herein.

696. Prior to the initial surgeries in which Plaintiffs' Exactech Hip, Knee, and Ankle 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 Plaintiffs, by orthopedic surgeons in the United States.

ANSWER: The Exactech Defendants admit that Exactech, Inc. designed, manufactured, marketed, labeled, and participated in the sale of the Devices for implantation into patients by orthopedic surgeons throughout the United States. The Exactech Defendants further admit that Exactech U.S., Inc. participated in the sale of the Devices generally. The Exactech Defendants deny the remaining allegations contained in Paragraph 696 of the Complaint.

697. Prior to, on, and after the dates of Plaintiffs' 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, advertisement, marketing, distribution, and sale of the Devices for implantation into consumers, such as Plaintiffs, by physicians and surgeons in the United States.

[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.

ANSWER: The Exactech Defendants admit only to those duties imposed upon them by applicable law. The Exactech Defendants deny the remaining allegations contained in Paragraph 697 of the Complaint.

698. Prior to, on, and after the dates of Plaintiffs' 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 698 of the Complaint.

699. Following Plaintiffs' 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 699 of the Complaint.

700. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 700 of the Complaint.

701. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 701 of the Complaint.

702. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 702 of the Complaint.

703. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 703 of the Complaint, including each subpart.

704. Exactech knew and/or should have known that it was foreseeable that consumers such as Plaintiffs 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 704 of the Complaint.

705. As a direct and proximate result of Exactech's negligence and breach of its duties, the Devices implanted into Plaintiffs failed.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 705 of the Complaint.

706. As a direct and proximate result of Exactech's negligence and the failure of Exactech's Hip, Knee, and Ankle Devices, Plaintiffs suffered serious physical injury, harm, damages, and economic loss, and will continue to suffer such harm, damages, and economic loss in the future.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 706 of the Complaint.

707. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 707 of the Complaint.

FIFTH CAUSE OF ACTION: BREACH OF EXPRESS WARRANTY

(Against Exactech Defendants and TPG Defendants[15])

708. Plaintiffs hereby incorporate by reference as if fully set forth herein, the factual allegations set forth in paragraphs 1 to 634 and further allege as follows.

ANSWER: The Exactech Defendants incorporate by reference their Answers to Paragraphs 1 through 707 above as their answer to this paragraph, as if fully set forth herein.

709. Prior to the initial surgeries in which Plaintiffs' Exactech Hip, Knee, and Ankle 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 Plaintiffs, by orthopedic surgeons in the United States.

ANSWER: The Exactech Defendants admit that Exactech, Inc. designed, manufactured, marketed, labeled, and participated in the sale of the Devices for implantation into patients by

[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.

orthopedic surgeons throughout the United States. The Exactech Defendants further admit that Exactech U.S., Inc. participated in the sale of the Devices generally. The Exactech Defendants deny the remaining allegations contained in Paragraph 709 of the Complaint.

710. Exactech expressly warranted the Devices were safe and effective orthopedic devices.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 710 of the Complaint, including because they did not offer an express warranty.

711. 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;

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 711 of the Complaint, including each subpart.

712. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 712 of the Complaint, including because they did not offer an express warranty.

713. 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.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 713 of the Complaint and therefore deny them.

714. 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.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 714 of the Complaint and therefore deny them, including because they did not offer any express warranties.

715. Plaintiffs used the Devices for their intended purpose, and in a reasonably foreseeable manner.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 715 of the Complaint and therefore deny them.

716. 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 Plaintiffs when used as recommended and directed.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 716 of the Complaint, including because they did not offer an express warranty.

717. As a direct and proximate result of Exactech's breach of express warranty, Plaintiffs suffered serious physical injury, harm, damages, and economic loss, and will continue to suffer such harm, damages, and economic loss in the future.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 717 of the Complaint, including because they did not offer an express warranty.

718. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 718 of the Complaint.

SIXTH CAUSE OF ACTION:
BREACH OF IMPLIED WARRANTY

(Against Exactech Defendants and TPG Defendants[16])

719. Plaintiffs hereby incorporate by reference as if fully set forth herein, the factual allegations set forth in paragraphs 1 to 634 and further allege as follows.

ANSWER: The Exactech Defendants incorporate by reference their Answers to Paragraphs 1 through 718 above as their answer to this paragraph, as if fully set forth herein.

720. Prior to the initial surgeries in which Plaintiffs' Exactech Hip, Knee, and Ankle 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 Plaintiffs, by orthopedic surgeons in the United States.

ANSWER: The Exactech Defendants admit that Exactech, Inc. designed, manufactured, marketed, labeled, and participated in the sale of the Devices for implantation into patients by orthopedic surgeons throughout the United States. The Exactech Defendants further admit that Exactech U.S., Inc. participated in the sale of the Devices generally. The Exactech Defendants deny the remaining allegations contained in Paragraph 720 of the Complaint.

[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.

721. 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.

ANSWER: The Exactech Defendants admit only to those implied warranties imposed upon them by law. The Exactech Defendants deny any express warranties. The Exactech Defendants deny the remaining allegations contained in Paragraph 721 of the Complaint.

722. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 722 of the Complaint.

723. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 723 of the Complaint.

724. Plaintiffs and/or Plaintiffs' 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.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs' and/or their physicians' reliance contained in Paragraph 724 of the Complaint and therefore deny them. The Exactech Defendants deny the remaining allegations in Paragraph 724 of the Complaint.

725. 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 Plaintiffs 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 725 of the Complaint.

726. As a direct and proximate result of Exactech's breach of implied warranty, Plaintiffs suffered serious physical injury, harm, damages, and economic loss, and will continue to suffer such harm, damages, and economic loss in the future.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 726 of the Complaint.

727. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 727 of the Complaint.

SEVENTH CAUSE OF ACTION:
NEGLIGENT MISREPRESENTATION
(Against Exactech Defendants and TPG Defendants[17])

728. Plaintiffs hereby incorporate by reference as if fully set forth herein, the factual allegations set forth in paragraphs 1 to 634 and further allege as follows.

ANSWER: The Exactech Defendants incorporate by reference their Answers to Paragraphs 1 through 727 above as their answer to this paragraph, as if fully set forth herein.

729. Prior to the initial surgeries in which Plaintiffs' Exactech Hip, Knee, and Ankle 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 Plaintiffs by orthopedic surgeons in the United States.

ANSWER: The Exactech Defendants admit that Exactech, Inc. designed, manufactured, marketed, labeled, and participated in the sale of the Devices for implantation into patients by orthopedic surgeons throughout the United States. The Exactech Defendants further admit that

[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.

Exactech U.S., Inc. participated in the sale of the Devices generally. The Exactech Defendants deny the remaining allegations contained in Paragraph 729 of the Complaint.

730. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 730 of the Complaint.

731. Exactech knew that such information was not readily available to Plaintiffs or their physicians and that Plaintiffs and their 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.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 731 of the Complaint regarding the knowledge or reliance of Plaintiffs and Plaintiffs' surgeons. The Exactech Defendants deny the remaining allegations contained in Paragraph 731 of the Complaint.

732. 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.

ANSWER: The Exactech Defendants admit only to those duties imposed upon them by applicable law. The Exactech Defendants deny the remaining allegations contained in Paragraph 732 of the Complaint.

733. Prior to and following Plaintiffs' implant surgeries, Exactech made negligent misrepresentations and omissions to patients and physicians, including Plaintiffs and Plaintiffs' 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 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 733 of the Complaint, including each subpart.

734. As described above, each of Exactech's representations and omissions about its Hip, Knee, and Ankle Devices was false and misleading.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 734 of the Complaint.

735. In the exercise of reasonable care, Exactech should have known that each of these representations and omissions was false and misleading.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 735 of the Complaint.

736. Plaintiffs and Plaintiffs' surgeons relied upon Exactech's representations and omissions in deciding to use an Exactech Device in their joint replacement surgeries.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 736 of the Complaint regarding the reliance of Plaintiffs and Plaintiffs' surgeons. The Exactech Defendants deny the remaining allegations contained in Paragraph 736 of the Complaint.

737. Each of the representations and omissions stated above were material to Plaintiffs' and Plaintiffs' surgeons' decision to use an Exactech Device in their joint replacement surgery.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 737 of the Complaint regarding what was material to Plaintiffs and Plaintiffs' surgeons. The Exactech Defendants deny the remaining allegations contained in Paragraph 737 of the Complaint.

738. It was not only foreseeable to Exactech, but also intended that patients and physicians, such as Plaintiffs and Plaintiffs' surgeons, would receive and rely upon these representations when deciding which device to use for joint replacement surgery.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 738 of the Complaint.

739. Plaintiffs' surgeons exercised reasonable care in relying upon Exactech's representations and omissions in choosing to use Exactech's Devices in Plaintiffs' surgeries.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 739 of the Complaint regarding the care of Plaintiffs' surgeons. The Exactech Defendants deny the remaining allegations contained in Paragraph 739 of the Complaint.

740. Plaintiffs' 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.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 740 of the Complaint regarding the care of Plaintiffs' surgeons. The Exactech Defendants deny the remaining allegations contained in Paragraph 740 of the Complaint.

741. As a direct and proximate result of Exactech's misrepresentations and omissions, Plaintiffs received Exactech's Hip, Knee, and Ankle Devices, which subsequently failed.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 741 of the Complaint.

742. As a direct and proximate result of Exactech's negligent misrepresentations and omissions, and the failure of Exactech's Devices, Plaintiffs suffered serious physical injury, harm, damages, and economic loss, and will continue to suffer such harm, damages, and economic loss in the future.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 742 of the Complaint.

743. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 743 of the Complaint.

EIGHTH CAUSE OF ACTION:
FRAUD
(Against Exactech Defendants and TPG Defendants[18])

744. Plaintiffs hereby incorporate by reference as if fully set forth herein, the factual allegations set forth in paragraphs 1 to 634 and further allege as follows.

ANSWER: The Exactech Defendants incorporate by reference their Answers to Paragraphs 1 through 743 above as its answer to this paragraph, as if fully set forth herein.

745. Prior to the initial surgeries in which Plaintiffs' Exactech Hip, Knee, and Ankle 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 Plaintiffs by orthopedic surgeons in the United States.

ANSWER: The Exactech Defendants admit that Exactech, Inc. designed, manufactured, marketed, labeled, and participated in the sale of the Devices for implantation into patients by orthopedic surgeons throughout the United States. The Exactech Defendants further admit that Exactech U.S., Inc. participated in the sale of the Devices generally. The Exactech Defendants deny the remaining allegations contained in Paragraph 745 of the Complaint.

746. 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.

[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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 746 of the Complaint.

747. Exactech knew that such information was not readily available to Plaintiffs or their physicians and that Plaintiffs and their 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.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 747 of the Complaint regarding the knowledge or reliance of Plaintiffs and Plaintiffs' surgeons. The Exactech Defendants deny the remaining allegations contained in Paragraph 747 of the Complaint.

748. 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.

ANSWER: The Exactech Defendants admit only to those duties imposed upon them by applicable law. The Exactech Defendants deny the remaining allegations contained in Paragraph 748 of the Complaint.

749. Prior to and following Plaintiffs' implant surgeries, Exactech made fraudulent representations and omissions to patients and physicians, including Plaintiffs and Plaintiffs' surgeon, about 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'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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 749 of the Complaint, including each subpart.

750. As described above, each of Exactech's fraudulent representations and omissions about its Hip, Knee, and Ankle Devices was false and misleading.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 750 of the Complaint.

751. Exactech made each of these fraudulent representations and omissions knowing that they were false and misleading.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 751 of the Complaint.

752. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 752 of the Complaint.

753. Plaintiffs and Plaintiffs' surgeons relied upon Exactech's fraudulent representations and omissions in deciding to use an Exactech Device in their joint replacement surgeries.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 753 of the Complaint regarding the reliance of Plaintiffs and Plaintiffs' surgeons. The Exactech Defendants deny the remaining allegations contained in Paragraph 753 of the Complaint.

754. Each of the representations and omissions stated above were material to Plaintiffs and Plaintiffs' surgeons' decision to use an Exactech Device in their joint replacement surgeries.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 754 of the Complaint regarding what was material to Plaintiffs and Plaintiffs' surgeons. The Exactech Defendants deny the remaining allegations contained in Paragraph 754 of the Complaint.

755. It was not only foreseeable to Exactech, but also intended that patients and physicians, such as Plaintiffs and Plaintiffs' surgeons, would receive and rely upon these false and fraudulent representations and omissions when deciding which device to use for joint replacement surgery.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 755 of the Complaint.

756. Plaintiffs' surgeons exercised reasonable care in relying upon Exactech's fraudulent representations and omissions in choosing to use Exactech's Devices in Plaintiffs' surgeries.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 756 of the Complaint regarding the care exercised by Plaintiffs' surgeons. The Exactech Defendants deny the remaining allegations contained in Paragraph 756 of the Complaint.

757. Plaintiffs' 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.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 757 of the Complaint regarding the care exercised by Plaintiffs' surgeons. The Exactech Defendants deny the remaining allegations contained in Paragraph 757 of the Complaint.

758. As a direct and proximate result of Exactech's fraud, Plaintiffs received Exactech's Hip, Knee, and Ankle Devices, which subsequently failed.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 758 of the Complaint.

759. As a direct and proximate result of Exactech's fraud, and the failure of Exactech's Devices, Plaintiffs suffered serious physical injury, harm, damages, and economic loss, and will continue to suffer such harm, damages, and economic loss in the future.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 759 of the Complaint.

760. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 760 of the Complaint.

NINTH CAUSE OF ACTION:
FRAUDULENT CONCEALMENT
(Against Exactech Defendants and TPG Defendants[19])

761. Plaintiffs hereby incorporate by reference as if fully set forth herein, the factual allegations set forth in paragraphs 1 to 634 and further allege as follows.

ANSWER: The Exactech Defendants incorporate by reference their Answers to Paragraphs 1 through 760 above as their answer to this paragraph, as it fully set forth herein.

762. Prior to the initial surgeries in which Plaintiffs' Exactech Hip, Knee, and Ankle 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 Plaintiffs by orthopedic surgeons in the United States.

ANSWER: The Exactech Defendants admit that Exactech, Inc. designed, manufactured, marketed, labeled, and participated in the sale of the Devices for implantation into patients by orthopedic surgeons throughout the United States. The Exactech Defendants further admit that Exactech U.S., Inc. participated in the sale of the Devices generally. The Exactech Defendants deny the remaining allegations contained in Paragraph 762 of the Complaint.

[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.

763. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 763 of the Complaint.

764. Exactech knew that such information was not readily available to Plaintiffs or their physicians and that Plaintiffs and their 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.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 764 of the Complaint regarding the reliance of Plaintiffs and Plaintiffs' surgeons. The Exactech Defendants deny the remaining allegations contained in Paragraph 764 of the Complaint.

765. 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.

ANSWER: The Exactech Defendants admit only to those duties imposed upon them by applicable law. The Exactech Defendants deny the remaining allegations contained in Paragraph 765 of the Complaint.

766. Prior to and following Plaintiffs' implant surgeries, Exactech, through its affirmative misrepresentations and omissions, actively and fraudulently concealed from Plaintiffs and Plaintiffs' 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 766 of the Complaint.

767. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 767 of the Complaint.

768. As described above, each of Exactech's acts, fraudulent representations, and omissions about its Hip, Knee, and Ankle Devices was false and misleading.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 768 of the Complaint.

769. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 769 of the Complaint.

770. The facts that Exactech fraudulently concealed, misrepresented, and omitted were material to Plaintiffs' and Plaintiffs' surgeons' decision to use Exactech Devices in their joint replacement surgeries.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 770 of the Complaint regarding what was

material to Plaintiffs and Plaintiffs' surgeons. The Exactech Defendants deny the remaining allegations contained in Paragraph 770 of the Complaint.

771. Indeed, Plaintiffs and Plaintiffs' surgeons relied upon Exactech's fraudulent misrepresentations and omissions in deciding to use an Exactech Device in their joint replacement surgeries.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 771 of the Complaint regarding the reliance of Plaintiffs and Plaintiffs' surgeons. The Exactech Defendants deny the remaining allegations contained in Paragraph 771 of the Complaint.

772. It was not only foreseeable to Exactech, but also intended that patients and physicians, such as Plaintiffs and Plaintiffs' 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 772 of the Complaint.

773. Plaintiffs' surgeons exercised reasonable care in relying upon Exactech's fraudulent representations and omissions in choosing to use Exactech's Devices in Plaintiffs' surgeries.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 773 of the Complaint regarding the care exercised by Plaintiffs' surgeons. The Exactech Defendants deny the remaining allegations contained in Paragraph 773 of the Complaint.

774. Plaintiffs' 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.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 774 of the Complaint regarding the care

exercised by Plaintiffs' surgeons. The Exactech Defendants deny the remaining allegations contained in Paragraph 774 of the Complaint.

775. As a result of Exactech's fraudulent concealment, omissions, and misrepresentations of material facts, Plaintiffs and their healthcare providers were unaware, and could not have reasonably known, learned, or discovered that the Exactech Devices being implanted were defective and unreasonably dangerous.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 775 of the Complaint regarding the knowledge of Plaintiffs and their healthcare providers. The Exactech Defendants deny the remaining allegations contained in Paragraph 775 of the Complaint.

776. Moreover, as a result of Exactech's fraudulent concealment, omissions, and misrepresentations, following implantation, 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.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 776 of the Complaint regarding the knowledge of Plaintiffs and their healthcare providers. The Exactech Defendants deny the remaining allegations contained in Paragraph 776 of the Complaint.

777. As a direct and proximate result of Exactech's fraudulent concealment, omissions, and misrepresentations, Plaintiffs received Exactech's Hip, Knee, and Ankle Devices, which subsequently failed.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 777 of the Complaint.

778. As a direct and proximate result of Exactech's fraudulent concealment, omissions, and misrepresentations, and the failure of Exactech's Devices, Plaintiffs suffered serious physical injury, harm, damages, and economic loss, and will continue to suffer such harm, damages, and economic loss in the future.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 778 of the Complaint.

779. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 779 of the Complaint.

TENTH CAUSE OF ACTION:
PUNITIVE DAMAGES
(Against Exactech Defendants and TPG Defendants[20])

780. Plaintiffs hereby incorporate by reference as if fully set forth herein, the factual allegations set forth in paragraphs 1 to 634 and further allege as follows.

ANSWER: The Exactech Defendants incorporate by reference their answers to Paragraphs 1 through 779 above as their answer to this paragraph, as if fully set forth herein.

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. 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;

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.

[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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 781 of the Complaint, including each subpart.

782. As a direct and proximate cause of these actions and the actions further described above that were intentional, malicious, reckless, wanton, fraudulent, beyond all standards of decency, and without regard for human life or Plaintiffs' rights, Plaintiffs were implanted with Exactech Hip, Knee, and Ankle Devices that failed causing Plaintiffs to suffer serious physical injury, harm, damages, and economic loss, and Plaintiffs will continue to suffer such harm, damages, and economic loss in the future.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 782 of the Complaint.

783. Plaintiffs are thus entitled to punitive damages.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 783 of the Complaint.

784. Plaintiffs demand judgment against Defendants and request punitive damages and all other such relief as the Court deems equitable and just.

ANSWER: Paragraph 784 of the Complaint contains rhetorical statements that are not allegations against the Exactech Defendants to which response is required. To the extent Paragraph 784 can be construed as containing allegations against the Exactech Defendants requiring a response, the Exactech Defendants admit that Plaintiffs demand judgment and punitive damages. The Exactech Defendants deny the remaining allegations contained in Paragraph 784 of the Complaint.

ELEVENTH CAUSE OF ACTION: LOSS OF CONSORTIUM

(Against Exactech Defendants and TPG Defendants[21])

785. Plaintiffs hereby incorporate by reference as if fully set forth herein, the factual allegations set forth in paragraphs 1 to 634 and further allege as follows.

[21] 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.

ANSWER: The Exactech Defendants incorporate by reference their Answers to Paragraphs 1 through 784 above as their answer to this paragraph, as if fully set forth herein.

786. At all relevant times, Plaintiffs had spouses and/or family members (collectively referred to as "Loss of Consortium Plaintiffs") who suffered injuries and losses as a result of Plaintiffs' injuries.

ANSWER: The Exactech Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 786 of the Complaint and therefore deny them.

787. As a direct and proximate cause of Exactech's previously described actions, misrepresentations, and omissions and the failure of the Exactech Devices implanted into Plaintiffs, 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 787 of the Complaint.

788. As a direct and proximate cause of Exactech's previously described actions, misrepresentations, and omissions, and the failure of the Exactech Devices implanted into Plaintiffs, Loss of Consortium Plaintiffs have suffered and will continue to suffer great emotional pain, distress, and mental anguish.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 788 of the Complaint.

789. As a direct and proximate result of Exactech's previously described actions, misrepresentations, and omissions, and the failure of the Exactech Devices implanted into Plaintiffs, Loss of Consortium Plaintiffs have suffered and will continue suffer to injuries, damages, and economic loss in the future.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 789 of the Complaint.

790. 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.

ANSWER: The Exactech Defendants deny the allegations contained in Paragraph 790 of the Complaint.

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;

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.

ANSWER TO PRAYER FOR RELIEF

WHEREFORE, the Exactech Defendants deny that Plaintiffs are entitled to any relief from the Exactech Defendants based on the matters alleged in the Complaint. The Exactech Defendants demand judgment in their favor, the dismissal of the Complaint with prejudice, costs of suit, and all other relief, legal and equitable, to which they are entitled.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury.

SEPARATE, ALTERNATE, AND AFFIRMATIVE DEFENSES

Without assuming any burden they would not otherwise bear, the Exactech Defendants assert for their separate, alternative, and affirmative defenses:

FIRST DEFENSE

The Exactech Defendants state that Exactech U.S., Inc. may not be a proper party.

SECOND DEFENSE

The Court lacks personal jurisdiction over one or more of the Exactech Defendants.

THIRD DEFENSE

The Court lacks subject matter jurisdiction over the claims.

FOURTH DEFENSE

The Complaint fails to state, in whole or in part, a claim upon which relief may be granted.

FIFTH DEFENSE

The Exactech Defendants dispute the venue of certain transferee courts, and thereby, preserve their right to object to venue, and choice of law, as it becomes necessary.

SIXTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the applicable statutes of limitations and/or repose.

SEVENTH DEFENSE

Plaintiffs' claims are barred because Plaintiffs were advised of the risks associated with the matters alleged in the Complaint and knowingly and voluntarily assumed them. Under the doctrine of assumption of the risk, informed consent, release, waiver, or comparative fault, this conduct bars, in whole or in part, the damages that Plaintiffs seek to recover herein.

EIGHTH DEFENSE

Plaintiffs' claims are barred because the injuries allegedly sustained by Plaintiffs were not proximately caused by any act or omission of the Exactech Defendants.

NINTH DEFENSE

If Plaintiffs have sustained injuries or incurred expenses as alleged, their injuries or expenses were the result of intervening and/or superseding causes, and not as a result of the acts or omissions of the Exactech Defendants.

TENTH DEFENSE

Plaintiffs' recovery, if any, should be diminished, reduced, offset, or barred pursuant to the comparative and/or contributory negligence, fault, responsibility, or actions, omissions or causation of others, including but not limited to Plaintiffs.

ELEVENTH DEFENSE

In the event that it is determined that Plaintiffs are entitled to recover against the Exactech Defendants, Plaintiffs' recovery, if not barred, should be reduced in proportion to the degree or percentage of negligence, fault, or exposure to products attributable to Plaintiffs or others, including any party immune because bankruptcy renders them immune from further litigation, as well as any party, co-defendant, or non-parties with whom Plaintiffs have settled or may settle in the future.

TWELFTH DEFENSE

Plaintiffs' claims are barred to the extent that the injuries alleged in the Complaint were caused by the misuse, abnormal use, or use of the Device in a manner not intended by the Exactech Defendants and over which the Exactech Defendants had no control.

THIRTEENTH DEFENSE

If Plaintiffs have sustained injuries or incurred expenses as alleged, their injuries or expenses were caused in whole or in part by the conduct of one or more persons or entities for whose conduct the Exactech Defendants were not responsible and with whom the Exactech Defendants have no legal connection.

FOURTEENTH DEFENSE

The alleged injuries and damages, if any, were the result of unavoidable circumstances that could not have been prevented by any person, including the Exactech Defendants.

FIFTEENTH DEFENSE

If Plaintiffs sustained injuries or incurred expenses as alleged, the injuries and/or expenses may have resulted from the pre-existing and/or unrelated medical conditions, injuries or illnesses of Plaintiffs.

SIXTEENTH DEFENSE

Plaintiffs' alleged injuries and damages, if any, were caused directly, solely, and proximately by sensitivities, medical conditions, and idiosyncrasies peculiar to Plaintiffs, not found in the general public, which were unknown, unknowable, or not reasonably foreseeable to the Exactech Defendants.

SEVENTEENTH DEFENSE

Plaintiffs' alleged damages should be barred or reduced due to failure to mitigate or avoid the alleged injuries and damages.

EIGHTEENTH DEFENSE

Plaintiffs' claims are barred by the equitable and/or legal doctrines of laches, waiver, estoppel, and/or statutory and regulatory compliance.

NINETEENTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the doctrines of merger, bar, collateral estoppel, res judicata, release, discharge, and accord and satisfaction.

TWENTIETH DEFENSE

The Exactech Defendants aver that they did not participate in, authorize, ratify, or benefit from the alleged misrepresentations or wrongful acts that are asserted in the Complaint.

TWENTY-FIRST DEFENSE

The Device is a prescription medical device that is reasonably safe because reasonable health care providers prescribe the Device for a class of patients, knowing the Device's foreseeable risks and therapeutic benefits.

TWENTY- SECOND DEFENSE

The Device is neither defective nor unreasonably dangerous because it falls within Comment k to Section 402A of the Restatement (Second) of Torts, and applicable state law interpreting, upholding, and applying those principles, and, thus, is excepted from claims of strict liability.

TWENTY- THIRD DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the principles set forth in the Restatement (Second) of Torts Section 402A, Comments k and j, and applicable state law interpreting, upholding, and applying those principles.

TWENTY- FOURTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the principles set forth in the Restatement (Third) of Torts: Product Liability, including but not limited to Section 4, Section 6 (including but not limited to Sections 6(c), 6(d), and comment f) and Section 19, and the comments thereto, and applicable state law interpreting, upholding, and applying those principles.

TWENTY- FIFTH DEFENSE

The learned intermediary doctrine bars Plaintiffs' claims. Plaintiffs have no cause of action based on an alleged failure to warn, as the Exactech Defendants' only duty is to warn physicians, who act as learned intermediaries between a product-device manufacturer and a patient. Further, the Exactech Defendants provided adequate and complete warnings to treating physicians. Accordingly, Plaintiffs' claims are barred, in whole or in part, by the learned intermediary and/or sophisticated user doctrine and/or principles to Section 388 of the Restatement (Second) of Torts.

TWENTY- SIXTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the principles set forth in the Restatement (Second) of Torts Section 388, Comment n and/or similar doctrines and principles contained in the Restatement (Third) of Torts: Products Liability, and applicable state law interpreting, upholding, and applying those principles.

TWENTY- SEVENTH DEFENSE

Plaintiffs cannot recover under the Complaint because the Exactech Defendants complied with all applicable codes, standards, regulations, or specifications established, adopted, promulgated, or approved by the United States, all fifty states and/or any territories of the United States, or by an agency of the United States or any state or territory, as well as non-governmental industry standards.

TWENTY- EIGHTH DEFENSE

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of the Device.

TWENTY- NINTH DEFENSE

Plaintiffs cannot show that any reasonable alternative design would have rendered the Device to be safer overall under the Restatement (Third) of Product Liability § 2, cmt. F, and applicable state law interpreting, upholding, and applying those principles, nor could the Exactech Defendants have known of any alternative design that may be identified by Plaintiffs.

THIRTIETH DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the lack of a defect, as the Device was manufactured and sold in accordance with the applicable standard of care.

THIRTY-FIRST DEFENSE

Plaintiffs' product liability causes of action are barred because the benefits of the Device outweighed its risks and/or the device met the consumer expectations test, as applicable.

THIRTY- SECOND DEFENSE

Plaintiffs' claims are barred because, based on the state of scientific, medical, and technical knowledge at the time the Device was marketed, the Device was reasonably safe for its normal and foreseeable uses at all times, it was not unreasonably dangerous or defective, and its benefits exceeded any associated risks.

THIRTY- THIRD DEFENSE

Plaintiffs' claims are barred because the methods, standards, and techniques utilized by the Exactech Defendants in manufacturing, distributing, marketing, and labeling the Device and in issuing warnings and instructions with respect to its use, conformed with the generally recognized, reasonably available, and reliable state of the art and knowledge and industry standards at the time Device was manufactured and distributed.

THIRTY- FOURTH DEFENSE

The Device(s) are prescription medical products that are neither defective nor unreasonably dangerous, which are reasonably suitable and reasonably safe for their intended use, and the warnings and instructions accompanying them at the time of the occurrence of the injuries alleged by Plaintiffs were legally adequate.

THIRTY- FIFTH DEFENSE

Plaintiffs' recovery is barred because the Device was in conformity with the generally recognized state of the art at the time it was designed, manufactured, packaged and labeled.

THIRTY- SIXTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, because the Exactech Defendants did not owe any legal duty to Plaintiffs, or, if the Exactech Defendants owed any such legal duty, the Exactech Defendants did not breach that duty.

THIRTY- SEVENTH DEFENSE

The Exactech Defendants had no duty to warn about any possible risks of the Device that were not known at the time of the Device's manufacture and sale.

THIRTY- EIGHTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, because the Exactech Defendants acted reasonably and in good faith at all material times, based on all relevant facts and circumstances known by the Exactech Defendants at the time they allegedly acted or failed to act.

THIRTY- NINTH DEFENSE

If there was any defect in the Device—and the Exactech Defendants deny that there was any defect—there was no causal connection between any alleged defect and the Device on the one hand and any injury or damage to Plaintiffs on the other, if any, with the result that Plaintiffs are not entitled to recover against the Exactech Defendants in this case.

FORTIETH DEFENSE

The Exactech Defendants' conduct, as well as the Device, conformed with the Federal Food, Drug and Cosmetic Act and the requirements of the Food and Drug Administration, and all state and federal statutes, regulations, and industry standards based upon the state of knowledge existing at the relevant time alleged in the Complaint.

FORTY-FIRST DEFENSE

Plaintiffs' claims may be barred, in whole or in part, by the doctrine of federal preemption.

FORTY- SECOND DEFENSE

In particular, but without limiting the Exactech Defendants' other preemption defenses, Plaintiffs' claims are barred by the doctrine of implied preemption to the extent that they are premised on alleged misrepresentations or misstatements to the FDA or violations of FDA regulations without state law counterparts. *See Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001).

FORTY- THIRD DEFENSE

The conduct of the Exactech Defendants and all activities with respect to the Device have been and are under the supervision of the Federal Food and Drug Administration ("FDA"). Accordingly, this action, including any claims for monetary and/or injunctive relief, is barred by the doctrine of primary jurisdiction and exhaustion of administrative remedies.

FORTY- FOURTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, because the promotion of the products at issue is protected by the First Amendment of the United States Constitution and similar provisions in applicable State constitutions.

FORTY- FIFTH DEFENSE

To the extent the claims asserted in the Complaint are based on a theory providing for liability without proof of causation, the claims violate the Exactech Defendants' rights under the Constitution of the United States and analogous provisions of the applicable states' constitutions.

FORTY- SIXTH DEFENSE

Should the Exactech Defendants be held liable to Plaintiffs, which liability is specifically denied, the Exactech Defendants would be entitled to a set-off for the total of all amounts paid to Plaintiffs from all collateral sources. The Exactech Defendants are entitled to a set-off from any recovery by Plaintiffs to the extent of the value of benefits paid or payable to or on behalf of Plaintiffs from any collateral source.

FORTY- SEVENTH DEFENSE

Notwithstanding Plaintiffs' claims and contentions, Plaintiffs received all or substantially all of the benefit from the Device that Plaintiffs hoped and intended to receive, and, to that extent, any damages and/or restitution that Plaintiffs might be entitled to recover from the Exactech Defendants must be correspondingly reduced.

FORTY- EIGHTH DEFENSE

To the extent Plaintiffs are required to plead claims with sufficient particularity and/or specificity to satisfy the requirements of Fed. R. Civ. 9, and any other applicable state requirement, Plaintiffs have failed to do so and Plaintiffs' claims must be dismissed.

FORTY- NINTH DEFENSE

The Exactech Defendants have no legal relationship or privity with Plaintiffs and owe no duty to Plaintiffs by which liability could be attributed to them.

FIFTIETH DEFENSE

Plaintiffs' warranty-based claims are barred, in whole or in part, by Plaintiffs' lack of reliance on any such alleged warranties.

FIFTY-FIRST DEFENSE

Plaintiffs' warranty-based claims are barred, in whole or in part, by Plaintiffs' failure to provide adequate notice or to satisfy all conditions precedent or subsequent to the enforcement of any such alleged warranties.

FIFTY- SECOND DEFENSE

The cause of the alleged physical harm was due to a modification or alteration of the Device made after the Device's delivery to the initial user or consumer and the modification or alteration was not reasonably foreseeable to the Exactech Defendants.

FIFTY- THIRD DEFENSE

Plaintiffs' claims are barred to the extent that the injuries alleged in the Complaint were caused by a substantial change in the Device after leaving the possession, custody, and control of the Exactech Defendants.

FIFTY- FOURTH DEFENSE

If there was any defect in the Device—and the Exactech Defendants deny that there were any defects—to the extent Plaintiffs, and/or other defendants, and/or third parties for whom or which the Exactech Defendants were not responsible, failed to observe any obvious defective conditions in any products, Plaintiffs' recovery against the Exactech Defendants is barred or must be reduced.

FIFTY- FIFTH DEFENSE

Plaintiffs' causes of action are barred because a reasonable purchaser and/or consumer would have been aware of the alleged risks of the Device.

FIFTY- SIXTH DEFENSE

No act or omission of the Exactech Defendants was malicious, willful, wanton, reckless, grossly negligent or intentional and, therefore, any award of punitive damages is barred.

FIFTY- SEVENTH DEFENSE

Plaintiffs' claims for punitive damages are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the

Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution. Any law, statute or other authority purporting to permit the recovery of punitive damages is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) unconstitutionally may permit recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiffs; (4) unconstitutionally may permit recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiffs and to the amount of compensatory damages, if any; (5) unconstitutionally may permit jury consideration of net worth or other financial information relating to the Exactech Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages award; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1, 111 S. Ct. 1032 (1991); *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443, 113 S. Ct. 2711 (1993); *BMW of North America, Inc. v. Gore*, 517 U.S. 559, 116 S. Ct. 1589 (1996); and *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 123 S. Ct. 1513 (2003).

FIFTY- EIGHTH DEFENSE

The Exactech Defendants adopt the terms of any applicable legislative act or court decision in any State or Commonwealth of the United States which now or hereafter precludes punitive damages or limits the amount of punitive damages that can be recovered in an action at law.

FIFTY- NINTH DEFENSE

Plaintiffs' claims are barred, reduced and/or limited pursuant to applicable statutory and common law regarding limitations of awards, caps on recovery and set-offs.

SIXTIETH DEFENSE

Plaintiffs' claims are barred, in whole or in part, due to the doctrine of spoliation and any failure to properly preserve evidence necessary to the determination of the alleged claims against the Exactech Defendants.

SIXTY-FIRST DEFENSE

Any claims Plaintiffs may make for equitable relief are barred because Plaintiffs have an adequate remedy at law.

SIXTY- SECOND DEFENSE

Plaintiffs fail to allege facts or state a cause of action against the Exactech Defendants sufficient to support a claim for attorneys' fees and/or legal costs.

SIXTY- THIRD DEFENSE

Plaintiffs lack standing because the Exactech Defendants did not engage in deceptive conduct with regard to Plaintiffs or otherwise.

SIXTY- FOURTH DEFENSE

The Exactech Defendants assert all available defenses to individual Plaintiff's claims related to the respective state consumer protection statute, to the extent such a claim is made by an individual Plaintiff adopting the Master Long Form Complaint.

SIXTY- FIFTH DEFENSE

The Exactech Defendants assert all available defenses to individual Plaintiff's claims related to the respective state product liability act or laws, to the extent such a claim is made by an individual Plaintiff adopting the Master Long Form Complaint.

SIXTY- SIXTH DEFENSE

Plaintiffs' claims are barred, in whole or part, because those claims are preempted and/or subsumed by the applicable state specific product-liability related act or laws.

SIXTY- SEVENTH DEFENSE

The Exactech Defendants assert all available defenses to individual Plaintiff's claims related to the respective commercial code or laws, to the extent such a claim is made by an individual Plaintiff adopting the Master Long Form Complaint.

SIXTY- EIGHTH DEFENSE

The Exactech Defendants expressly preserve, and do not knowingly or intentionally waive, any of the other affirmative defenses set forth in Fed. R. Civ. P. 8, or any applicable state law, which discovery may reveal to be applicable.

SIXTY-NINTH DEFENSE

The Exactech Defendants are entitled to the benefit of all defenses and presumptions contained in, or arising from, any rule of law or statute of any state whose substantive law controls the action.

RESERVATION OF DEFENSES

The Exactech Defendants hereby give notice that they intend to rely upon such other affirmative defenses as may become available or apparent during the course of investigation, discovery, or trial, and the Exactech Defendants reserve the right to amend their Answer to assert such other defenses to which it may be entitled. Upon request and after having completed discovery in this case, the Exactech Defendants may voluntarily withdraw defenses that prove to be unsupportable by the facts revealed in the pre-trial discovery and investigation or which the Exactech Defendants choose not to pursue. The Exactech Defendants hereby reserve the right to amend their Answer to assert any other defenses, affirmative or otherwise, that may become available during discovery proceedings in this case. *See* Case Management Order No. 1, Doc. 87.

JURY DEMAND

The Exactech Defendants pray for trial by jury of this matter.

WHEREFORE, the Exactech Defendants pray for relief and judgment against Plaintiffs as follows:

1. That Plaintiffs take nothing by reason of the Complaint;
2. That this action be dismissed with prejudice;
3. That the Exactech Defendants recover their fees, costs, and attorneys' fees incurred herein; and
4. Such further and other relief as the Court deems proper.

Dated: April 21, 2023

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on April 21, 2023, a true and correct copy of the foregoing Exactech Defendants' Master Long Form Answer and Additional Defenses was filed electronically. Parties may access this filing through the Court's electronic filing system.

/s/ Michael J. Kanute
Michael J. Kanute