Exhibit A

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Case No. 2026-0129-MTZ

IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

ELLEN K. REISMAN, TRUSTEE, on behalf of the Exactech Settlement Trust, a Delaware Trust, Plaintiff, v. TPG, INC., TPG PARTNERS VII L.P., TPG VII MANAGEMENT, LLC, TPG VII OSTEON HOLDINGS, L.P., TPG OPERATIONS, LLC, TPG HOLDINGS II SUB, LP, TPG CAPITAL – FO, LLC, JEFFREY BINDER, KENDALL GARRISON, JOHN SCHILLING, TODD SISITSKY, MICHAEL TEPATTI, BENNETT YASSKIN, WILLIAM PETTY, DAVID PETTY, and JOHN LIN, Defendants.	C.A. No. 2026-0129-MTZ PUBLIC VERSION February 5, 2026

VERIFIED COMPLAINT

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Dated: January 30, 2026

HOGAN♦McDANIEL

Daniel K. Hogan (#2814)
1311 Delaware Avenue
Wilmington, Delaware 19806
Telephone: (302) 656-7540
Email: dkhogan@dkhogan.com

Counsel to Ellen K. Reisman, Trustee, on behalf of the Exactech Settlement Trust, a Delaware Trust

A public version of this document will be filed on or before February 5, 2026.

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Ellen K. Reisman, in her capacity as Trustee (the "Trustee" or "Plaintiff") of the Exactech Settlement Trust, a Delaware Trust (the "Trust"), by and through counsel, for her Complaint against defendants TPG, Inc., TPG Partners VII LP, TPG VII Management, LLC, TPG VII Osteon Holdings, L.P., TPG Operations, LLC, TPG Holdings II Sub, LP, TPG Capital – FO, LLC (collectively, "TPG" or the "TPG Defendants"), and Jeffrey Binder, Kendall Garrison, John Schilling, Todd Sisitsky, Michael Tepatti, Bennett Yasskin, John Lin, Dr. William Petty, David Petty, and other individuals and/or entities the Trust may add as defendants as the Trust's investigation continues (collectively, the "Individual Defendants," and collectively with the TPG Defendants, the "Defendants") alleges as follows:

NATURE OF ACTION

1. This case arises from a scheme by TPG and the Individual Defendants to avoid billion-dollar liability for the systemic failures of the medical implant devices of Exactech, Inc. ("Exactech" or the "Company"), and the harm those defective devices have caused thousands of Exactech's patients. In February 2018, Defendant TPG, a global alternate asset manager with nearly $300 billion in assets currently under management, acquired and took full control of Exactech (the "TPG Acquisition"). Defendant TPG populated the Company's Board of Directors with TPG partners and loyalists, and through this domination and control perpetuated and materially expanded Exactech's pre-existing scheme to hide defects, in order to

preserve Defendant TPG's investment in Exactech. But as scrutiny of the Company by the U.S. Food and Drug Administration ("FDA") increased, and thousands of personal injury lawsuits were filed against the Company and TPG, Defendant TPG saw no viable path to a recovery of its investment and instead desperately focused on avoiding its own billion-dollar liability. In late October 2024, cognizant of its massive liability, Defendant TPG forced Exactech into bankruptcy (in order to attempt to secure a cheap release), and try to conceal the veil piercing/alter ego and other liability of TPG and liability of its affiliates. During the bankruptcy, TPG attempted to use a handpicked "Special Committee" to negotiate a cheap bankruptcy-approved release to extinguish TPG's liability for the damages suffered by the severely injured tort victims. When TPG's efforts to secure this bogus settlement and release failed in June 2025, the unreleased liability claims against Defendants were instead assigned to the Trust, which is pursuing these claims in this action.

2. TPG's scheme to escape liability related to the Company's defective products dates back to February 2018. When problems arose with various of the Company's devices implanted in patients (resulting in device failure that required "revision" surgery to replace defective devices and repair—or attempt to repair—the often-significant damage done to patients), the Company, led pre-TPG by

Defendants William Petty and David Petty and post-acquisition run by TPG, would claim—falsely—that the fault was either with the physician's surgical technique or with the patient, steadfastly refusing to acknowledge any responsibility for the defective devices. The Company's management, controlled and dominated post-acquisition by TPG and populated at senior levels post-acquisition by TPG management and/or senior advisors, never told doctors and patients who reported premature device failures to Exactech that similar problems were being reported by other doctors and patients, thus concealing the true (and increasing) extent of reported revision surgeries involving Exactech's devices. By contrast, the Exactech product flaws ignored by the Company publicly were openly acknowledged in internal discussions, including among TPG and the Individual Defendants, where they became an increasing cause for concern.

3. Despite learning of material irregularities and deficiencies in Exactech's operations through its pre-acquisition due diligence, TPG disregarded the multiple red flags and moved forward with its acquisition of Exactech. To protect its investment, TPG first ensured its day-to-day operational control over Exactech by installing one of its senior advisors, Individual Defendant Jeffrey R. Binder ("Mr. Binder"), as "Co-Executive Chairman" of Exactech. Upon the TPG Acquisition, Mr. Binder exercised operational control over Exactech, becoming the sole

Executive Chairman in 2020 and, for a period of time, the CEO of Exactech. However, Mr. Binder remained a senior advisor to TPG (as confirmed by an express provision in his employment agreement) throughout his work for Exactech, and his loyalty was first and foremost to TPG. In return, TPG paid him a $1 million bonus in connection with the TPG Acquisition of Exactech.

4. Notwithstanding holding various positions at Exactech, Mr. Binder reported directly to senior TPG personnel, at least three of whom (Individual Defendants Mr. Garrison, Mr. Sisitsky, and Mr. Schilling) joined him as members of the Exactech Board of Directors ("Exactech Board") and of the Board of Exactech's parent, Osteon Holdings, Inc. Within months of the TPG Acquisition cementing his role as the key "on-site" protector of TPG's investment in Exactech, Mr. Binder was alerted to substantial defects in Exactech's products, including premature wear of Exactech's polyethylene inserts in its hip and knee products. Rather than acting in the Company's best interest, by complying with industry standards and regulations, Mr. Binder along with other TPG Defendants sought to bury prompt disclosure at all costs, which contributed to the continued implantation into patients of Exactech's defective polyethylene and exacerbated liability.

5. TPG exercised full control and domination over Exactech from the time of the TPG Acquisition. At the time of the TPG Acquisition, TPG created "a host

of wholly owned subsidiaries" in an attempt to insulate TPG from liability for any acts or omissions by Exactech.[1] Despite this effort to cosmetically distance TPG from Exactech on paper, TPG quickly disregarded any guise of corporate separateness and instead exerted direct control of Exactech from the top down. TPG's full control and domination over Exactech was effectuated through, *inter alia*, complete control of Exactech's parent, Osteon Holdings, Inc., and a takeover of the Exactech Board—TPG installed four (4) TPG partners and/or senior advisors to serve on the six-person Exactech Board and Board subcommittees (each, a "Board Committee"). TPG further appointed its own personnel or advisors in key management positions at Exactech, including the Chief Executive Officer (Mr. Binder), Chief Financial Officer (Mr. Bolukbasi), and VP of Business Development (Mr. Hann). Other TPG personnel regularly attended Exactech Board and Board Committee meetings, further erasing any appearance of corporate separateness between Exactech and TPG. Through such complete dominion over Exactech's leadership, TPG exercised tight control over Exactech's day-to-day affairs at every level.

6. Once TPG took control and ownership of Exactech—and despite the fact that TPG's employees and advisors, including Mr. Binder and TPG's Exactech

[1] Such subsidiaries included Osteon Holdings, Inc., Osteon Intermediate Holdings I, Inc., and Osteon Intermediate Holdings II, Inc.

Board designees, became fully aware of Exactech's pre-TPG Acquisition scheme—TPG employees and advisors became not only active participants in efforts to delay public disclosure of the scheme, but doubled down on and directed key aspects of the scheme, and even materially expanded the scheme as part of a concerted effort to protect TPG's investment in Exactech until TPG could arrange for an exit from its investment and/or a potential release for its billion dollar liability.

7. Mr. Binder, for his part, participated in and encouraged—and at critical times closely directed and coordinated—the continuation of the fraudulent scheme to delay or minimize any recall of Exactech's devices and protect TPG's investment. For example, in late 2018, Mr. Binder directed Exactech in its efforts to attempt to prevent the Hospital for Special Surgery ("HSS"), the leading orthopedic surgical hospital in the United States (and Exactech's largest institutional customer), from publicly disclosing the rising incidents of increased oxidation and delamination of polyethylene components related to Exactech knee devices.

8. [redacted]

who had performed many surgeries with Exactech devices and had been a keynote speaker at Exactech's national sales conferences in 2013 and 2014, that [redacted] had tried, without success for over two years to persuade Exactech to recall

Exactech's defective Optetrak Logic Total Knee Arthroplasty ("TKA") device (or take it off the market).

9. Instead of investigating [redacted] explicit warnings, Mr. Binder ignored them and doubled down on the scheme to imply that [redacted] experience with Exactech device problems was atypical. Mr Binder later, along with Defendant John Schilling, [redacted] in an effort to deflect FDA investigation into such complaints. TPG (via Mr. Binder and other TPG representatives) abused its control of Exactech by causing Exactech management to delay any real investigation into the root cause of the issues raised by [redacted], to mislead the surgeon as to Exactech's efforts, and, ultimately, to be dismissive of [redacted] complaints before the FDA. As alleged herein, others at TPG, such as Defendant Schilling, a senior TPG officer who was designated by TPG as an Exactech Board member, actively contributed to TPG's and Mr. Binder's efforts to be dismissive of [redacted] complaints before the FDA. [redacted]

10. By mid-2021, when, according to TPG, the packaging non-conformity was "discovered" confirming that numerous of Exactech's polyethylene implants had been sold without an EVOH or oxidation resistant barrier, TPG, primarily

through Defendants Mr. Binder and Mr. Schilling (assisted by others from TPG), carefully orchestrated and micro-managed all of Exactech's responses to the FDA. Instead of prioritizing patient safety, Mr. Binder and Mr. Schilling and others at TPG designed Exactech's recall strategy to allow Exactech to continue to sell defective products and delay a more expansive recall as long as possible, to protect TPG's investment, exacerbating the harm to patients. To that end, TPG (primarily through Mr. Binder, Mr. Schilling and other TPG Individual Defendants) directed Exactech to resist the FDA's efforts to expand Exactech's recall of certain of its joint replacement devices after the FDA rejected Exactech's limited recall strategy. Critically, TPG and its advisors controlled every step of Exactech's response, displacing Exactech management in making all critical decisions in what to tell, and not tell, the FDA, even drafting documents on TPG's own word processing system and leading interactions with the FDA. During this period, TPG, Mr. Binder, and Mr. Schilling directed Exactech to make numerous misrepresentations to the FDA, surgeons, and patients, all while withholding critical information through a series of dilatory recalls that were misleading or incomplete. This conduct continued until, as alleged herein, the FDA forced the Company to make various corrective disclosures and recall all its polyethylene inserts packaged in non-EVOH bags regardless of shelf-life.

11. In October 2022, an order was issued consolidating all federal product liability lawsuits against the Company into a multidistrict litigation in the Eastern District of New York (the "MDL Court"), *In re: Exactech Polyethylene Orthopedic Products Liability Action, MDL No. 3044*, Case No. 1:22-md-03044 (the "MDL"). TPG had been named as a defendant along with Exactech in several pre-MDL lawsuits and would be named in the master complaint in the MDL on a veil piercing theory. [redacted]

[2] The Trustee discovered, after its recent receipt of documents required under Exactech's bankruptcy Plan to be turned over to the Trustee, the following: [redacted], even though, as Bankruptcy Judge Silverstein later held in the Exactech bankruptcy, "Exactech and TPG are and always have been adverse as to [alter ego and veil piercing] claims." *Exactech, Inc., et al.*, Case No. 24-12441 (D. Del. Bankruptcy Ct. May 20, 2025) (Dkt. 1183). The MDL docket reflects that in early March 2023, Kirkland & Ellis formally appeared on behalf of TPG and promptly sought dismissal of the veil piercing/alter ego claims against TPG (and against Osteon Holdings and Osteon II, which TPG counsel identified collectively as "TPG"), [redacted]

[redacted]

[redacted] TPG also would conceal various other material facts from the MDL Court as set forth below, including TPG's actual role in orchestrating delays and disinformation in the recall efforts and the actual facts as to its domination and control of Exactech.

12. Furthermore, in 2022, a collective proceeding was duly authorized in the Circuit Court of the Eighth Judicial Circuit in and for Alachua County, Florida (the "Florida Master Case," together with the MDL and other non-consolidated product liability actions concerning Exactech's defective products, collectively, the "Product Liability Litigation" or "Product Liability Actions," and together with the [redacted] discussed herein, the "Litigation" or "Lawsuits").

13. Exactech's tort victims, including the approximately 2,600 plaintiffs who filed lawsuits based on the Company's defective products, have suffered severe and life-altering injuries as a result of having Exactech devices implanted in their bodies. When the defective replacement components at issue fail, patients can suffer a myriad of injuries including osteolysis (an immunologic adverse bodily reaction

[redacted]

of bone degeneration (bone resorption) where bone is destroyed as a part of a pathological response to inflammation), implant loosening, adverse local tissue reaction, infection, excessive fluid buildup causing debilitating swelling, incapacitating pain, loss of function, and other disabling complications necessitating one or numerous revision surgeries, even amputation or death. The longer these defective components remain in a patient's body, the more harm a patient suffers. Revision surgery to replace the defective device is more complicated than the initial or primary surgery, since there is often scar tissue that must be cleaned out, synovitis (inflammation of the joint lining), the implant must be removed (and replaced) and extreme care must be taken to preserve soft tissue around the knee, among other surgical risks.

14. When there is loss of bone caused by the body's inflammatory response to the defective device debris, additional augment components such as cones and hinges often must be used since there is not sufficient bone available to which the revision implant can attach. If a patient needs a re-revision with those augments, they are at great risk of fracture and not having a functional knee thereafter.

15. Many of Exactech's knee implants have prematurely failed due to multiple defects. These defects include severe oxidation of the polyethylene and loosening (or even severance) of components in the patient's body. The defects

caused material undisclosed risks to thousands of patients implanted with defective devices. The defective products at issue caused permanent destruction of the hip, knee, and ankle bone and muscular structure, permanent alteration of gait, loss of limb, and have even caused death due to complications associated with revision or corrective surgery.

16. **Numerous patients have endured multiple revision surgeries as a direct consequence of TPG improperly delaying corrective action. Of note, claims data from the Product Liability Litigation suggests most revisions have occurred since the TPG Acquisition**. **Tragically, patients who had revision surgeries prior to the recalls were often revised with equally defective Exactech products that were subsequently recalled.** Moreover, many revisions that were performed after the TPG Acquisition used defective revision components for those patients who received replacements of poly liners also known as "poly swap." Some revisions had to be re-revised due to the failure of the revision polyethylene component. Revisions can result in devastating outcomes. For some patients, multiple revision surgeries performed on the same knee or hip caused such irreversible bone loss that any further surgical intervention became impossible. **Due to Defendants' misconduct, as alleged herein, thousands of patients were**

harmed by defective devices that could have been avoided had Exactech's devices not been used.

17. TPG turned to bankruptcy to attempt to evade accountability for the harm caused to thousands under TPG's watch [redacted] On October 29, 2024 (the "Bankruptcy Petition Date"), Exactech commenced a voluntary case under chapter 11 of title 11 of the United States Code in the United States Bankruptcy Court for the District of Delaware. *See In re Exactech, Inc. et. al*, Case No. 24-12441 (LSS) (Bankr. D. Del.) (2024) ("Bankruptcy Case" and together with the jointly administered chapter 11 cases of certain of Exactech's affiliates described below, the "Bankruptcy Cases"). In addition to Exactech, four affiliate entities—three of which are shell companies (created by or at the direction of TPG) in the corporate chain between Exactech and TPG and one of which is a wholly owned subsidiary of Exactech—also commenced voluntary chapter 11 cases on the Bankruptcy Petition Date. The Exactech affiliates included Exactech's direct parent, Osteon Intermediate Holdings II, Inc. ("Osteon Intermediate II"); Osteon Intermediate II's direct parent, Osteon Intermediate Holdings I, Inc. ("Osteon Intermediate I"); Osteon Intermediate I's direct parent, Osteon Holdings, Inc. ("Osteon Holdings"); and XpandOrtho, Inc., a wholly owned

subsidiary of Exactech ("XpandOrtho" and collectively with Exactech, Osteon Intermediate II, Osteon Intermediate I, and Osteon Holdings, the "Debtors" or the "Exactech Entities"). Notably, underscoring TPG's control of the Exactech Entities, in the MDL in each of TPG's filings, TPG collectively referred to itself, Osteon Holdings, and Osteon Intermediate II (among other entities) as "TPG," a further indication of the blurred lines between TPG and the Exactech Entities.

18. By the Bankruptcy Petition Date, Exactech faced approximately 2,600 separate lawsuits (in the MDL and Florida state court), which Exactech's Chief Restructuring Officer asserted constituted only 1.7% of the affected patient population in the United States. The first Bellwether hip case in the Florida state court Master Case was scheduled to go to trial in December 2024, with fact and expert discovery having been completed (the Exactech Entities' bankruptcy filing prevented this trial from going forward). Further, the Alabama Qui Tam Action had been moving forward to trial, notwithstanding Exactech's motions to dismiss an Amended Complaint, and for summary judgment, both of which were substantially denied. By then, by Exactech's own admission, [redacted]

[redacted] was one of Exactech's largest individual customers in the United States before he stopped using certain Exactech devices due to surgical failures.

19. In this action, the Trust seeks a determination, *inter alia*, that (i) TPG acted as an alter ego of Osteon Holdings, Inc. and Exactech and that the TPG Defendants (as defined herein) are liable for both the defective product liability of Exactech and its affiliated entities and related misconduct, and for the TPG Defendants' own misconduct, and (ii) the Individual Defendants (as defined herein), *inter alia*, breached their fiduciary duties to the Company as a result of their fraudulent course of conduct including self-dealing and related misconduct, as alleged herein, and, in so doing, harmed many thousands of patients who had the Company's defective medical device products implanted in their bodies. The Trust seeks damages, in an amount to be determined at trial, but no less than $1 billion.

PARTIES AND RELEVANT NON-PARTIES

I. PLAINTIFF

20. The Trustee, on behalf of the Trust, is the Plaintiff. The Trust is a Delaware trust that was established under the *Fifth Amended Joint Chapter 11 Plan of Exactech, Inc. and its Debtor Affiliates Pursuant to Chapter 11 of the Bankruptcy Code*, filed as Docket Item 1647-1 (the "Plan") in the bankruptcy proceedings captioned *In re Exactech, Inc.*, Case No. 24-12441 (LSS) (the "Exactech Bankruptcy") to consolidate and administer the claims of the Trust beneficiaries. The Trust's core purpose is to liquidate direct and indirect personal injury and wrongful death claims and distribute recoveries to Trust beneficiaries, all of whom are eligible holders of such claims, on an equitable basis. Trust beneficiaries include residents of various states, including the States of Delaware, Florida, Texas, Illinois and California. The Trustee, acting as fiduciary and supported by a Trust Advisory Committee, administers the Trust, manages its assets, and has authority to commence, prosecute, and settle related causes of action, including "Estate Causes of Action," as defined in the Plan.

21. The Trust was formed to assume the Debtors' liability for Personal Injury/Wrongful Death or "PI/WD Claims" (as defined in the Plan) and general unsecured claims, to pursue Estate Causes of Action, and to ensure claimants are compensated without resort to direct suits against the reorganized company. The

Trust has inherited the Estate Causes of Action for each of the Debtor entities in the Bankruptcy Cases, including Exactech, Inc. and Osteon Holdings, Inc. For purposes of the Plan, "Estate Causes of Action" are broadly defined to include all rights of action belonging to the Debtors' estates—such as avoidance claims, indemnity, contribution, subrogation, contract and tort claims, defenses, and any statutory or equitable remedies—that vest in the Trust for administration and enforcement. All of the Estate's claims against Defendants and others have been assigned to the Trust.

II. DEFENDANTS

22. Defendant TPG, Inc. ("TPG, Inc.") is a Delaware corporation that is publicly traded on the Nasdaq Stock Market and has its principal place of business at 301 Commerce Street, Suite 3300, Fort Worth, Texas 76102. Defendant TPG was formerly known as TPG Capital, LP and TPG Partners, LLC. In or around December 2021, TPG Partners, LLC converted to TPG, Inc. Defendant TPG, Inc. is a private equity firm that operates as an alternative asset manager, purchasing companies operating in many sectors, including healthcare, and within the broad healthcare sector, the medical device sector. The healthcare sector is one of Defendant TPG, Inc.'s most active sectors, and 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."

23. TPG Partners VII L.P. ("TPG Partners VII") is a Delaware limited partnership that has its principal place of business at 301 Commerce Street, Suite 3300, Fort Worth, Texas 76102. TPG Partners VII L.P. is a fund or alternative investment vehicle of TPG, Inc., which directly funds and controls the Sponsor TPG VII Osteon Holdings, L.P.

24. Defendant TPG VII Osteon Holdings, L.P. ("TPG VII Osteon") is a Delaware limited partnership that has its principal place of business at 301 Commerce Street, Suite 3300, Fort Worth, Texas 76102. Defendant TPG VII Osteon is the Sponsor and controlling shareholder

of Osteon Holdings, Inc.

25. Defendant TPG Operations, LLC ("TPG Operations") is a Delaware limited liability company that has its principal place of business at 301 Commerce Street, Suite 3300, Fort Worth, Texas 76012. Defendant TPG Operations charged Exactech for purported consulting services.

26. Defendant TPG Holdings II Sub, LP ("TPG Holdings II Sub") is a Delaware limited partnership that has its principal place of business at 301 Commerce Street, Suite 3300, Fort Worth, Texas 76012. Defendant TPG Holdings II Sub, LP charged Exactech for purported consulting services.

27. Defendant TPG Capital – FO, LLC ("TPG Capital – FO") is a Delaware limited liability company that has its principal place of business at 301 Commerce Street, Suite 3300, Fort Worth Texas 76012. Defendant TPG Capital – FO charged Exactech for purported consulting services.

28. Defendant TPG VII Management, LLC ("TPG Manager") is a Delaware limited liability company that has its principal place of business at 301 Commerce Street, Suite 3300, Fort Worth, Texas 76102. Defendant TPG Manager acted as Manager under the MSA (as defined herein).

29. Defendant Jeffrey Binder ("Binder"), historically a Co-Executive Chairman (or Executive Chairman) of Exactech and during certain relevant times a Director of Exactech and Osteon Holdings, has served as a Senior Advisor to TPG Capital since 2015. Mr. Binder resides in Austin, Texas. Mr. Binder, with Defendants Messrs. Sisitsky, Schilling, and Garrison, in particular, and others, led the efforts to acquire Exactech, and after the TPG Acquisition, that group, led by Mr. Binder, exercised effective management control over Exactech's operations. From February 2018 to in or about September 2023, Mr. Binder served as Co-Executive Chairman or Executive Chairman of Exactech and Osteon Holdings. According to Mr. Binder, the CEO of Exactech at the time in February 2018 (David Petty) reported initially to Dr. Petty (David Petty's father) and to Mr. Binder during

the period that Mr. Binder was Co-Executive Chairman. Mr. Binder served as "Co-Executive Chairman" with Dr. Petty from February 2018 through 2020, when Dr. Petty stepped down as "Co-Executive Chairman." Thereafter, Mr. Binder served as sole Executive Chairman. Even while Mr. Binder was "Co-Executive Chairman," he exercised primary day-to-day control over Exactech. By August 2019, at the latest, Mr. Binder's day-to-day control of Exactech was such that TPG, in an August 2019 Performance Report, described Mr. Binder as having "direct reporting control of Sales, Large Joints and Extremities BUs, Advanced Tech, & Bus. Dev." The same report confirms: "**Jeff now has day-to-day control of all commercial activities at Exactech**" (emphasis supplied).

30. From March 2022 to in or about March 2023, Mr. Binder served as CEO and Executive Chairman of Exactech, during which all major functions of Exactech continued to report directly to Mr. Binder. While Mr. Binder described this as a "full-time job," he continued serving TPG as a Senior Advisor during the same period he served as either Executive Chairman or CEO, or Director of Exactech. Mr. Binder's primary allegiance at all relevant times was to TPG, and it appears that TPG even used Exactech to get reimbursed for substantial TPG-related expenses that Mr. Binder incurred during the period of Mr. Binder's association with Exactech. After late 2023, Mr. Binder served as a Director of Exactech. Prior to

joining Exactech, Mr. Binder was Chairman of Immucor, Inc., a former TPG portfolio company where he was involved since June 2015. Mr. Binder also served as President and CEO for Biomet, Inc ("Biomet"), a former TPG portfolio company, from February 2007 to June 2015, and as Senior Vice President of Diagnostic Operations of Abbott Laboratories, from January 2006 to February 2007.

31. Mr. Binder has been a Senior Advisor to TPG Global, LLC since June 2015, including during the entire time that Mr. Binder has served as Executive Chairman, Director, and/or CEO of Exactech. Given Mr. Binder's TPG-related roles that he held while also serving as an officer and/or director of Exactech, Mr. Binder was at all times severely conflicted. In his capacity as a Senior Advisor to TPG, Mr. Binder reported to TPG's John Schilling and Todd Sisitsky, both Defendants herein. During Mr. Binder's tenure at Exactech through at least 2022, he remained on the board of directors of Immucor along with Defendants Schilling, Sisitsky, and Garrison, further enmeshing Mr. Binder's interests with TPG and his co-defendants. Mr. Binder's conduct alleged herein, undertaken while he has been either an executive or director of Exactech, at all times was designed to protect the interests of TPG (to which he has maintained primary loyalty), not the best interests of Exactech or those of Exactech's creditors, including thousands of injured plaintiffs; therefore, Mr. Binder consistently has been in material breach of his duties owed to

Exactech and Osteon Holdings. Mr. Binder also has acted, at all relevant times since 2015, as an agent for TPG and his knowledge and conduct alleged herein must be imputed to TPG.

32. Defendant Todd Sisitsky ("Sisitsky") was at all relevant times a member of the Exactech and Osteon Holdings Board and also served as President and Co-Managing Partner of TPG Capital. Mr. Sisitsky resides in San Francisco, California. In the event it is determined that Mr. Sisitsky was not formally appointed a member of the Exactech Board, he functioned as a *de facto* member of Exactech's Board. Mr. Sisitsky joined TPG Capital in 2003. In 2021, Mr. Sisitsky was appointed as an officer and director of TPG, Inc. Mr. Sisitsky also has served as Managing Partner of TPG Partners VII L.P. Mr. Sisitsky, with Defendants Messrs. Binder, Schilling, and Garrison, in particular, and others, led the efforts to acquire Exactech, and after the TPG Acquisition, that group, exercised complete management control over Exactech's operations. Mr. Sisitsky, having served as a Director of Exactech and Osteon Holdings, has acted in material breach of the duties he owed to Exactech and Osteon Holdings because of, among other things, his TPG-affiliated positions and obligations.

33. Defendant John Schilling ("Schilling") was at all relevant times a member of the Exactech and Osteon Holdings Board who also currently serves as

Partner, Head of Operations, of TPG Capital. Mr. Schilling resides in Lake Bluff, Illinois. In the event it is determined that Mr. Schilling was not formally appointed a member of the Exactech Board, he functioned as a *de facto* member of Exactech's Board. Mr. Schilling joined TPG in 2011. Mr. Schilling, with Defendants Messrs. Binder, Sisitsky, and Garrison, in particular, and others, led the efforts to acquire Exactech, and after the TPG Acquisition, that group exercised effective management control over Exactech's operations. Mr. Schilling, serving at all relevant times as a Director of Exactech and Osteon Holdings, has acted in material breach of the duties he has owed to Exactech and Osteon Holdings, because of, among other things, his TPG-affiliated positions and obligations.

34. Defendant Kendall Garrison ("Garrison"), a Principal of TPG Capital, and a partner of TPG during relevant times was a member of the Exactech and Osteon Holdings Board and one or more Board Committees. Mr. Garrison resides in San Francisco, California. In the event it is determined that Mr. Garrison was not formally appointed to Exactech's Board, he functioned as a *de facto* member of Exactech's Board. Mr. Garrison, with Defendants Messrs. Binder, Schilling, and Sisitsky, in particular, and others, led the efforts to acquire Exactech, and after the TPG Acquisition, that group exercised effective management control over Exactech's operations. Mr. Garrison, serving at all relevant times as a Director of

Exactech and Osteon Holdings, has acted in material breach of the duties he has owed to Exactech and Osteon Holdings, because of, among other things, his TPG-affiliated positions and obligations.

35. Defendant Bennett Yasskin ("Yasskin") has been a vice president at TPG Capital's healthcare team since July 2024. Mr. Yasskin resides in San Francisco, California. Mr. Yasskin started at TPG as an associate in August 2021. Mr. Yasskin played an active role in TPG's domination and control of Exactech's product recall process.

36. Defendant Michael Tepatti ("Tepatti") has been a Principal of TPG Capital since at least August 2014. Mr. Tepatti resides in San Francisco, California. Mr. Tepatti was part of the TPG deal team with Defendants Messrs. Binder, Sisitsky, Schilling, and Garrison, among others, in the TPG Acquisition. Mr. Tepatti played an active part in TPG's due diligence of Exactech and was actively involved with Exactech on behalf of TPG after the TPG Acquisition, *inter alia*, attending over 30 Exactech Board or Exactech Audit and Compliance meetings between January 2019 and September 2024 and playing an active role in TPG's domination and control of Exactech's product recall process.

37. Defendant John Lin ("Lin"), a partner in TPG's Healthcare team, was actively involved in the recall process discussed herein, working closely with Mr.

Binder and Mr. Schilling, on behalf of TPG. Mr. Lin resides in San Francisco, California.

38. Defendant Dr. William Petty ("Dr. Petty") is an orthopedic surgeon and a co-founder of Exactech. Dr. Petty resides in Gainesville, Florida. Dr. Petty served as Exactech's CEO from 1985 until 2014, after which he served as the Executive Chairman of the Board of Exactech, Inc. prior to the TPG Acquisition. Following the TPG Acquisition, Dr. Petty served alongside Mr. Binder as Co-Executive Chairman of the Exactech and Osteon Holdings Boards through January 2020. Dr. Petty appears to have "retired" from Exactech day-to-day management on or about January 6, 2020, though Dr. Petty continued attending meetings of the Exactech Board "at the invitation of the Board."

39. Defendant David Petty ("Mr. Petty") is the son of Dr. Petty. David Petty became Exactech's first employee in 1988. Mr. Petty resides in Gainesville, Florida. David Petty served as Exactech's Vice President of Operations from April 1991 until April 1993, Vice President of Marketing from 1993 until 2000, Executive Vice President of Sales and Marketing from February 2000 until December 2007, President from 2007 until 2014, and CEO from 2014 until January 2020, leading Exactech through the TPG Acquisition. In January 2020, Mr. Petty was transitioned from his role as Chief Executive Officer to Vice Chairman of the Exactech and

Osteon Holdings Board. At all relevant times from February 14, 2018 through the Bankruptcy Cases, Mr. Petty was a member of the Exactech and Osteon Holdings Board.

III. RELEVANT NON-PARTIES

A. TPG-Controlled Osteon Entities

40. Osteon Holdings, Inc. ("Osteon Holdings") is a Delaware corporation with its principal place of business at 2320 NW 66th Court, Gainesville, Florida 32653. From 2018 through 2024 Osteon Holdings, Inc. was majority owned by TPG VII Osteon Holdings, L.P. and direct Parent of Exactech.[3] Further, from 2018 through immediately prior to the filing for bankruptcy, the Osteon Holdings and Exactech Boards were indistinguishable.

41. Osteon Intermediate Holdings I, Inc. ("Osteon I" or "Osteon Intermediate I") is a Delaware corporation with its principal place of business at the same address as Exactech, Inc. in Gainesville, Florida. Osteon Intermediate I is a wholly owned subsidiary of Osteon Holdings. Osteon Intermediate I was created by TPG "exclusively" to add one more corporate layer between Exactech and the ultimate parent TPG. Osteon Intermediate I is merely a shell entity, with no board of directors, no identifiable management, and no record of any board meetings. It

[3] During such period, TPG VII Osteon Holdings, L.P. owned 88% of Osteon Holdings, Inc.

only exists as an extension of the pathway between its parent Osteon Holdings and its subsidiary Exactech. On the Bankruptcy Petition Date, for example, Donna Edwards was the Senior Vice President and General Counsel of Osteon Intermediate I and Tony Collins was the Chief Financial Officer—both officers also held the exact same positions at Osteon Intermediate II and Exactech. Osteon Intermediate I filed the exact same list of 30 largest creditors as Exactech, and identified the exact same quantum of liabilities and estimated creditors as Exactech.

42. Osteon Intermediate Holdings II, Inc. ("Osteon II" or "Osteon Intermediate II") is a Delaware corporation with its principal place of business at same Gainesville, Florida address as Exactech, Inc. and Osteon Intermediate I. Osteon II, like each of the Osteon Holdings Entities, was originally formed by TPG. Osteon Intermediate II is a wholly owned subsidiary of Osteon Intermediate I, and Exactech is a wholly owned subsidiary of Osteon Intermediate II. Like Osteon Intermediate I, Osteon Intermediate II has never been more than a shell entity. Osteon Intermediate II likewise has no distinguishable difference between itself, Osteon Intermediate I and Exactech. There is no record of any action by an Osteon Intermediate II board of directors until after TPG was sued for Exactech's product defects under alter ego and veil theories and TPG anticipated forcing the Exactech Entities into bankruptcy. At that point, in November 2023, Elizabeth Abrams was

appointed as an "independent" director on Osteon Intermediate II's board of directors in an effort to create a false appearance of separation and independence between TPG and Exactech. [redacted] On the Bankruptcy Petition Date, Donna Edwards was the Senior Vice President and General Counsel of Osteon Intermediate II and Tony Collins was its Chief Financial Officer—both officers also held the exact same positions at Osteon Intermediate I and Exactech. Osteon Intermediate II filed the exact same list of 30 largest creditors as Exactech, and identified the exact same quantum of liabilities and estimated creditors as Exactech.

B. Other Relevant Non-Parties

43. Darin Johnson ("Johnson"), during certain periods, was Exactech's CEO. Previously, Mr. Johnson was the Vice President of Marketing, Extremities from 2002 to 2016, and 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. At that time, he was appointed

to the Board of Directors for both Exactech and Osteon Holdings, and he remained a member of both boards through the Bankruptcy Cases. In March 2022, following the initial Poly Recalls, Mr. Johnson was replaced as CEO by TPG's Mr. Binder, continuing in the role of President. One year later, in March 2023, Mr. Johnson was appointed as Exactech's Interim CEO and was reappointed to the CEO position in September 2023. While CEO, Mr. Johnson reported to, and acted at the direction of, Mr. Binder.

44. Luis Alvarez ("Alvarez"), Exactech's Director, Engineering and Development, since January 2020, began his career at Exactech as a Product Design Engineer in November 2008. He advanced to Product Development Engineer in February 2011 and Senior Product Development Engineer in February 2013. Mr. Alvarez was the Manager, Engineering and Development, between February 2017 and January 2020. Mr. Alvarez conspired with and/or was directed by others (such as Mr. Binder), as set forth herein, to facilitate the scheme to defraud surgeons and delay a proper reporting of device failures reported by such surgeons. As alleged herein, Mr. Alvarez also was involved in a scheme to conceal the fact that Exactech had failed to properly instruct its internal manufacturing personnel with regard to how the surface roughness of femoral knee components were to be manufactured, resulting in over 370,000 femoral components being manufactured "in-house"

during the period from late 2004 to November 17, 2021, under incorrect manufacturing specifications. These faulty instructions resulted in femoral devices being manufactured with improper and insufficient "roughness," exposing such implanted devices to premature femoral loosening or loss of fixation to the bone, and patients to revision surgery. Mr. Alvarez was also involved in a scheme, led by and/or in participation with TPG, Mr. Binder and other Individual Defendants, to conceal that HSS had by no later than 2018 notified Exactech (and several Exactech Board members) as to delamination problems, as alleged herein. Exactech and TPG failed to make proper disclosure regarding these material defects and manufacturing errors, including to surgeons, patients and the FDA, nor did Exactech (controlled by TPG at the time) issue any recalls relating to this femoral "roughness" manufacturing error.

45. Laurent Angibaud ("Angibaud"), the Vice President of Engineering, Advanced Surgical Technologies, since January 2020, joined Exactech as a Senior Product Development Engineer no later than 2004. Between 2008 and the TPG Acquisition, he rose from Materials & Testing Manager–Principal Knee Engineer to Senior Engineering Manager–Knee and Computer-Assisted Surgery ("CAS") Systems. Thereafter, he was the Senior Director of Engineering, Knee and CAS systems, from February 2018 to January 2020. Mr. Angibaud conspired with Dr.

Petty and Mr. Binder to facilitate the scheme to defraud surgeons, such as [redacted], and delay any proper reporting of device failures reported by such surgeons.

46. [redacted]

47. Daniel P. Hann ("Hann") served as Exactech's Senior Vice President, Business Development beginning in 2018, also immediately after serving as a Senior Advisor to TPG Capital. As a TPG Senior Advisor, he reported to Messrs. Tepatti and Garrison of TPG. Mr. Hann, with Defendants Messrs. Binder, Sisitsky, Schilling, and Garrison, in particular, and others, led the efforts to acquire Exactech, and after the TPG Acquisition, that group exercised effective management control over Exactech's operations. Like Mr. Binder, Mr. Hann formerly worked at Biomet, including serving as Biomet's Interim President and CEO prior to Mr. Binder's appointment as CEO. Mr. Hann was forced to leave Biomet due to his involvement in an illegal stock options back dating scheme, for which Biomet was required to restate its financial statements.

48. Kerem Bolukbasi ("Bolukbasi") was installed by TPG as Exactech's Chief Financial Officer and an Executive Vice President from August 2020 to May 2022. From November 2014 to on or about December 31, 2018, he served as a

consultant for TPG pursuant to certain consulting agreements. From on or about January 1, 2020, to August 2020, he was a Field Operations Advisor in the TPG Capital Operations Group. As of the TPG Acquisition, Mr. Bolukbasi worked for Exactech in a consultant capacity while simultaneously serving as a TPG advisor, consultant, and/or executive. While at TPG, he held interim CFO and Chief Operating Officer roles at Vice Media Group LLC, Transplace, Inc., Fleetpride, Inc., and Adare Pharmaceuticals Inc.

IV. TPG'S STRUCTURE.

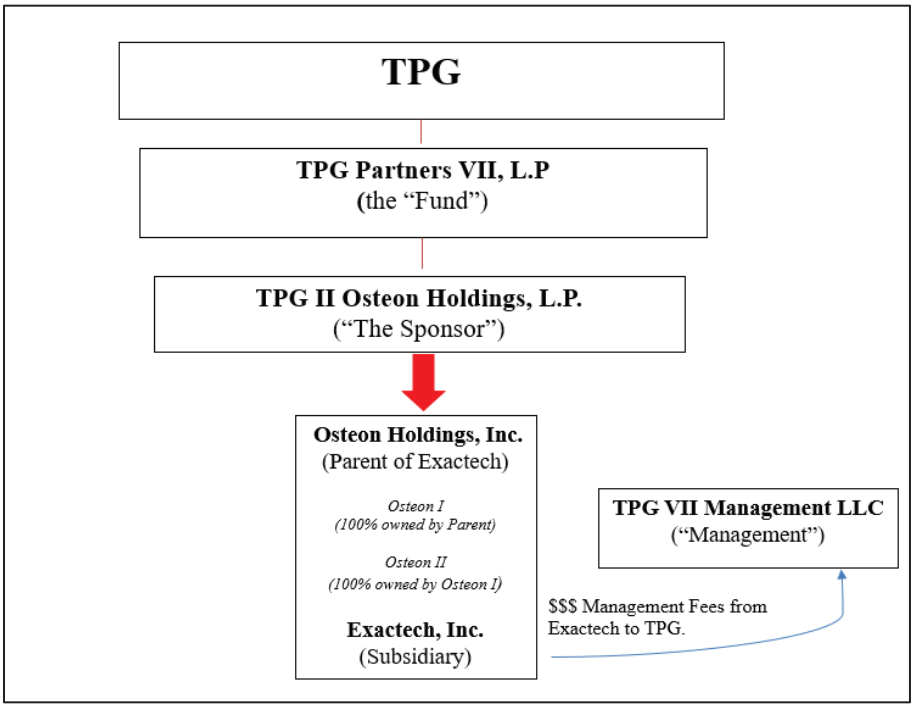
49. TPG, Inc's direct link to Exactech ran through two key entities, which included Defendant TPG Partners VII, L.P. (the "Fund") and Defendant TPG VII Osteon L.P. (the "Sponsor"), while all "management fees" would flow from Exactech to Defendant TPG VII Management LLC ("Management**").**

50. Defendant TPG, Inc., at the top of the corporate chain, is one of the largest private equity firms in the world.[4]

51. One of Defendant TPG, Inc.'s funds is Defendant TPG Partners VII L.P., which held a 95% ownership interest in and funded the Sponsor, Defendant TPG VII Osteon Holdings, L.P.

[4] Also known as TPG Capital L.P. from 2018 through 2022, prior to TPG going public.

52. The Sponsor, TPG VII Osteon Holdings, L.P., owned a substantial majority of the outstanding stock of Osteon Holdings, which owned 100% of Osteon I and II, and ultimately its subsidiary Exactech. The relevant corporate structure is illustrated as follows:



JURISDICTION AND VENUE

53. This Court has personal jurisdiction over each of the TPG Defendants because each entity is a Delaware corporation, limited liability company, or limited partnership.

54. This Court has personal jurisdiction over each of the Individual Defendants, *inter alia*, pursuant to 10 Del. C. § 3114(a) inasmuch as Individual Defendants were directors of Osteon Holdings, Inc., a Delaware corporation, during

times relevant to the allegations herein, or otherwise are subject to personal jurisdiction before this Court. This action is against Individual Defendants, in part, for violations of duties arising from their capacity as officers or directors of that Delaware corporation.

55. This Court also has personal jurisdiction, alternatively, over Defendants William Petty, David Petty, and Jeff Binder pursuant to Section 14.2 of an Osteon Holdings, Inc. Shareholders' Agreement, for any claim involving, *inter alia*, a breach of fiduciary duty by any director of Osteon Holdings, Inc. or any director or officer of a subsidiary of Osteon Holdings, Inc.

56. The Court has subject matter jurisdiction over this action pursuant to, *inter alia*, Art. IV, 10 of the Delaware Constitution, 10 *Del. C.* § 341, and 8 *Del. C.* § 111.

57. Venue is proper in this Court pursuant to 10 Del. C. §§ 3104, 3114, and 341 because Defendants include Delaware corporations and persons who served as directors and/or officers of Delaware corporations, and the claims asserted arise out of or relate to such service. Venue is further proper in New Castle County, Delaware, where the Defendant entities are incorporated and where the acts and omissions giving rise to this action are appropriately adjudicated.

FACTUAL BACKGROUND

58. Except where stated to be made on actual knowledge, allegations herein are made upon information and belief based on the discovery record developed to date, the investigation of counsel, matters of public record, and inferences drawn from such sources. The Trust's investigation is ongoing, and the Trust reserves all rights to amend this Complaint to allege additional facts and causes of action.

I. FOUNDING OF THE COMPANY AND SUBSEQUENT OPERATIONS

59. In November of 1985, Exactech, Inc. was founded and incorporated under the laws of the State of Florida by Defendant Dr. Petty, together with Dr. Miller and Betty Petty.

60. Dr. Petty is an orthopedic surgeon who served as Exactech's CEO for an extended period of time, among other roles. Dr. Miller is a biochemical engineer who served as an "innovation leader" upon Exactech's founding, as well as Exactech's Executive Vice President, Research and Development prior to the TPG Acquisition.

61. The Company's product portfolio, as of Exactech's October 2024 Petition Date, consisted of: (a) extremities (shoulder and ankle, which accounted for 61% of 2023 sales), (b) large joints (knee and hip, which accounted for 33% of 2023 sales), and (c) other product lines (ExactechGPS and other supporting materials, which accounted for 6% of 2023 sales). Certain physicians maintained "royalty"

programs with the Company. The Company paid physicians a certain percentage of net sales revenue for the sales of specific product lines.

62. Exactech's portfolio of shoulder, hip, knee, and ankle joint replacement systems (collectively, the "Exactech Devices") encompasses the following products, which each historically contained Ultra High Molecular Weight Polyethylene ("UHMWPE"):[5]

- ***Shoulder Implant Systems:*** Equinoxe Reverse Total Shoulder Arthroplasty (rTSA) and the Equinoxe Anatomic Total Shoulder Arthroplasty (aTSA) (together, the "Exactech Shoulder Devices");

- ***Hip Implant Systems:*** MCS (Conventional UHMWPE and GXL), AcuMatch (Conventional UHMWPE, GXL, and XLE), Novation (Conventional UHMWPE, GXL, and XLE), and Alteon (XLE) (collectively, the "Exactech Hip Devices");

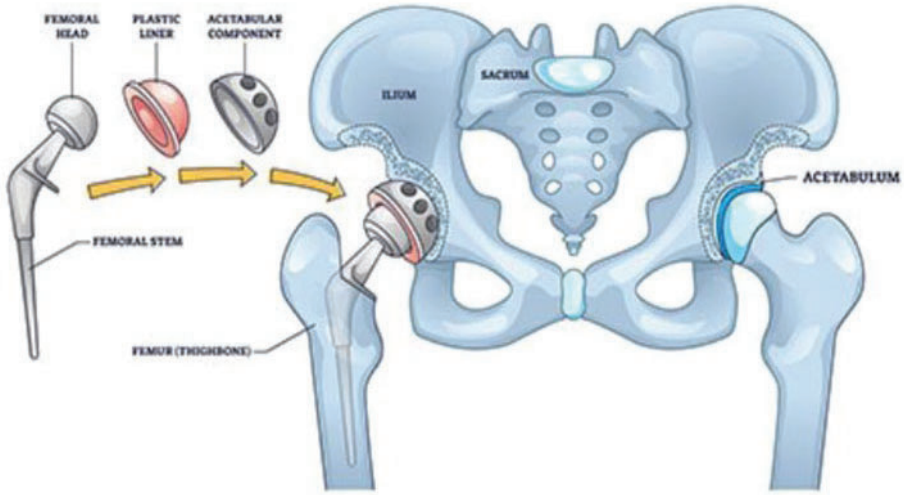
- ***Knee Implant Systems:*** Optetrak Comprehensive Total Knee System ("Optetrak TKR"), Optetrak Logic Comprehensive Knee System ("Optetrak Logic"), and Truliant Comprehensive Total Knee System ("Truliant," and together with Optetrak TKR and Optetrak Logic, the "Exactech Knee Devices"); and

- ***Ankle Implant Systems:*** Vantage Total Ankle System ("Vantage" or the "Exactech Ankle Devices").

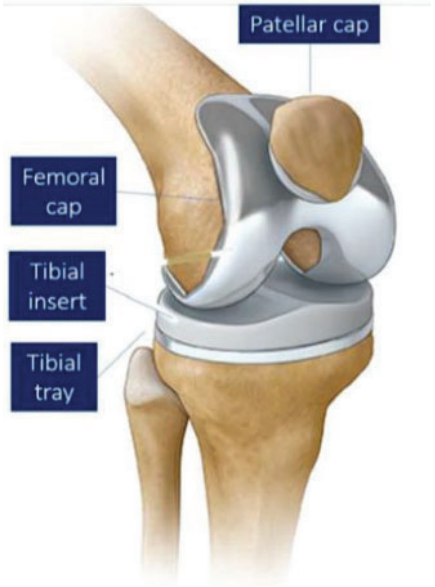
63. The basic components associated with the Exactech's Hip Devices include: (i) an acetabular cup/shell, (ii) a polyethylene/plastic cup or liner that fits

[5] UHMWPE is a polymer or plastic that has been used for over four decades as a bearing surface in total joint replacements. It is essentially a plastic ball, cup, or wedge utilized in joint replacement devices to replicate cartilage to mitigate wear and friction between the metallic components.

inside the acetabular shell; (iii) a femoral stem that fits inside the femoral shaft; and (iv) a femoral head or ball that mechanically connects to the femoral stem:



64. The basic components associated with Exactech's Optetrak, Optetrak Logic, and Truliant total knee systems include: (i) a polyethylene patellar cap, (ii) a femoral component, (iii) a polyethylene tibial insert, and (iv) a tibial tray, as illustrated below:



65. "Polyethylene wear" means plastic debris generated via surface delamination (*i.e.,* cracking, splitting, breaking of the plastic) or debris from loading, pounding, or force of the tibial insert or plastic liner. "Oxidation" or exposure to oxygen during storage post-manufacture or in "in vivo" (in the body) can make polyethylene/plastic liners more brittle, more rigid and more fragile, causing the implant to wear faster and no longer withstand the normal joint forces the way it should, resulting in premature failure and revision surgery.

66. From 2004 until mid-2021, Exactech's Polyethylene was manufactured in Sarasota and Gainesville, and supposed to have been packaged in oxygen resistant vacuum bags with a crucial barrier containing ethylene vinyl alcohol ("EVOH") to ensure oxygen resistance. After packaging, Exactech's polyethylene apparently was shipped to a third-party sterilization company, which would sterilize the

polyethylene through a process called "gamma sterilization." This involved exposure to doses of radiation resulting in a process called "crosslinking," which would simultaneously increase "fracture toughness" but result in "crosslinking" within the polymer resulting in "free radicals" which are highly reactive when exposed to oxygen – hence the critical need for proper, oxygen resistant packaging.

II. THE DEFECTIVE PRODUCTS

67. The full range of Exactech Devices at issue below have been recalled to date, though the Trustee is investigating whether there are yet further recalls that TPG, Mr. Binder, Mr. Schilling and other Defendants may have concealed and/or resisted making:

Figure 2: Recalled Exactech Devices

Business Unit	Line(s)/System(s)	Recall Event ID / Recall Initiation Date	88126 6/29/21	88570 8/30/21	90279 8/11/22	94092 3/6/24	94409 4/18/24	94410 4/26/24	96102 12/31/24
Shoulder	Equinoxe					x			
Hip	MCS		x		x				
	AcuMatch		x		x			x	x
	Novation		x		x				x
	Alteon								x
Knee	Optetrak			x			x		
	Optetrak Logic			x					
	Arthrofocus			x					
	Truliant			x					
Ankle	Vantage			x					
Supplemental Recall Data:									
	Distribution Pattern (as reported)		*US*	*Worldwide*	*Worldwide*	*Worldwide*	*Worldwide*	*Worldwide*	*Worldwide*
	Reported quantity of "units in commerce" (as reported)		*89,050*	*430,517*	*107,529*	*171,322*	*Undisclosed*	*589*	*1,575*
	"Affected Devices Distributed in the US" (as reported)		*Undisclosed*	*Undisclosed*	*40,105*	*Undisclosed*	*Undisclosed*	*Undisclosed*	*Undisclosed*
	Affected Units "Implanted" / "Sold" in the US (as reported)		*Undisclosed*	*147,732*	*Undisclosed*	*124,231*	*Undisclosed*	*Undisclosed*	*Undisclosed*
	Abbreviated scope description		*GXL Liners implanted since 2015*	*UHMWPE Inserts implanted since 2004*	*GXL or UHMWPE Liners implanted since 2004*	*UHMWPE humeral liners and glenoids implanted since 2005*	*Patellas (lot-specific)*	*AcuMatch L-Series 22mm Inner Diameter Bipolar Hip Liners (lot-specific)*	*XLE hip liners implanted since 2018*

68. As reflected in the chart above, following TPG's acquisition of the Company in February 2018, and entirely under TPG's control and direction in the years thereafter, Exactech issued recalls affecting nearly all of its knee, hip, ankle, and shoulder inventory which comprised of over 500,000 implants, including many devices already implanted in patient's bodies. But each of the above recalls, notwithstanding various significant product defects discussed herein, all shared the same failure mode and packaging non-conformity (*i.e.,* premature wear of the polyethylene and packaging without EVOH).

69. Specifically, these polyethylene inserts, which were used in nearly all of Exactech's joint replacement devices, had been packaged in out-of-specification vacuum bags lacking an EVOH layer that was intended to keep out oxygen. However, since these polyethylene inserts had already been sterilized with gamma irradiation, they contained free radicals post-sterilization that would thereafter combine with oxygen while in storage and sitting on the shelves of hospitals which accelerated oxidation – a chemical process that causes polyethylene to degrade, fracture, delaminate, exhibit pitting, and wear and otherwise age faster than normal. To compound these problems, it appears devices were stored in an Exactech warehouse with inadequate climate control in the hot and humid Sarasota, Florida climate, further negatively impacting the stability of the polyethylene.

70. Mr. Binder was made directly aware of serious concerns with respect to Exactech's polyethylene as early as 2018. By the summer of 2021 at the latest, TPG and all the individual TPG Defendants named herein, knew Exactech's polyethylene was at risk of premature oxidation and that the packaging non-conformity adversely impacted nearly all polyethylene components manufactured since 2004 irrespective of shelf life or product line.[6] In fact, approximately 80% of polyethylene inserts manufactured since 2004 were packaged in out-of-specification vacuum bags without EVOH. Despite this, TPG, in an effort to protect its investment, made the strategic decision (highly detrimental to patients) that Exactech move forward with a series of recalls each covering only a portion of the each product line's inventory to maintain the appearance that the Company's sales revenue was stable, which would enable Exactech to continue to sell defective product and would be beneficial to TPG's IPO plans.

71. For example, on June 29, 2021, Exactech issued a recall of its Exactech Connexion GXL hip polyethylene ("GXL liners"). But this recall was initially limited to **GXL Liners implanted after 2015.**

6 "Shelf life" means the amount of time between the packaging of the finished product and implantation surgery. "Shelf life" measures how long a particular polyethylene insert was held in storage before being implanted in a patient's body.

72. Likewise, in August 2021, after confirming that a large majority of Exactech's polyethylene inserts had been packaged without EVOH (including the GXL), **only knee and ankle devices that had a shelf life greater than five years** were recalled (*i.e.,* a small portion of Exactech's knee inventory).

73. In both instances, the FDA thereafter stepped in, ultimately forcing Exactech to expand the scope of its incomplete recalls as the company should have done from the start. For example, on February 7, 2022, after pressure from the FDA, Exactech issued an Urgent Medical Device Correction Notice to surgeons, hospitals, and healthcare professionals explaining "Exactech is now expanding the recall to include all knee and ankle arthroplasty inserts packaged in non-conforming bags **regardless of….shelf life.**[7] Thereafter, on August 11, 2022, after pressure from the FDA, Exactech expanded the scope of its original GXL Hip liner recall to all polyethylene inserts manufactured **since 2004.**

74. In January 2024, the FDA issued a Safety Communication regarding Exactech's Equinoxe reverse total shoulder device also packaged in non-conforming packaging. Less than three months later, on April 18, 2024, Exactech was forced to recall its Patella polyethylene devices manufactured since 2004 (*i.e.,* a plastic

[7] *See* February 7, 2022 Urgent Medical Device Correction Letter (Exactech UHMWPE) Knee and Ankle Polyethylene Inserts.

polyethylene cap pinned to the kneecap used in all knee implants). But for thousands of patients, this recall would be issued far too late. This is because many patients **had already undergone revision surgery to remove the recalled polyethylene insert** while their surgeon **left the recalled patella intact**. Of all Exactech's recalls, its delay in issuing the patella recall was among the most destructive considering it was common for many surgeons to proceed with "liner swap" revision surgeries (*i.e.,* removing just the polyethylene liner) as opposed to total revision surgery which involved removal of all components. For many of these patients, the only option was to have re-revision surgery to remove the recalled patella resulting in avoidable and further damage and bone loss or destruction of the knee joint from repetitive revision surgeries.

75. Lastly, in 2025, Exactech made four (4) additional product recalls affecting its hip products. In February 2025, Exactech recalled the XLE Novation, Alteon, and AcuMatch hip products. Like the Patella patients, many hip patients who had already undergone revision surgery to remove the recalled GXL Liner were thereafter informed that they had been re-implanted with a recalled XLE liner for the same packaging issue.

76. Each of the foregoing recalls (all of which involved efforts by TPG to avoid, delay or limit the recall), including the thousands of avoidable revision

surgeries that took place from 2021 until present, can be directly traced to TPG's domination and control over Exactech's initial recall strategy and TPG's manipulation of Exactech's communications with the FDA.

77. Notwithstanding the packaging non-conformity that plagued Exactech's products since the inception of TPG's acquisition of the company, TPG knew and understood as well that there existed other significant product defects, design flaws, and/or outright manufacturing errors that made Exactech's medical devices even more dangerous.

78. A brief summary of certain significant product defects, all of which continued to occur after TPG's acquisition of Exactech and for which most revision surgeries occurred during TPG's ownership of Exactech, along with certain regulatory non-compliance and quality control lapses, is set forth below.

A. Manufacturing Defect of Exactech's Femoral Knee Components.

79. Among the most destructive failure mode that occurred under TPG's ownership and control of Exactech involved debonding of the Optetrak, Optetrak Logic, and Truliant Cemented Femoral Components. The femoral component is a curved metallic shell which is impacted between the femur and tibia secured by bone cement during knee replacement surgery. Debonding occurs when the cement used to secure the femoral component to the bone has fallen off in the patient's body. Mr. Binder, in particular, was on notice of this problem early on in his tenure at Exactech.

This "femoral debonding" problem seen in revisions involving Exactech knee implants resulted in surgeons raising concerns of catastrophic loosening of the femoral component such that during a revision surgery, the non-articulating surface of the femoral component was found completely devoid of cement and so loose that it could be pulled from the body by hand. While debonding is independent of the packaging-related polyethylene defects, as alleged herein, Exactech and thereafter Mr. Binder (and other TPG-designated Directors and Officers) became aware of significant concerns raised by HSS and others regarding a direct connection of aseptic femoral loosening and/or de-bonding to polyethylene delamination. As alleged herein, the debonding issue would become a major, long-term product ongoing defect for TPG-controlled Exactech, which TPG and the Individual Defendants continued to conceal the root cause of, from surgeons, patients and even the FDA.

80. As part of the investigation by the Official Committee of Unsecured Creditors (the "Committee") during the Exactech Bankruptcy Cases, the Committee discovered that during the period from late 2004 until November 17, 2021, Exactech had manufactured its femoral knee components using an incorrect non-articulating surface roughness specification. This glaring manufacturing error continued in place for 3 ½ years after TPG's acquisition of Exactech. This error involved potentially

up to 371,986 femoral knee devices. Rather than informing the FDA about the design change necessitated by the error in articulating the proper surface roughness, Exactech, led by Binder-directed employee Mr. Alvarez, instead buried any disclosure of this issue in November 2021 via a "memorandum-to-file" (just as the FDA arrived on-site to conduct its polyethylene delamination investigation). As further alleged herein, this issue related to the ongoing concerns that Exactech, Mr. Binder, and TPG had been aware of involving aseptic femoral loosening and/or femoral debonding, which implicated, *inter alia*, femoral loosening or even debonding due to improper surface roughness of the femoral components.

B. Defective Design of the GXL Hip Polyethylene

81. The scheme by TPG to delay any proper recall in order to allow defective products to continue to be sold extended to other Exactech devices, including Exactech's GXL Hip device. As TPG, and in particular Mr. Binder, were aware, the GXL design made exposure to oxygen extremely dangerous. The lack of EVOH could only have exposed the polyethylene in the GXL Hip device to even more oxygen, making for toxic exposure. Notwithstanding this, TPG, Mr. Binder and Mr. Schilling delayed a proper recall of the GXL Hip device, leading to numerous otherwise avoidable hip revisions.

82. The context is as follows: By the 1990s, orthopedic manufacturers understood that subjecting polyethylene to gamma irradiation created free radicals

and that those free radicals, when exposed to air/oxygen, would initiate oxidation and wear.[8] To mitigate those risks, companies began to irradiate polyethylene in inert (oxygen free) environments and to thermally or chemically treat or quench those free radicals. Despite that industry awareness, Exactech developed and continued to sell the GXL (moderately crosslinked) Polyethylene Liner (one subjected to a higher dose of irradiation) that, unbeknownst to operating surgeons, (i) could be sitting exposed to air for up to 5 years before being cut, packaged and implanted into patients, and (ii) was the only moderately or highly crosslinked polyethylene on the market that **did not employ any type of thermal or chemical process to eliminate free radicals.**

83. In August 2017, as discussed below, HSS advised one of Exactech's founders of an instance of severe oxidation with a GXL hip insert, which HSS noted was worse than HSS had observed in other crosslinked polyethylene from other manufacturers.

84. At the time of the TPG Acquisition in February 2018, the GXL liner was performing poorly and in early post-Acquisition Exactech/Osteon Holdings

8 "Gamma irradiation" is a process by which medical devices are exposed to high energy gamma-rays or radiation to kill microorganisms throughout the product and its packaging. This process functions to sterilize the implant, but also significantly alters the characteristics of UHMWP Polyethylene, leaving long-lived "free radical" particles in the plastic which react with oxygen and can accelerate aging and wear.

board meetings, the TPG Individual Defendants expressed concern about the decline in sales of the GXL observed overseas. Likewise, Mr. Binder, based on his extensive prior experience as CEO at Biomet (as discussed below) would have been well aware and understood the role of thermal annealing and antioxidants (*i.e.,* Vitamin E) and would have known that Exactech's GXL liner design lagged behind industry standards as to safety and effectiveness. By 2018, Biomet (Mr. Binder's former company), had sold a similarly moderately crosslinked polyethylene that was thermally annealed (ArCom XL) and a second-generation polyethylene infused with Vitamin E (E1).[9]

85. To keep up with its competitors, Exactech's solution was to introduce an "XLE" Liner for its hip products - that was infused with Vitamin E – an antioxidant that would neutralize free radicals' premature wear and failure. In fact, less than one month after the TPG Acquisition, in March 2018, Exactech received marketing clearance for the Novation and AcuMatch XLE Acetabular Liner.[10]

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[9] *See* Lachiewicz, P., *et al.,* Bearing Surfaces for Total Hip Arthroplasty. AAOS, January 15, 2018, Vol. 26, No.2.

[10] While Exactech would introduce Vitamin E infused Hip Liners, Exactech inexplicably would not secure Vitamin E poly clearance for any knee devices until July 2023 (for the Truliant knee), even though Mr. Binder had been well aware of the utility of Vitamin E to prevent oxidation in knee devices from his tenure as CEO of Biomet. This allowed Exactech, under Mr. Binder's and TPG's direction, to continue to sell defective product until forced to make a more expansive knee recall.

86. Nonetheless, Exactech continued sell off its GXL polyethylene liner inventory until December 2020, while failing to inform surgeons of the availability of the Vitamin E-induced XLE. Exactech continued the sale of GXL despite internal bench testing confirming "that Exactech's new XLE liner does outperform the Connexion GXL liner in both volumetric and edge loading assessments." Around the same time, TPG personnel also recognized "issues with the GXL," as confirmed by internal notes drafted by Kerem Bolukbasi (a TPG consultant installed as Exactech's CFO).

87. In January 2020, a paper was published further citing poor performance of the GXL, noting "The Exactech Connexion GXL Liner may be prone to a high rate of early failure from wear and severe secondary osteolysis."[11] But rather than taking affirmative steps to inform the medical community of the availability of a safer alternative design that directly addressed the issues identified in the Parvataneni paper, Exactech, under TPG's and Mr. Binder's control, retained and paid another, non-U.S. licensed doctor ([redacted]) to prepare a response to the Thomas paper and to, at best, edit or, at worst, simply put his name on a paper

[11] Thomas, Parvataneni, *et al.,* Early Polyethylene Failure in a Modern Total Hip Prosthesis: A Note of Caution. Journal of Arthroplasty 35 (2020) 1297-1302.

that Exactech had drafted internally falsely touting the GXL based on incomplete and short term data without any disclosure of conflict.

88. In August 2021, following discovery of the packaging issue and aware that all of Exactech's GXL liners were already at risk of increased oxidation due to design flaws, Mr. Binder, together with other TPG personnel intentionally and deliberately chose not to expand the GXL recall to cover *all* GXL Liners. In an internal board meeting in August 2021, Mr. Binder addressed the limited nature of the initial GXL Liners recall, cognizant that the GXL in and of itself was probably the most susceptible to wear through oxygen exposure as a result of packaging without EVOH.

89. In a September 2021 meeting with the FDA to discuss Exactech's August 2021 recall strategy, Mr. Binder acknowledged that the GXL liners were "not state of the art," and that Exactech's XLE liner (infused with Vitamin E) was, according to Mr. Binder, "state of the art." Nonetheless, Mr. Binder pressed for the entire GLX inventory to not be recalled and withheld disclosure of material information, allowing inferior, outdated and defective hip liners to remain in patient bodies until the FDA ultimately forced a full recall.

90. [redacted]

[redacted]

91. When the FDA pressed Exactech as to why its initial delamination recall strategy focused on only knee and ankle implants, and not the GXL (which had also been packaged without EVOH) or why the limited June 2021 recall of the GXL should not be expanded, Mr. Binder (in conjunction with Mr. Schilling), again scripted Exactech's misleading response to the FDA. [redacted]

92. Not until August 2022, six months after the expanded recall addressing the packaging non-conformity, did Exactech finally expand the GXL recall to include all liners manufactured since 2005. The timing here was particularly egregious, considering among other issues addressed above, as Mr. Binder, Mr. Schilling and others at TPG were aware, the actual design of the GXL made those liners more vulnerable to oxidation and wear. Once again, under TPG's direction, implemented by Mr. Binder and Mr. Schilling, Exactech had delayed a proper recall

in order to facilitate the sale of defective and in this case inferior product, resulting in increased revision surgeries (here, with respect to hip implants).

C. Failure to Comply with Regulatory Safety Standards

93. Federal statutory and regulatory law provides a wide range of medical device manufacturing requirements. Exactech failed to comply with these federal statutes, regulations, and good manufacturing practices. On repeated occasions, including many after TPG's acquisition of Exactech, the FDA has found Exactech in violation of federal regulations and good manufacturing practices, as depicted in the following chart of 20 FDA citations (for the period from 2017-2023) for violations of a dozen distinct regulations (13 of which were issued after TPG's acquisition of Exactech).

Figure 3: FDA Citations Since 2017 (Blue Font Represents Repeat Offenses)

			Inspection End Date			
Index	Act/CFR Number	"Short Description" of Citation (as reported)	3/10/2017	1/31/2020	11/17/2021	9/26/2023
1)	21 CFR 803.50(a)(1)	Report of Death or Serious Injury	X			X
2)	21 CFR 820.100(a)	Lack of or inadequate procedures	X	X		X
3)	21 CFR 820.30(h)	Incorrect translation to production specifications			X	
4)	21 CFR 820.30(h)	Design transfer- lack of or inadequate procedures		X		
5)	21 CFR 820.75(a)	Lack of or inadequate process validation			X	
6)	21 CFR 820.80(b)	Lack of or inadequate receiving acceptance procedures			X	
7)	21 CFR 820.250(b)	Sampling plans			X	
8)	21 CFR 820.30(f)	Design verification- lack of or inadequate procedures		X		
9)	21 CFR 820.30(g)	Design validation- risk analysis not performed/inadequate	X	X		
10)	21 CFR 820.30(g)	Design validation- lack of or inadequate procedures	X	X		
11)	21 CFR 820.50	Purchasing controls, lack of or inadequate procedures	X	X		
12)	21 CFR 820.90(a)	Nonconforming product, lack of or inadequate procedures		X		
13)	21 CFR 820.25(b)	Training - lack of or inadequate procedures	X			
14)	21 CFR 820.198(a)	Lack of or inadequate complaint procedures	X			

94. Moreover, prior to the product recalls that began in 2021, Exactech, as was known by TPG and the Individual Defendants, 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 to maximize profits at the cost of patient safety.

D. Lack of Quality Control & Defective Packaging

95. As noted, while Exactech's failure to properly monitor its supply of polyethylene bags began prior to the TPG Acquisition, such failure continued for 3

½ years after TPG took over. As discussed herein, Mr. Binder became aware of the delamination issues associated with such bags due to complaints from Exactech's largest domestic customer (HSS). In an effort to protect TPG's investment in Exactech, Mr. Binder sought to deter HSS from publicly disclosing the delamination problem. Mr. Binder, Mr. Schilling and the other individual TPG defendants sought to conceal, *inter alia*, what was known as early as 2018 by Exactech Board members and TPG about this defect, delay proper recalls from being timely issued, and conceal from regulators the true facts of this product failure and the correct timeline of when Exactech's Board (populated by TPG employees/advisor(s) or designees) learned of the details from HSS. [redacted]

96. The context of the delamination fiasco is as follows: From 2004 to 2021, Exactech sourced its supply of polyethylene vacuum bags from Hillman

Supply Company, Inc., a local Florida company located near Exactech's headquarters that specialized in providing *janitorial supplies*. Hillman had no experience with the manufacturing or supply of polyethylene inserts or polyethylene vacuum bags. Hillman did not actually manufacture the bags, but outsourced manufacturing to other third-party manufacturers, some of whom further outsourced the manufacturing of the bags to yet other third-party manufacturers. Exactech's quality control was virtually non-existent. Exactech did not test or inspect any of the vacuum bags packaging to confirm whether they contained required liners to protect against oxidation, and, for virtually all, they did not contain the required EVOH liners, as discussed in more detail below. This non-compliant quality control was known to TPG even before it acquired Exactech. While TPG would claim that Exactech's quality control was adequate, it was not. And TPG knew it was not.

97. [redacted]

[redacted]

98. Correct packaging is critical to reducing the risk of oxidation during the period between the completion of the manufacturing process and implantation in the patient. According to an FDA Safety Communication issued on March 23, 2023, all Exactech joint replacement devices contain a plastic component that should be in packaging that contains multiple oxygen barrier layers. The non-conforming packaging of Exactech devices made pre-implanted oxidation more likely in the affected Exactech devices. Once implanted, oxidized plastic is more susceptible to damage under the normal stress of movement, which can lead to premature failure.[12]

[12] *See* https://www.fda.gov/medical-devices/safety-communications/risks-exactech-joint-replacement-devices-defective-packaging-fda-safety-communication?utm_medium=email&utm_source=govdelivery

99. As set forth herein, Exactech had packaging specifications in place to, for example, require the ultra-high molecular weight polyethylene (UHMWPE) components of its Hip, Knee, and Ankle Devices be packaged in vacuum bags consisting of layers of low-density polyethylene, nylon, and an EVOH barrier to protect against oxidation, but it had no quality control steps at all in place to ensure those specifications were met.

100. Incredibly, for 17 years (prior to the TPG Acquisition and thereafter until mid-2021), Exactech never conducted any proper basic quality control due diligence on the over 1.4 million vacuum sealed packages supplied by Hillman, its local Florida janitorial supply services company (located a few minutes from the Company), virtually none of which included the EVOH barrier. This non-conforming packaging, as alleged herein, appears to have been one of the root causes of the oxidation defects with the critical polyethylene inserts that plagued Exactech Devices, including Exactech Hip and Shoulder Devices. To the extent any form of quality control had occurred, [redacted], Exactech failed to take any corrective measures to ensure that such bags complied with the packaging instruction (and never tested the bags to confirm the presence of EVOH), and it appears that Exactech's own design specifications were incorrect.

101. After the TPG Acquisition, Mr. Binder and others at TPG learned of the non-conforming packaging issue. Given Mr. Binder's prior industry experience at Biomet, he well understood the implications of oxidation defects with polyethylene inserts; Biomet had developed methods to avoid oxidation defects in the manufacturing process. To avoid any discovery by regulators that TPG and its TPG-designated Exactech and Osteon Holdings' Board members were aware of the underlying issues years prior to the first 2021 recall, TPG endeavored to conceal the facts as to precisely when Exactech, and Board members, including Mr. Binder and Dr. Petty, had first become aware of this packaging issue, and tried to shift blame to others for such manufacturing non-compliance. [redacted]

III. TPG AND THE INDIVIDUAL DEFENDANTS KNEW OR LEARNED EXACTECH'S PRODUCTS WERE DEFECTIVE BUT CHOSE TO HIDE THIS INFORMATION.

102. Exactech's pattern of deceit pre-TPG Acquisition was perpetuated and expanded by TPG after its acquisition of Exactech. Such misconduct included, *inter*

alia, efforts (i) to inaccurately attempt to shift blame for defective products to either claimed patient conduct or claimed surgical error, (ii) to delay recalls in order to continue to sell defective products, (iii) to avoid making timely and accurate disclosures to regulators in order to prolong the sale of defective products, and (iv) to inaccurately claim that it and Exactech acted promptly to take corrective action. Here, history did repeat itself. TPG, once in control, not only failed to course correct, but unfortunately doubled down and materially expanded on Exactech's historical misconduct to preserve its investment.

103. After the TPG's Acquisition of Exactech, TPG, *inter alia*, (i) became fully aware of Exactech's defective products, (ii) was on notice in October 2018 of HSS's delamination complaints (via Mr. Binder), (iii) was on notice via Mr. Binder in March 2019 of the serious allegations made by [redacted], (iv) was aware of information which contradicted factual representations that had been made to TPG during due diligence, (v) was on notice of de-bonding and other material defects in Exactech's products, (vi) was aware that HSS had terminated its main business with Exactech in early 2021, (vii) orchestrated Exactech's dilatory machinations in delaying recalls, (viii) chose to try to prevent proper disclosure of both Exactech product defects and its knowledge of such defects and role in delaying product recalls, and (ix) delayed such disclosure

to allow for the continued sale of such defective products. TPG, represented in the MDL as of March 2023 [redacted]

104. TPG's receipt, in 2019, of an unsealed Alabama Qui Tam Complaint also made clear that the explanation that Exactech had provided about Dr. Lemak (a Relator for the Alabama Qui Tam), during pre-TPG Acquisition due diligence, was false. While TPG had examined information relating to Dr. Lemak's complaints during its due diligence, the Alabama Qui Tam, which became known to TPG in 2019, contradicted the information Exactech had provided to TPG during due diligence. The Alabama Qui Tam Action noted the following: (i) Dr. Lemak's initial revision surgeries began in 2014 and lasted through 2015, (ii) Dr. Lemak's patients who had received the Finned Tibia Tray Primary TKRs in the 2011 to April 2014 time period continued to return to his clinic afterwards, (iii) Dr. Lemak had performed at least 55 revision surgeries as of late 2017, (iv) Dr. Lemak had sent one of the Alabama Relators a text message that was forwarded to Carey Christensen, Exactech's VP of Sales for the Southeast Region, about Exactech's inaction in response to his repeated requests for an explanation and a review of cases, and (v)

numerous other related complaints regarding tibial loosening conveyed by one the Alabama Relators.

105. The Alabama Qui Tam Action also alleged a pattern of misconduct by Exactech and its management, led by Defendant William Petty. The Alabama Qui Tam Action, *inter alia*, alleged: (i) the Relators included an orthopedic surgeon with over 20 years' experience who had been employed by Exactech from 2006-2011 and two former Exactech sales representatives, (ii) multiple surgeons whose patients experienced Exactech's Finned Tibia Tray defects, reported device failures to Exactech and required revision surgery, (iii) a misleading course of practice to cover up Exactech's tibial loosening problems, (iv) that Exactech's then-CFO, Jody Phillips (who continued as CFO until 2020) had refused to recall the Finned Tray and advocated continuing to sell the defective device because recalling it would be economically damaging to Exactech, (v) Exactech offered numerous surgeons illegal remuneration in the form of consulting agreements to buy their silence and retain their business after their patients had suffered a failed knee replacement and required a revision surgery, and (vi) an ongoing scheme by Exactech to provide inaccurate or misleading information surgeons, patients and the government that continued up until and after the TPG Acquisition.

106. The Alabama Qui Tam Action made it clear, what should have been known by TPG all along, *inter alia,* that there were significant discrepancies between Exactech's due diligence representations and reality, including that: (i) Dr. Lemak's initial revision surgeries began in 2014 and lasted through 2015 (not 2011-2013, as TPG had been told), (ii) Dr. Lemak had performed at least 55 revision surgeries as of late 2017, far more than the 5-6 reported to TPG during due diligence, and (iii) Exactech failed to disclose Dr. Lemak's messages to Carey Christensen, Exactech's VP of Sales for the Southeast Region.

107. Exactech's scheme to mislead and conceal, led initially by Defendants William Petty and David Petty, extended to trying to suppress information about revision surgeries to doctors, and to publicly disclose inaccurate revision rates, a practice which would continue in the years ahead, during TPG's control. As alleged herein, TPG also materially exacerbated the harm to patients by virtue of its own misconduct.

108. Exactech was well aware of a major de-bonding problem and other related instances of aseptic loosening, which Mr. Binder and others at TPG would become aware of shortly after the TPG Acquisition. In August 2014, in response to complaints about aseptic loosening (*i.e.,* where the implant becomes loose without any infection being present), including specific inquiries as to whether Exactech had

received any complaints regarding "bone cement de-bonding issues" and whether Exactech had any "special instruction" to avoid aseptic loosening, Exactech Vice President for Marketing of Knee Systems Joseph Pizzurro ("Pizzurro") (who would play a similar role in efforts to deceive other surgeons, such as [redacted]) claimed, disingenuously, that "aseptic loosening is very rare." In fact, as Dr. Petty and David Petty were aware, Exactech would be notified repeatedly about incidents around the world of aseptic loosening, which appears to have been caused, *inter alia*, by a design flaw that Exactech's management refused to publicly acknowledge.

109. In November 2015, Mr. Pizzurro, responding to yet another "de-bonding" incident, where the "[c]ement femoral component debond[ed] when removing the rest of the tibia components," claimed that he would "analyze the component."

110. In December 2015, Mr. Alvarez was notified by HSS that it had observed an Optetrak Logic knee femoral component that loosened and had a revision, where "there was almost complete debonding of the cement from the femoral component." In HSS's report, it notified Mr. Alvarez that it had retrieved the "component" and "the tibial tray has a lot of cement bonded to it and the surface …looks much rougher than the femoral component backside surface." HSS warned Mr. Alvarez, correctly, that "[t]oo smooth may not be good." HSS also suggested

that Exactech should "set a [surface Ra] range like you do on the trays," something which it does not appear that Exactech did in response. It does not appear that Exactech engaged in any form of quality control or quality review or other corrective measures in response to this specific warning in December 2015 that femoral de-bonding might be tied to improper surface roughness. This HSS warning to Mr. Alvarez would prove to be extremely prophetic, since, as the Committee discovered during its investigation in the Exactech Bankruptcy Cases, Exactech had been improperly manufacturing femoral components with the wrong surface roughness and did not correct the manufacturing defect until November 17, 2021. In fact, the smooth surface and the detachment of cement from the femoral component were powerful evidence of a hazardous design defect or manufacturing defect, which Mr. Alvarez and others at Exactech (including Defendants William and David Petty) would recklessly disregard and later conceal from public disclosure and from proper disclosure to the FDA, surgeons and patients.

111. In 2017, Exactech also received seven (7) citations as a result of an FDA inspection. These citations (some issued during TPG's due diligence in connection with the TPG Acquisition) were issued due to, among other violations: delayed reporting on events that resulted in serious injury or death; design and

corrective procedures being inadequate/non-existent; and lack of procedures to ensure that all purchased/received products conformed to specified requirements.

112. In July 2017, [redacted], a prominent Maryland surgeon who, as noted, had been the keynote speaker at the 2013 and 2014 national sales meeting of Exactech, learned, to his shock, during a revision procedure that a patient's Exactech Optetrak Logic polyethylene component had completely deteriorated within three years of implantation.

113. [redacted], and reported to Exactech, two other patients whose implanted Exactech Optetrak Logic devices showed significant and premature wear of the Optetrak Logic polyethylene component and who also had elevated titanium blood levels and suspected osteolysis.

114. On August 4, 2017, HSS advised Dr. Gary Miller of Exactech of a "badly worn GXL acetabular [(hip)] insert" that "seems to have experienced considerable oxidation, more than what we've seen in other crosslinked polyethylene from other manufacturers." This appears to have been the first of the HSS oxidation complaints.

115. By [redacted] told Exactech's Mr. Pizzurro that the catastrophic premature polyethylene wear was a widespread problem impacting all Exactech patients who received the Optetrak Logic system. [redacted] urged

Exactech to take Optetrak Logic "off the market." While Mr. Pizzurro was on notice of other material problems with the Exactech Knee Devices, it does not appear that he disclosed them to [redacted].

116. After this October 2017 conversation, Mr. Pizzurro and Exactech Director of Knee Engineering Laurent Angibaud (who was involved repeatedly in Exactech efforts to mislead surgeons and regulators, working closely with Mr. Binder following the TPG Acquisition) met with [redacted] and falsely represented to [redacted] that Exactech would perform a meaningful investigation into failures of the polyethylene liners used in the Optetrak Logic (the "Optetrak Logic Polyethylene").

117. [redacted]

[redacted]

118. On November 8, 2017, given the series of revisions that he had observed and his concern that senior management and the founders of Exactech needed to pull the Optetrak Logic Polyethylene device immediately off the market, [redacted] sent an email to the founders and corporate officers of Exactech, including founder and Executive Vice President Gary Miller, founder and Executive Chairman Dr. William Petty, Chief Executive Officer David Petty and the entire Knee Engineering Team and informed these engineers and corporate officers that the Optetrak Logic Polyethylene was a major problem, causing catastrophic failure and that Exactech needed to pull the product off the market and fix the problem.

119. While [redacted] further emphasized his concerns to Mr. Pizzurro and Exactech engineer Anil Matura ("Matura"), [redacted]. Despite Exactech's actual knowledge that such device was woefully defective, causing catastrophic failure, revision surgeries and irreversible bone loss in patients, Exactech continued to sell the known defective

device to surgeons, hospitals and government healthcare programs solely because issuing a recall would be financially detrimental to Exactech and, in particular, the Pettys, who wanted the personal gain that would come from TPG's acquisition of the company.

120. While it does not appear that Exactech's management disclosed to TPG during due diligence the specific concerns raised by HSS [redacted], Mr. Binder and TPG learned of all such concerns raised by [redacted] after the TPG Acquisition. Post-acquisition, Mr. Binder became actively involved in directing efforts to prevent both [redacted] and HSS from getting to the root cause of the product defects.

IV. TPG'S INTEREST IN THE COMPANY

121. TPG began investing in the orthopaedics space prior to its Exactech investment. Specifically, affiliates of TPG Capital orchestrated Zimmer's acquisition of Biomet, an effort headed by some of the same TPG team that directed the TPG Acquisition and directed Exactech thereafter.

122. After Mr. Hann was forced out of Biomet for his involvement in an illegal options back-dating scandal, Mr. Hann became a TPG consultant, reporting to Messrs. Tepatti and Garrison. On April 4, 2017, Mr. Hann directly contacted Exactech's CEO and President, about a possible meeting with members of Exactech's management team. On this call, Mr. Hann disclosed that "certain

partners affiliated with TPG wanted to meet with Exactech to discuss potential strategies that could capitalize on *certain issues* affecting Exactech and others in the industry due to the consolidation of, and cost reduction initiatives by, certain of Exactech's competitors." Mr. Hann and Mr. Binder travelled to Florida for an introductory meeting with Dr. Petty on or about May 1, 2017.

123. Over the ensuing months, first Mr. Hann and Mr. Binder (who was a senior advisor to TPG at the time and remains so today) and thereafter Mr. Binder and Mr. Sisitsky (then "Managing Partner of TPG Capital North America"), met with members of Exactech's executive team. By on or about June 21, 2017, Mr. Binder and Mr. Sisitsky had a TPG outline of potential transaction opportunities. Thereafter, members of Exactech's senior management team recommended "a potential transaction with TPG and/or one of its portfolio company affiliates … at a robust premium," "with Hann and Binder … involved as advisors."

124. TPG Capital also stressed how important it was that Mr. Binder, who had previously been CEO of Biomet (a competitor of Exactech) play "a central role in any potential transaction[.]" TPG wanted Mr. Binder to join Exactech as the eyes and ears of TPG.

125. TPG Capital claimed that Exactech needed to accelerate its consideration of a transaction due to Mr. Binder's allegedly uncertain availability

because [redacted]

TPG urged Exactech's management to move "promptly so as not to jeopardize … Binder's availability to play a central role in … [Exactech]."

126. TPG's indication of the importance of Mr. Binder's involvement in the acquisition demonstrates that TPG wanted to ensure that one of its key consultants and advisors—Mr. Binder—would be able to join and direct Exactech management. As noted, Mr. Binder was paid a $1 million success fee by TPG when the acquisition closed.[13]

127. Meanwhile, TPG Capital continued to tout its knowledge of Exactech's industry-specific challenges and its expertise in investing—and running—healthcare companies after their acquisition. When Mr. Hann had first approached Exactech, he had emphasized TPG Capital's knowledge of "issues affecting Exactech and others in the industry," and Exactech had met with him precisely because it thought "it would be productive to discuss conditions and trends in the industry with an industry leader whose experience it both trusted and respected."

128. Later, Mr. Hann, Mr. Binder, and Mr. Sisitsky showcased TPG Capital's past healthcare investments and tried to demonstrate their familiarity with

[13] While at his deposition in the Bankruptcy Cases he initially disclaimed receiving such a $1 million fee, when confronted with TPG documentation that he had received such $1 million fee, he finally conceded that he had received it.

not just the orthopedic industry but with Exactech. At an August 17, 2017, meeting with Exactech's management team and certain independent members of its board of directors, TPG Capital presented "a comprehensive overview of its investment portfolio in the healthcare industry."

V. TPG'S DUE DILIGENCE

129. In August 2017, TPG launched its formal due diligence investigation of Exactech.

130. As detailed herein, while it appears that Exactech founders, including Defendants William Petty and David Petty (who were material beneficial Selling Shareholders, as defined herein) attempted to hide from TPG the full scope of the claims and product liability Exactech faced, TPG nonetheless identified during due diligence numerous critical and material red flags. TPG elected to proceed with the acquisition notwithstanding the red flags it had identified. This enabled the Company's insiders and the Selling Shareholders to extract hundreds of millions of dollars in cash from a Company that arguably was insolvent in February 2018.

A. TPG Saw, and Disregarded, Material Red Flags

131. On August 24, 2017, Messrs. Tepatti and Garrison received documents from Exactech's CFO, Jody Phillips, related to Exactech's (i) Sales by Market and by Product Line; (ii) CAPA listings, and (iii) recall history 2012 to current.

132. Operational meetings followed on August 29 and 30, 2017, by and among various TPG advisors and Exactech's Vice President, Regulatory and Clinical Affairs, Director, Regulatory Affairs; Senior Director, Manufacturing Operations; and Senior Manager, Quality Engineering. At these meetings, TPG Capital's representatives reviewed Exactech's "regulatory affairs, clinical research and quality and manufacturing operations."

133. On September 2, 2017, Mr. Binder received a due diligence report prepared at his request by Robin Barney, whom Mr. Binder would later hire to serve as SVP, Operations of Exactech. The report explained that Exactech's quality system had not "kept pace with current industry customs." While the report made no specific reference to the supplier of Exactech's vacuum bags missing an additional oxygen barrier layer consisting of EVOH, it does not appear that TPG or its advisors conducted any due diligence interview of such a critical supplier, nor visited the supplier's warehouse, which was located approximately 15 minutes from Exactech's Florida headquarters.

134. TPG also got access, it appears, during its due diligence, to the results of the FDA's March 2017 inspection of Exactech, which resulted in seven critical observations. During this inspection, an FDA investigator found Exactech had no established procedures for receiving, reviewing, and evaluating complaints by a

formally designated unit. The FDA also found that Exactech had no requirement or definition of good faith effort to obtain full complaint details in its complaint handling procedures. According to a report prepared by Robin Barney for Mr. Binder, "the sheer number of 7 [critical observations] and that several of them point to gaps into key quality sub-systems such as CAPA [corrective and preventive actions], Complaints, and Design Control, make it a serious FDA audit." In the same report, Ms. Barney highlighted: "the biggest gap in supplier quality is the lack of regular audits. […] This approach to supplier quality does not meet industry standards." Ms. Barney's report was forwarded to the rest of the TPG deal team the next day, September 3, 2017, making key decision-makers at TPG (*e.g.,* Messrs. Sisitsky, Schilling, and Garrison, each of whom would become directors of the Exactech and Osteon Holdings Boards following the TPG Acquisition) aware of deficiencies requiring immediate attention.

135. Exactech also failed to include the results of specific investigations in medical device reports ("MDRs") and failed to send the FDA supplemental MDRs to make the FDA aware of the investigations' conclusions. 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." 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.

136. TPG, however, had access to these FDA reports during its merger diligence process. TPG and its advisors, including Mr. Binder, were therefore on notice of this patent deficiency in Exactech's FDA reporting practices prior to consummating the TPG Acquisition.

137. On September 8, 2017, Mr. Sisitsky called Dr. Petty to inform him that TPG intended to submit a non-binding indication of interest with respect to a proposed transaction to the Exactech Board.

138. At a September 13, 2017, meeting of the Exactech Board, TPG, led by Messrs. Sisitsky, Binder, Schilling and Garrison, presented a written non-binding indication of interest to acquire 100% of Exactech's outstanding common stock for $39.00 per share in cash (the "TPG LOI").

139. On September 14, 2017, Dr. Petty advised Exactech's longtime banker, J.P. Morgan ("JPM") that Exactech had "been in discussions with … Sisitsky," and the Exactech Board now "contemplate[d] a public to private transaction with TPG."

140. On October 14, 2017, Mr. Tepatti of TPG noted that Mr. Binder and Mr. Schilling "are hyper focused on understanding what appears to be an uptick in

knee revisions from Osteon [*i.e.,* Exactech] products." Mr. Binder requested follow up from Exactech's management regarding "revision rates in France."

141. [redacted]

142. In fact, not disclosed [redacted], *inter alia*, was that Exactech had offered Dr. Lemak a "consulting agreement" to buy his silence, that Exactech had lied to Dr. Lemak about its awareness of other complaints, and that as of late 2017, Dr. Lemak had performed approximately 55 revision surgeries on patients (not "5 cases+").

143. Critically, moreover, TPG's advisors had identified a lawsuit that recently had been filed against Exactech in federal court in the Northern District of Alabama, in which serious allegations had been raised regarding Exactech product defects. The lawsuit, named *Talley vs. Exactech, Inc., et al.,* alleged, *inter alia*, (i)

Exactech had been aware since as early as April 2008 of a "high rate of early failures with the 'finned' Optetrak products," (ii) Exactech "made the decision not to recall, stop selling, or otherwise change the warnings for the affected devices until there [was] a su[it]able replacement approved for the U.S. market," (iii) in 2013 there had been "complaints made includ[ing] for 'tibial loosening' just two years postoperatively, 'revision due to tibial loosening,' 'during revision, the tibial component was found to be loose and easily removed', 'revision of knee component due to loosening, 'revision due to pain and suffering,'" (iv) similar complaints for 2014, including revision due to "aseptic loosening," and (v) Exactech conduct in engaging in "a campaign of misinformation where any incidents of early onset failure were blamed on surgeon specific factors instead of admitting to any issues with the finned product itself." [redacted]

[redacted]

144. TPG, including Defendants Binder, Schilling, Sisitsky, Tepatti, and Garrison, were informed of the complaints raised in the *Talley* lawsuit, such as the "silent recalls" and increase in complaints by documents provided by Exactech during the due diligence process. In response, Mr. Schilling was particularly dismissive of these facts and appears to have endorsed the false "blame-the-surgeon" excuse of Exactech's then-management, commenting in an October 15, 2017 email, that "there are a lot of bad doctors out there." It does not appear that TPG, though put on actual notice of complaints identified in the *Talley* action that echo many of the complaints that would be thereafter asserted in the Alabama Qui Tam Action, took any steps to get to the bottom of or conduct other meaningful due diligence pre-closing of the issues that its advisors had identified through the *Talley* action and other red flags that had been spotted.

145. Exactech did appear to have filed, prior to the TPG Acquisition, some adverse events reports (containing limited information) with the FDA referencing [redacted], and such reports were publicly available to TPG, which does not appear to have contacted [redacted] or dug deeply pre-Acquisition [redacted].

146. During due diligence, TPG gained knowledge of surgeon/market perceptions which gave more than sufficient reasons for additional concern (or, at the very least, reason for a more thorough investigation, as the TPG LOI already promised). In a document prepared by TPG during due diligence, based purely on "selected … commentary," neutral and negative opinions predominated promoters' positive opinions as to shoulder products of Exactech and the large joint products of Exactech and other small players.

147. As to shoulder products, detractors described Exactech's implants as "complicated" and its "technology" as "limited compared" to Stryker's Tornier line. As to large joints, Exactech was criticized for "[l]ack of availability"—and for "[n]o longer innovating." A third comment highlighted a potential structural issue: "Osteon [*i.e.,* Exactech] does not have a constrained cup, which makes me nervous in some patient cases and ultimately drove me to use Biomet in those instances." This snapshot, notably, represented commentary TPG had chosen to highlight.

148. Ultimately, TPG and Exactech agreed on a $49.25 per share acquisition price, and the Agreement and Plan of Merger (as subsequently amended and supplemented, the "Merger Agreement") was entered into on October 22, 2017, amended on December 3, 2017, and closed on February 14, 2018.

149. As of February 14, 2018, however, the Company's liability for defective products exceeded the value of its assets and rendered the Company likely insolvent.

B. Mr. Binder Receives $1 Million Success Fee

150. Notably, Mr. Binder was paid a $1 million success fee by TPG, which appears to have been for TPG's acquisition of Exactech. While at his deposition in the Exactech Bankruptcy Cases he initially falsely disclaimed recollection of receiving such a $1 million fee, TPG documents confirmed such a payment was made to him for the TPG Acquisition, with Mr. Binder it appears providing an "invoice" to TPG for such $1 million payment two days prior to the February 14, 2018 closing. At his second deposition in the Exactech Bankruptcy Cases, confronted with such evidence, Mr. Binder finally admitted to having received the $1 million fee.

151. [redacted] These success fees made Mr. Binder [redacted] further beholden to TPG and to protecting TPG's interests, at any cost.

VI. TPG ACQUIRES THE COMPANY

152. As a result of the TPG Acquisition, among other consideration, Defendant William Petty received over $46 million, and Defendant David Petty received over $2.8 million.

153. Although Exactech had maintained a positive cash flow prior to the TPG Acquisition, it incurred substantial debt as a result of the TPG Acquisition, and by early 2018, shortly after the Merger, had expressed internal concerns whether it would be able to service its debt burden. This became an ever-increasing concern for TPG, as it sought to figure out an exit from Exactech as problems mounted at the Company. Post-Merger, Exactech was saddled with over $200 million of secured debt, and was under severe financial pressure by 2019. By 2019, Exactech was operating with consistently negative cash flow and had over $380 million of liabilities, an increase of total liabilities of over $300 million since 2016. As alleged herein, once TPG's efforts to exit its investment failed, and its efforts to delay or limit recall notices failed, leading to a flood of lawsuits and regulatory investigation of TPG and TPG's efforts to hide or obscure its actual role in Exactech's device failures and misconduct in the recall process, TPG forced Exactech into bankruptcy in a final "Hail Mary" effort to secure a cheap release for TPG's billion dollar liability. That ploy would fail as well, as alleged herein.

VII. TPG'S CONTROL AND DOMINATION OVER EXACTECH AND ITS SHAM OSTEON ALTER-EGOS.

154. In February 2018, TPG gained complete "ownership and financial control" of Exactech upon consummation of the merger. But TPG sought to exercise domination over all aspects of Exactech's business. Indeed, TPG's level of control

ran afoul of the basic principles of corporate separateness and, as even TPG and its counsel conceded, ultimately exposed TPG to veil piercing and alter ego and other liability. As alleged herein, there existed virtually no distinction between TPG (as the dominant shareholder), the Parent Osteon Holdings, Inc., Osteon I and II, and Exactech. Through such control, TPG used Osteon/Exactech for an improper purpose by, *inter alia*, directing a scheme to improperly delay recalls in an effort to hide product defects and facilitate sale of defective products (resulting in thousands of revision surgeries) and ultimately driving these entities in a Chapter 11 bankruptcy to attempt to evade liability, causing harm to thousands of creditors and Exactech's estate.

155. As alleged herein, TPG obtained complete domination and control of Exactech, *inter alia*, by: (i) putting TPG partners, advisors, and loyalists in four of the six seats of Osteon Holdings, Inc.'s and Exactech's Boards of Directors, and years later hand-selecting Exactech's so-called "independent" directors to fill additional seats; (ii) ensuring that TPG retained the majority of the Boards of both Exactech and Osteon, including majority voting power on all key company decisions, including who should sit on or who could be removed from the Board of Exactech or Osteon; (iii) installing a senior TPG advisor (Mr. Binder) as Co-Executive Chairman, and thereafter as Executive Chairman and CEO of Exactech,

and otherwise populating Exactech senior management with TPG loyalists and employees; (iv) creating additional shields of attempted limited liability in the form two additional intermediate sham entities of Osteon I and II for the sole apparent purpose of attempting to protect TPG shareholders from liability; (v) using numerous other avenues of managerial and operational day-to-day control over effectively all corporate actions; and (vi) critically, engaging in complete control over Exactech's 2021 recall strategy which failed miserably, harming patients, and further exacerbating Exactech's tort liabilities.

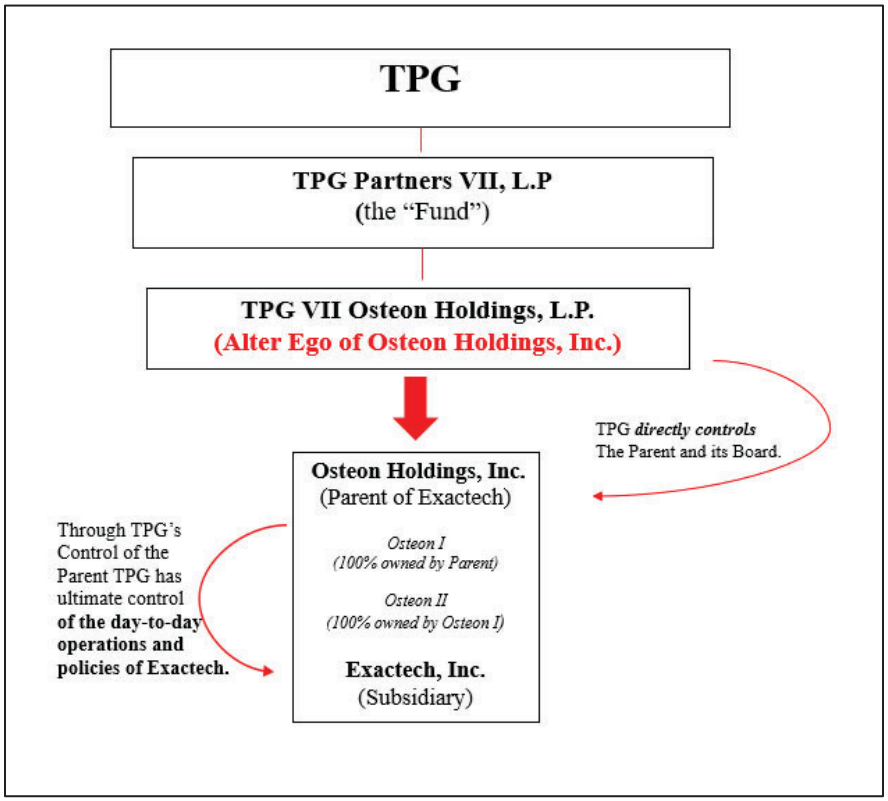
A. The "Blurred Line" Between TPG and Exactech

1. TPG was an Alter Ego of Exactech's Parent Osteon Holdings, Inc.

156. From February 2018 until October 2024, TPG, through TPG VII Partners L.P. (the "Fund") and TPG VII Osteon Holdings, L.P. ("the Sponsor") (collectively the "Lead Investors"), acted as an alter ego of Exactech's immediate parent Osteon Holdings, Inc. ("Osteon Holdings") which was a shell entity utilized solely to attempt to insulate TPG from all liability arising from its domination, control, and improper use of Exactech.[14]

[14] In internal documents, Osteon Holdings, Inc. is often referred to as "Holdings" or "Holdco" or "topco." Further, for simplicity, unless otherwise stated, Osteon Holdings, Inc., Osteon I, and Osteon II are collectively referred to as the "Osteon Entities."

157. Control of Osteon Holdings, Inc. was critical to TPG. Control of Osteon Holdings meant complete control of Exactech because these entities were indistinguishable from one another. As discovery has confirmed, TPG strategically and carefully orchestrated the below corporate structure to ensure TPG's control ran through its Fund; then to TPG VII Osteon Holdings, L.P; and ultimately Exactech, by positioning itself as the dominant shareholder and alter ego of Osteon Holdings:



158. As reflected above, TPG, its Fund, and the Sponsor gained control of Osteon Holdings (which directly and wholly owned the shells Osteon I and II) and

Exactech.[15] As a result, TPG maintained the right to appoint and fire any director of Exactech and Osteon Holdings. [redacted]

159. In fact, TPG as the "Lead Investors" through their control of Osteon Holdings had the unchecked power to name directors to and/or remove directors from the Board of Directors of both Osteon Holdings and Exactech, even over the rights of any Exactech representatives. Under the Osteon Holdings, Inc. Shareholders' Agreement dated February 14, 2018 (the "Osteon Holdings Shareholders' Agreement"), TPG held the power to dictate the majority of the Osteon Holdings Board of Directors, and consequently the Exactech Board. Per the Agreement, the number of directors for the Board for Osteon Holdings, Inc. was "fix[ed]" at the number so specified "by the Majority Lead Investors", *i.e.* TPG VII

[15] Osteon I and Osteon II serve no obstacle to piercing the corporate veil of Osteon Holdings. As mentioned in a June 2023 internal email, both Osteon Intermediate Holdings I and Osteon Intermediate Holdings II are parents to Exactech and neither have [redacted] The entities were [redacted]

Osteon Holdings, L.P. The Agreement also guaranteed only one "Exactech representative" on the Osteon Holdings Board. But such Exactech representative could only appoint a new board member "after consultation with the Lead Investor," *i.e.*, TPG. Thus, the Agreement guaranteed that at no time would any organization except for TPG have majority control of the Osteon Holdings Board. The Agreement appointed, effective Febuary 14, 2018, Defendants Jeff Binder (TPG Senior Advisor), Todd Sisitsky (TPG Affiliate), John Schilling (TPG Affiliate), Kendall Garrison (TPG Affiliate), William Petty and David Petty as the members of the Osteon Holdings Board.

160. At all times, Exactech understood that Osteon Holdings ***was*** TPG. In an April 2018 Confidential Memorandum sent to select Exactech employees following the merger, TPG admitted "[t]he Investors [TPG] …have the ultimate ability to control the policies and operations of Holdings [Osteon] and its subsidiaries [Exactech]." From 2018 through immediately prior to filing for bankruptcy, the Osteon Holdings and Exactech Boards were, as noted, indistinguishable. The Boards met together, had the exact same members, and the Osteon Holdings Board was dominated and controlled by TPG affiliates and appointees. The Osteon Holding Board was the Exactech Board and vice versa.

161. Likewise, [redacted]

2. Lack of Separateness Between Osteon Holdings, Inc. and Exactech

162. At the lowest level of the corporate chain, the corporate veil shielding TPG VII Osteon Holdings L.P. is ineffective and should be pierced because, *inter alia*, the following facts now show that Osteon Holdings, Inc. and its subsidiary Exactech were not kept separate and were often held out as one single entity:

- ***Operations not Kept Separate*** – As TPG admits in an internal memorandum dated April 27, 2018, "Holdings [Osteon Holdings, Inc.] exists as a 'shell' holding company whose profitability, if any, depends entirely upon that of Exactech" and "Holdings will have no assets, liabilities, or income that would differentiate its financial condition from…the financial statements of Exactech in any material respect."

- ***Common Stock Ownership*** **–** In the same memorandum, TPG confirms that "Holdings [*i.e.,* Osteon Holdings, Inc.] owns 100% of Exactech common stock…" and the Investors [*i.e.,* TPG] hold a substantial majority of Holdings' outstanding capital stock."

- ***Common Directors and Officers*** – From February 2018 until November 2023, there was no distinction between Osteon and Exactech's Board of Directors, which comprised of: Jeff Binder (TPG affiliate); Todd Sisitsky (TPG affiliate); John Schilling (TPG affiliate); Kendall Garrison (TPG Affiliate); David Petty (Exactech); and William Petty (Exactech) (replaced by Darin Johnson in 2020 when William Petty retired). Beginning in January 2021, additional purported "independent directors" were added to both Osteon and Exactech's board which included Karen Golz, Gwen Bingham, and Diana Nole. In November 2023, Ms. Elizabeth Abrams was the first board member to ever be appointed to the Exactech Board but not the Osteon Holdings Board. [redacted]

- ***Consolidated Financial Statements and Tax Returns*** – [redacted] Likewise, in April 2021, as reflected in a draft S-1 statement filed with the SEC when TPG was trying to take Exactech public, it was represented to the SEC "that "we," "us," "our" are intended to mean the business and operations of Osteon Holdings, Inc. and its consolidated subsidiaries" while referencing numerous financial statements based on Exactech's sales and revenue.

- ***Subsidiary Operates with Grossly Inadequate Capital*** – Prior to the TPG Acquisition, Exactech appeared to be maintaining positive cash flows and its assets outweighed its liabilities. [redacted] Indeed, on October 29. 2024, Exactech did file for Chapter 11 Bankruptcy recognizing "they would be unable to continue generating sufficient levels of

operating cash flows in the ordinary course of business to meet their pre-petition debt obligations and operate the business."[16]

- ***Corporate Formalities*** – As alleged herein, Osteon Holdings, Inc. at all times was a shell entity that adhered to virtually zero corporate formalities. In addition to a complete blurring of the lines regarding the Board, Osteon and Exactech shared the same corporate address, books, records, and kept board minutes reflecting meetings of the "Board of Directors of Exactech" which comprised of individuals who were Directors on both Exactech and Osteon's Board (*i.e.,* a March 3, 2021 minutes entry notes "a videoconference of the Board of Directors of Exactech, was held…Directors on the call were Jeff Binder, Todd Sisitsky, Kendall Garrison, John Schilling, and David Petty) (all of whom still held seats on Osteon's board).

- ***Commingling of Funds*** – As conceded by counsel to the Special Committee of Exactech's Board during the Bankruptcy Cases, Osteon Holdings, Inc. and Exactech also commingled bank accounts and finances through at least 2021. This also reflected a lack of corporate formalities.

- ***Same Creditors*** – In Exactech's bankruptcy proceedings, Osteon Holdings, Inc. filed the exact same list of 30 largest creditors as Exactech and identified the exact same quantum of liabilities and estimated creditors as Exactech.

- [redacted]

163. Thus, the above facts alone, irrespective of TPG's day-to-day control of Exactech and other facts as alleged herein, support, at a minimum, piercing the corporate veil of Osteon Holdings, Inc. to reach the Sponsor TPG VII Osteon

[16] *See* Bankruptcy Docket 18, Declaration of Jesse York at pg. 28, ¶ 65 (dated October 29, 2024).

Holdings, Inc., the Fund, and ultimately TPG for the purpose of holding TPG liable for all harm caused to Exactech's estate and its creditors.

3. Veil Piercing Admissions by Exactech and TPG's Counsel and Employees.

164. Following Exactech's recalls initiated in the summer of 2021 and the significant increase in litigation seeking to hold Exactech and TPG responsible for Exactech's enormous product liability related debts, TPG and Exactech's ***own*** counsel and employees expressed serious concern with respect to the "blurred" boundaries between Exactech and TPG, and the risk of veil piercing.

165. [redacted]

[redacted]

166. [redacted]

[redacted]

17 [redacted]

[redacted]

[redacted]

167. Moreover, [redacted], and the MDL Plaintiffs pursued alter ego/veil piercing claims against TPG in the MDL, [redacted]

In subsequent correspondence, which was cited thereafter by the Delaware Bankruptcy Court as "evidence recogni[zing]…the adversity by Exactech and TPG," TPG's own counsel expresses caution against providing ***"evidence of the blurred line between Exactech and TPG."*** [18]

4. TPG Controls the Exactech Board of Directors

[18] *See* May 20, 2025 "Letter Ruling on Further Discovery Disputes" by Judge Silverstein, at p. 2 & n.1 (*Exactech, Inc. et al*, Case No. 24-12441, Doc. 1183).

168. In 2018, immediately after the TPG Acquisition, TPG appointed Mr. Binder as Co-Chairman of the Exactech Board alongside Dr. Petty. At that same time, TPG appointed TPG senior partners Messrs. Garrison, Sisitsky, and Schilling to the Exactech Board. From 2018 through 2021 the total number of TPG Exactech Board members was no less than four (4), with only two (2) Exactech representatives. TPG "loyalists" held control of and dominated the Osteon Holdings Board (and consequently, the Exactech Board) from the TPG Acquisition and thereafter. In 2024, TPG internally acknowledged holding as many as six "TPG Board Seats" for an extended period at Exactech.

169. In 2018, TPG appointed Messrs. Garrison and Schilling as the sole members of the Exactech Audit and Compliance Committee. Messrs. Schilling and Garrison served on that committee from 2018 through at least late 2024. No non-TPG member served on that committee until 2021.

170. [redacted]

[redacted]

171. Not wanting to lose control but wanting to create the false appearance of independence for the IPO, TPG hand-picked and appointed three so-called "independent" directors in 2021. None of the three was in fact "independent." TPG selected and appointed these so-called independent directors.[19] The process by which they were selected underscored that they were not "independent" at all. Contemporaneous internal records reflect TPG's control of this process. [redacted]

[19] Diana Nole ("Nole"), Gwen Bingham ("Bingham"), and Karen Golz ("Golz" together with Nole and Bingham, the "TPG Appointed 'Independent' Directors") were each appointed by TPG as members of the Osteon Holdings Board of Directors in January 2021. Each served as members of the Osteon Holdings Board of Directors from 2021 through the Bankruptcy Cases. While it is unclear whether Nole, Bingham or Golz were ever formally appointed to the Board of Exactech, they acted as *de facto* Board members of Exactech at relevant times.

[redacted]

172. TPG appointed these "independent" directors, therefore, under the Osteon Holdings Shareholders' Agreement, which provided that TPG and TPG alone had the authority to remove these "independent" directors.

173. The new board members knew that TPG controlled the Exactech Board. Ms. Golz, one of the new board members [redacted]

174. From January 2021 forward, these three new "independent" directors were listed as members of Exactech Board on each of the Exactech Board meeting minutes. However, [redacted] The record suggests that, in fact, these three purported "independent" directors were never actually formally appointed as members of the Exactech Board, until November 2023 when TPG began the process of attempting to retroactively rewrite corporate history and create

a false illusion of board separateness after TPG had been sued in the MDL as the alter ego of Exactech.

175. But even the appointment of these new "independent" directors did not lessen TPG's complete control and domination over Osteon Holdings and Exactech. After appointing these "independent" directors, [redacted]

176. Exactech confirmed in its Board meeting minutes on May 6, 2021, that [redacted]

[redacted]

177. [redacted]

178. [redacted], TPG controlled the Board of Osteon Holdings, the shell company created for the appearance of being a purported corporate layer between TPG and Exactech. Contrary to this appearance, TPG, in fact, manipulated the Exactech Board through its control of the Osteon Holdings Board. From 2018 through late 2024 there was no effective difference between the Osteon Holdings Board and the Exactech Board. The Boards always met at the same time and shared members. While TPG would attempt to reinvent history and claim that the Exactech Board and the Osteon Holdings Board had separate members and existence and that TPG members did not serve on the Exactech Board, that was contrary to the factual record. Numerous contemporaneous board meeting minutes and the [redacted] makes clear that the Exactech Board at all relevant times was the Osteon Holdings Board and that the same Board members acted in a capacity as Board members of both entities. And at all relevant times, TPG dominated and controlled that collective Exactech Board.

179. The Exactech Board and the Osteon Holdings Board were at all relevant times one and the same. The same membership is reflected throughout contemporaneously kept Exactech Board meeting minutes, written consents, and resolutions. [redacted]

[redacted]

180. [redacted]

[redacted] the problems with Exactech's failure to follow corporate formalities at Exactech, especially with respect to the Boards of Osteon and Exactech being one and the same. At this time, TPG had already been sued as a Defendant in numerous lawsuits under alter ego and veil piercing theories to hold TPG accountable for the Exactech medical device failures. Such law firm, which had served as TPG's counsel in the acquisition of Exactech, was appointed by TPG as the Exactech and Osteon Holdings Entities' outside counsel in preparing for restructuring and throughout the Bankruptcy Cases. [redacted]

[redacted] an effort to attempt to retroactively, unsuccessfully create cosmetic separateness of the Boards of the Exactech Entities, including by appointing a new

director, Elizabeth Abrams, to the Exactech Board and the Osteon II Board. Ms. Abrams was the very first board member appointed to the Exactech Board directly, and not by way of the Osteon Holdings Board. But TPG controlled the appointment process for Ms. Abrams, just as it had done for the 2021 appointments of the "independent" directors. [redacted] Several weeks later, Ms. Abrams was appointed.

181. [redacted]

182. In July 2024, in preparation for Exactech's bankruptcy filing, TPG, which had been sued for alter ego liability in the MDL and had secured in March 2024 a dismissal by the MDL Court of the veil piercing/alter ego claim, nonetheless was anticipating that it might have exposure in any bankruptcy case to an estate

claim of alter ego liability.[20] TPG sought to concoct a new workaround to facilitate the broad estate release that it and its advisors sought via any Exactech bankruptcy.

183. Outside counsel, relying on the Osteon Holdings Shareholders' Agreement determined that TPG had [redacted] First, TPG directed the appointment of another "independent" director to the Exactech Board – Mr. Timothy Pohl to replace one TPG director Mr. Sisitsky. [redacted]

184. On [redacted]

[20] TPG well understood that under controlling Second and Third Circuit law, once Exactech filed for bankruptcy, the alter ego/veil piercing claim became property of the estate and could be pursued by the estate as an estate cause of action. TPG had good cause to be concerned about its exposure in the bankruptcy to a veil piercing claim, particularly since it had concealed material information from both the MDL Plaintiffs and the MDL Court, discussed herein, that underscored that TPG in fact had serious exposure for veil piercing/alter ego liability. TPG hoped to avoid such exposure by cutting a quick settlement with the Debtors that it controlled and attempt to secure a cheap estate release. That ploy, as discussed herein, failed.

[redacted] But there was a problem. Exactech and TPG's shared restructuring counsel identified that [redacted] In response, Exactech's general counsel admitted there was a [redacted] In fact, up through August 2024, Exactech's Annual Report filings show the Exactech Board as including the TPG board members. To attempt to reduce its veil piercing and alter ego exposure in connection with the anticipated bankruptcy proceeding, TPG attempted to retroactively "fix" the Exactech and Osteon Holdings board composition without admitting the fact that the boards were in fact identical for the relevant time periods of 2018 through 2023.

185. TPG, through outside counsel, then drafted a misleading [redacted]

[redacted] is also directly contradicted by the November 8, 2023 Written Consent of the Exactech Board by which Ms. Abrams was appointed to the Exactech Board. The November 2023 Written Consent clearly stated that "the board of directors of Exactech, Inc. consists of the following individuals: Darin Johnson, David Petty, Jeff Binder, Todd Sisitsky, John Schilling, Kendall Garrison, Diana Nole, Gwen Bingham, Karen Golz, and M. Elizabeth Abrams." The "whereas" clauses in the July 2024 Written Consent are an anomaly and make clear TPG's intent to retroactively and falsely attempt to rewrite the history of TPG's control of the Exactech Board. [redacted]

186. Critically, not only did TPG dominate the Exactech Board, but TPG ensured that its presence and control was felt at each board meeting by inviting TPG management and personnel to attend and present at board meetings. Eleven (11)

TPG employees, senior management, and advisors regularly attended Exactech Board meetings. By way example, at the October 15, 2020, Exactech Board meeting, Mr. Bolukbasi, who was "of TPG Capital" according to the minutes, presented on Exactech's finances, and he was asked questions during the meeting in particular by three TPG-appointed directors, Messrs. Binder, Sisitsky, and Schilling. Also, in attendance from TPG, at the Exactech Board's request according to the minutes, were Messrs. Tepatti, Yuan, and Chen of TPG.

187. TPG personnel not on the Exactech Board frequently attended Exactech board meetings that concerned product liability and regulatory compliance issues. For example, Mr. Tepatti, a TPG principal, attended over 30 Exactech Board or Exactech Audit and Compliance Committee meetings between January 2019 and September 2024. Messrs. Yasskin, Subhi Sherwell,[21] Michael Yuan,[22] and Fei Chen,[23] all of TPG, likewise attended many Exactech Board meetings, many of

[21] Subhi Sherwell ("Sherwell") began working at TPG in July 2010. Mr. Sherwell was a senior associate and then a vice president at TPG Capital's London office between July 2010 and December 2012 and January 2013 and July 2015, respectively. Thereafter, he served as senior advisor for field operations from September 2015 to December 2023, director for operations from January 2024 to December 2024, and managing director for operations from January 2025 to the Bankruptcy Petition Date. [redacted]

[22] Michael Yuan ("Yuan") was an associate at TPG Capital's healthcare group and TPG Strategic Partners between August 2019 and August 2022.

[23] Fei Chen ("Chen") has been a principal at TPG Capital since April 2017, and as of 2024 was a Vice President of TPG Capital.

which centered on the same issues: the Company's multiple liabilities, from the product recalls, product liability lawsuits, [redacted] and updates on packaging nonconformance and design defects.

5. TPG Controlled Key Management Positions of Exactech

188. At critical times, as noted, TPG exercised majority control of the Exactech Board. TPG controlled and dominated not only the Board but also the executive officers and key management roles.

189. In 2018, contemporaneous with the closing, TPG conveyed publicly to SEC regulators in a FORM D statement that **11 out of the 13 individuals listed as either "Directors" or "Executive officers" of Osteon Holdings, Inc. were TPG employees or affiliates**. TPG immediately appointed to Osteon Holdings, Inc. as executive officers Clive Bode, Michael LaGatta, Ken Murphy, Adam Fliss, Joann Harris, Steven Willmann, and Martin Davidson – all senior management at TPG.

190. TPG's advisors, such as Mr. Binder (Co-Executive Chairman), Mr. Bolukbasi (CFO and Executive Vice President), and Mr. Hann (Vice President, Business Development) were installed to run the day-to-day operations of Exactech.

191. Pursuant to Mr. Binder's June 29, 2015 Senior Advisor Agreement with TPG, which was amended as of March 6, 2018, shortly after the TPG Acquisition, at all relevant times Mr. Binder reported to three TPG personnel (Todd Sisitsky, Jeff Rhodes, and John Schilling), two of whom (Defendants Messrs. Sisitsky and

Schilling) served as directors on the Exactech Board with Mr. Binder. As noted, by August 2019, Mr. Binder's day-to-day control of Exactech was such that TPG, in an August 2019 Performance Report, described Mr. Binder as having "direct reporting control of Sales, Large Joints and Extremities BUs, Advanced Tech, & Bus. Dev. **Jeff now has day-to-day control of all commercial activities at Exactech**" (emphasis supplied). During that time, from 2018 to 2019 TPG (not Exactech) compensated Mr. Binder over $1 million for his work at Exactech. Defendant Mr. Johnson, Exactech's CEO, described Mr. Binder's "involvement" in 2020-2021 as "overwhelming" and "paralyzing."

192. The intertwined nature of Exactech and TPG at every level following the TPG Acquisition was pervasive. TPG embedded its personnel throughout the Exactech corporate structure: on the Board, in management, and closely interfacing with Exactech management otherwise. TPG dictated the Exactech Entities' financial policies, compensation of officers and certain directors, media strategy, and search for a chief executive officer.

193. Upon TPG's acquisition of Exactech, instead of taking prompt steps to determine the root cause of product failures, and take steps to protect patients through suspending further sales of such defective products, accurately reporting to the FDA the adverse events that were being reported to Exactech from surgeons and

others across the United States and elsewhere, or initiating prompt product recalls, TPG personnel, instead, assisted by TPG's installed directors and officers at Exactech, including Mr. Binder, took over and expanded the Exactech scheme to obfuscate, to blame the surgeons themselves and/or patients for product failures, and to focus on continuing to sell devices that should have been promptly subject to immediate, obvious root cause analysis, and recall.

194. The S-1 filing, as noted, which was submitted just prior to the slew of public product recalls emphasized TPG's control over Exactech's corporate decisions: **"As long as TPG owns or controls at least a majority of our outstanding voting power, it will have the ability to exercise substantial control over all corporate actions . . ."** and "**Even if [TPG's] ownership falls below 50%, TPG will continue to be able to strongly influence or effectively control our decisions." (Id.) It goes on to provide that "We are currently controlled by, and after this offering is completed will continue to be controlled, by investment funds affiliated with TPG."**

VIII. TPG USED ITS CONTROL OVER EXACTECH TO DIRECT EXACTECH'S COVER UP STRATEGY RELATED TO PRODUCT DEFECTS.

195. In mid-to-late 2021, Exactech was confronted with recall issues for its knee, hip, and ankle products. By that time, TPG (primarily through Mr. Binder and Mr. Schilling) had taken over all decision-making and completely dominated all

aspects of the recall process. But unlike the prior scheme employed by Dr. Petty and David Petty to provide misleading information to surgeons, patients, and the FDA to hide product defects, the seriousness of the failures and sheer magnitude of the scope of issues implicated in the 2021 recall was unprecedented in the Company's 30+ year history. TPG was aware of the problems and negative implications for its investment. TPG, however, ignored such risks, and through Defendants Binder and Schilling and others at TPG, was responsible, *inter alia*, for Exactech implementing a thoroughly inadequate and evasive recall strategy that involved concealment of the facts from surgeons, patients and the FDA, in an effort to forestall public disclosure of the actual extent and history of the problem and to facilitate continued sale of defective products to protect TPG's investment.

A. TPG's Discovery and Embracement of Pre-Acquisition Misconduct to Protect TPG's Investment

196. After TPG acquired Exactech, it quickly became aware of the full scope of product defect issues with the Exactech Devices and the regulatory issues facing the Company.

197. After the TPG Acquisition, as alleged, TPG and the Individual Defendants, including Messrs. Binder, Garrison, and Schilling, knew based on the Alabama Qui Tam Action that Exactech's conduct in response to Dr. Lemak's concerns disregarded the facts and would expose patients to surgical implants of

defective devices. TPG and the Individual Defendants, including Messrs. Binder, Garrison, and Schilling fully embraced, continued and expanded the pre-acquisition Exactech approach in order, *inter alia*, to protect TPG's investment in Exactech. [redacted] After the TPG Acquisition, TPG took over management of Alabama Qui Tam issues. TPG, now in charge of Company decision-making, refused to recall a defective devices and instead continued sales of such devices.

B. TPG's Post-Acquisition Misconduct Materially Increased Exactech's Liability

198. Following the TPG Acquisition, the FDA continued citing Exactech for certain violations – often the same type of violation – following inspections, *e.g.*, in January 2020 (inspection ID 1116804) and November 2021 (inspection ID 1158246). The available documentation suggests a chronic lack of prioritization and urgency in enhancing internal procedures. In particular, the four citations from the 2021 FDA inspection (discussed in greater detail below), conducted at a time when TPG was in complete control of the Company, highlight a clear lack of procedures and controls that could have prevented or, at a minimum, promptly detected the packaging non-conformity leading to Poly Recalls:

Figure 5: Citations from the FDA Inspection ended Nov. 17, 2021 (ID 1158246)

Related Act/CFR Number	Description of FDA Citation	Quotes from FDA Citation
21 CFR 820.30(h)	The device design was not correctly translated into production specifications.	"**Product requirements intended to prevent device oxidation** were not adequately translated into applicable production specifications." (Emphasis added).
21 CFR 820.75(a)	A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures.	"[I]t was disclosed during the inspection that **no process validation activities have been conducted since the manufacturing process was first implemented**. A total of approximately 1,405,000 finished devices have been manufactured with the vacuum sealing process since 02/2007 until present." (Emphasis added).
21 CFR 820.80(b)	Procedures for acceptance of incoming product have not been established.	"Vacuum bags utilized to seal devices during production consists of bags containing three seals produced by external supplier. A fourth seal is applied as part of routine production during the vacuum sealing process. Nevertheless, **inspections conducted during incoming inspection of the vacuum bags do not challenge the integrity of the seals produced by supplier.**" (Emphasis added.)
21 CFR 820.250(b)	Sampling plans are not based on valid statistical rationale.	"As per 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 1073 B Tyvek Pouches', dated '2/22/07', a population of samples

> tested for resulting device density was representative of only 3 device units at each given time point to be tested. **There is no documented evidence to justify that the sample size was based on valid statistical rational.**" (Emphasis added).

1. TPG Was Aware of the Concerns Raised by HSS and [redacted]

199. As explained herein, HSS and [redacted] began warning Exactech's pre-acquisition management (including Defendants William and David Petty) in 2017 about widespread problems with de-bonding (among other problems) impacting all Exactech patients who received the Optetrak Logic system and that the device should be taken off the market. Following the TPG Acquisition, TPG's appointed Chairman, Mr. Binder, was told directly by [redacted] in March 2019, of his warnings and the full history of prior management, including Dr. Petty and David Petty, ignoring the issue.[24] Despite being directly informed of the need to take the product off the market, TPG failed to take prompt, corrective action, thereby permitting defective products to continue to be marketed, sold, and implanted in people's bodies. While, as discussed herein, actively disparaging [redacted] to the

[24] As alleged herein, TPG was first informed of the HSS complaints related to catastrophic premature polyethylene wear in Exactech products in 2017, and again in 2018.

FDA as part of the scheme, *inter alia*, to provide inaccurate information to regulators and limit or delay any recall of Exactech's defective products.

200. Leading up to the TPG Acquisition, [redacted]

201. [redacted] (ironically, the same day the TPG Acquisition closed), [redacted].

202. On or about March 16, 2018, [redacted] advised Defendant Dr. Petty and others that a revision surgery he performed only 2 1/2 years after the original replacement showed significant distal femoral bone loss, **significant femoral loosening**, and significant polyethylene wear, and he suspected the cause concerned the Logic design or an issue with the polyethylene. While Exactech was aware that it had been receiving mounting complaints regarding femoral loosening tied to

cement that prematurely broke off the femoral component, [redacted] was not notified of these other complaints.

203. On or about December 6, 2018, [redacted] sent Mr. Matura (of Exactech) photos of a failed polyethylene that another renowned orthopaedic revision specialist surgeon had performed, and informed Mr. Matura of yet another patient who had experienced such rapid polyethylene failure that his femur had snapped while walking up a flight of stairs due to massive osteolysis, bone loss and bone weakening. The photos showed the patient's Optetrak Logic Polyethylene was shredded and completely delaminated – meaning the polyethylene debris was disbursed throughout the patient's knee. It appears that Exactech (which was at this point completely under the control of TPG) did not report the December 2018 revision and photos as adverse events or problem products to the FDA, in violation of the Medical Device Reporting requirements, and there continued to otherwise be a lack of any meaningful response by Exactech.

204. On March [redacted], 2019, [redacted], aware that TPG had acquired Exactech and had appointed Mr. Binder as Co-Executive Chairman, reached out directly to Mr. Binder, hoping that the TPG-installed Co-Executive Chairman would be more receptive than the stonewalling and misdirection he had received over the prior two years from Exactech's prior senior management. As discussed below, [redacted]

provided Mr. Binder with all the information noted above that [redacted] had previously shared with Exactech's senior management.

205. By March 2019 at the latest, therefore, Mr. Binder was fully aware of all of [redacted] concerns.

206. Given [redacted] stature, and the fact that he was respected enough by Exactech to have given its keynote sale address at its 2013 and 2014 national sales meetings, the information provided by [redacted] directly to Mr. Binder should have been taken very seriously by both Mr. Binder and TPG and was yet another set of red flags to Mr. Binder and TPG.

207. On March 21, 2019, [redacted] spoke directly with Mr. Binder to raise his concerns with Mr. Binder regarding the Optetrak Logic device failure. [redacted] took that step, as noted, because all of his prior efforts in communicating with prior Exactech management had been rebuffed, and [redacted] decided to try to speak directly to the new owner's Board and management designee, Mr. Binder, to alert TPG to the severity and urgency of the situation.

208. Shortly thereafter, on or about March 26, 2019, although [redacted] had previously shared extensive documentation with Exactech, [redacted] sent to Mr. Binder numerous x-rays, photos of catastrophic device failure and other information related to the Optetrak Logic device failures. Mr. Binder, in turn,

forwarded them to Laurent Angibaud, the Exactech engineer who previously had been involved in efforts to give the false impression to surgeons of engaging in a good faith effort to determine the root cause of device failures.

209. [redacted]

210. [redacted], but in fact, Exactech did not properly report these device failures to the FDA.

211. By March 28, 2019, Exactech in its internal updates to Mr. Binder had linked their concerns regarding [redacted] with their concerns regarding HSS, and Mr. Angibaud recommended a similar approach be taken with [redacted] as with HSS. It does not appear, however, that Exactech or Mr. Binder disclosed to [redacted] that a parallel investigation was occurring at HSS, or that HSS had expressed ongoing serious concerns regarding the delamination issue.

212. For his part, Dr. Petty generally continued to falsely attribute the issues raised by [redacted] to poor surgical technique. Dr. Petty did, however, internally advise Mr. Binder of the "femoral loosening" issue experienced by one or more of [redacted]. **In a March 28, 2019 email to Mr. Binder, Dr. Miller, and Mr. Angibaud, Dr. Petty acknowledged the need for a "solution" to the widespread femoral loosening problem whether by "implant modification, technique, instrumentation, whatever." Dr. Petty had internally stated that "[i]t is important that we pursue the femoral fixation issue…." In fact, it would take several more years before Exactech internally sought to address the femoral loosening issue and continued to conceal the nature and extent of the problem from surgeons, patients, and the FDA.** In that same email thread, Mr. Binder, underscoring the severity of the femoral loosening problem, asked Dr. Petty how "we 'rehabilitate' our reputation with the surgeons who have been impacted," and if Exactech could persuade Dr. Wright of HSS to assist.

213. Mr. Binder directed the follow up response to [redacted] with Dr. Petty and others at Exactech, including Mr. Angibaud. [redacted]

214. On April 9, 2019, Mr. Binder advised [redacted] that Mr. Angibaud would lead the follow-up for Exactech. On April 16, 2019, [redacted] emailed Mr.

Binder and Mr. Angibaud records for Exactech device failures for at least 17 of his patients.

215. On June 6, 2019, Mr. Angibaud and Luis Alvarez met with [redacted] and his staff at [redacted] Maryland offices and provided information that Mr. Angibaud and Mr. Alvarez had requested. [redacted] and his staff spent the full day answering any questions that were posed to them by Messrs. Angibaud and Alvarez about the Optetrak Logic polyethylene device failures and revision surgeries. This was the third time that [redacted] provided this basic information to Exactech.

216. Despite the fact that Mr. Binder and Dr. Petty were aware that [redacted] and HSS were reporting the same issues, Mr. Binder and Dr. Petty never acknowledged one's complaints to the other. A few days after Mr. Angibaud's meeting with [redacted], Mr. Angibaud **met at HSS and was told that HSS also had experienced problems with "de-bonding."** On June 19, 2019, Mr. Angibaud reported to Mr. Alvarez and others at Exactech that HSS at a recent meeting stated that its **"main issue relates to the fixation of the femoral component; where in accordance with our review of retrieved components, the femur starts to debond and move into flexion over time."**

217. On July 12, 2019, [redacted] emailed Mr. Binder and Mr. Angibaud, advising them: "At this point I have approximately 25 or 26 out of 1800 total knees

and I've got to believe this problem is showing up somewhere else with the amount of knees that are done at hospital for special surgery in Maine and in Florida can you give me any update on that." It does not appear that Mr. Binder or Mr. Angibaud provided a response to [redacted] request for further data. It was not until over two years later, in September 2021 [redacted] was able to confirm indirectly that HSS had experienced the same repeated polyethylene device failure with Exactech devices.

218. **In August 2019, Mr. Angibaud reported to Mr. Binder and others that HSS was "considering the fact that the femoral loosening may be a predecessor to the poly damage." By September 2019, Mr. Binder was well aware that, based on HSS's review of retrieved components, the "HSS lab considers that the femoral loosening preceded the observed** of **poly damages (due to the release of PMMA particles[25])" and that HSS was in the process reviewing femoral components that were "burnished**.[26]"

219. By 2020, Exactech was admitting internally that "an increase in femoral loosening complaints started in 2018." Beginning in 2020, information about the

[25] "FMMA particles" refers to cement microparticles. This suggested that HSS believed that the femoral loosening and corresponding release of cement microparticles may have been a contributing cause to the poly damages.

[26] In total knee arthroplasty, "burnished" refers to a surface change on the backside of a femoral component, where it becomes polished as a result of cement-implant interface and is indicative of aseptic loosening.

product defect issues began to make its way to not just Mr. Binder, but the other TPG members of the Exactech Board. **By 2020 at the latest, notes from Exactech Board meetings (attended by Messrs. Binder, Schilling, Sisitsky, Garrison, and other TPG-designees) and strategic planning sessions describe an awareness of "knee quality issues (femorals coming off w/o cement)."**[27] Knowledge, *inter alia*, of the femoral debonding issue was at the highest levels within Exactech, including Mr. Binder and TPG's other designees. Meeting notes from a May 2020 Exactech Board meeting or "planning session" refer to the need to "[i]mprove cement adherence on the back of [the] femurs," "[u]nderstanding why certain femurs have failed," "Cement on femur/Are we clear on the problem – must understand the root cause – Luis [Alvarez] should declare root cause," and consideration whether in light of the "knee/hip" problems it would be "cheaper" to simply "start from scratch with a new product" than "to buy some [sales] reps," and active participation by Mr. Binder in such discussions. July 2020 meeting notes observe that the "[p]ackaging department is all over the place." **Meeting notes for the "2021 Budget" note concern with "Knee quality issues (femorals coming off w/o cement)."**

[27] Such notes also refer to an issue involving "orange peel," which is characterized as a type of defect related to metallic surfaces.

220. [redacted]

C. TPG's Knowing Failure to Correct Material Quality Control Deficiencies Perpetuated Additional Defects.

221. TPG had observed during its due diligence the lack of quality control, but TPG and the Individual Defendants, including Mr. Binder, took no steps whatsoever to ensure that any basic form of quality control was implemented following the TPG Acquisition.

222. TPG was aware post-acquisition that quality control was a risk to the Company. In November 2019, an "Enterprise Risk Management" Report was provided to the Exactech Board, including Mr. Binder, Mr. Schilling, Mr. Sisitsky, Mr. Garrison, Dr. Petty, and David Petty. The Report was prepared by Robin Barney, the same person who prepared the due diligence report for Mr. Binder in September 2017. Presciently, the Report indicated that Exactech had a high level of

risk, *i.e.* an [redacted] level for which [redacted] with (i) "Defense against a Whistleblower Lawsuit" (*i.e.,* the Alabama Qui Tam action), (ii) "Non-compliance with Federal Laws Governing Physician Fraud and Abuse," (iii) Non-compliance with Industry laws, Regulations and Codes (in the U.S), and (iv) "Product Liability." But TPG did not take [redacted] to improve quality control as was [redacted]

223. Mr. Binder, for his part, was quite experienced with the risks of oxidation to polyethylene. Indeed, during his tenure as CEO of Biomet (prior to Mr. Binder becoming CEO of Exactech), he publicly touted Biomet's development of a product called "E1," which was an antioxidant infused technology. During his tenure as CEO of Biomet, Biomet publicly explained the importance of "wear resistance and prevent[ion of] oxidative degradation of … polyethylene." Biomet product literation noted: "The mounting evidence is clear: **oxidation** threatens the longevity of joint replacement." (emphasis in original). Such Biomet literature cited articles published prior to and during 2010, underscoring that it had been well-known for a long time that prevention of oxidation was of critical importance to the use of polyethylene in implant surgery.

224. Mr. Binder also was aware of the risk of polyethylene degradation due to his tenure at Biomet and other companies engaged in manufacturing and sale of

orthopedic devices similar to those manufactured and sold by Exactech. He knew, for example, of the risks to patients of "wear debris" caused by polyethylene delamination, and the associated risks of premature loosening of the implant and significant bone loss. Indeed, one of his colleagues at Biomet (who later joined him at Exactech) noted that "the objective of [Biomet's] E1 is to increase wear resistance by reducing oxidative degradation of the PE and to maintain mechanical properties."

225. As a result, it was well-known to Mr. Binder, prior to joining Exactech, and certainly to Defendants Dr. Petty and David Petty, that packaging plays a large part in reducing the risk of oxidation during the shelf-life period between the completion of the manufacturing process and implantation in the patient. Mr. Binder also knew that infusing crosslinked polyethylene with Vitamin E was a common added measure against oxidation, as he had done at Biomet years prior to joining Exactech.

226. He further knew that Exactech's manufacturing process for polyethylene, as of February 2018, when he joined as Co-Executive Chairman, was not state of the art. Mr. Binder, Dr. Petty, and David Petty also knew that it was important to ensure the polyethylene components of Exactech's Hip, Knee, and Ankle Devices were stable from an oxidation standpoint throughout the Device's shelf-life.

227. The risks were high: 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 the patients.

228. Notwithstanding Mr. Binder's background in the industry prior to the TPG Acquisition and TPG's expertise in the medical device industry, Mr. Binder and TPG turned a blind eye to the pleas of HSS, [redacted] and others to promptly get to the root cause of Exactech device failures. HSS alone on at least two occasions implored Exactech to investigate packaging issues as the root cause. Mr. Binder, Mr. Schilling and other TPG-appointed personnel instead took the lead in efforts to misdirect surgeons and the FDA and to put the blame on surgeons, patients, and anyone other than Exactech, until finally in late 2021, the FDA rejected Mr. Binder's misdirection and began to direct a full recall be implemented on the poly issues.

229. TPG, as noted, also sought to conceal how early Exactech and TPG had been made aware of Exactech's manufacturing non-conformities.

230. TPG's failure to ensure that Exactech maintained any basic quality control extended to other manufacturing errors, including a significant one that the UCC discovered during its investigation of the conduct of TPG, Mr. Binder, and Mr. Alverez during Exactech's bankruptcy proceedings. The UCC discovered that during a period in 2021, when Mr. Alvarez was directly reporting to Mr. Binder

about efforts to discovery the root cause of the delamination issues, Mr. Alvarez also was engaged in a covert effort to correct and conceal a catastrophic "in-house" manufacturing error involving the surface roughness of femoral components that had been occurring concurrently with the defective packaging problem. Despite the fact that this manufacturing error appeared to be directly correlated to serious de-bonding concerns that patients had reported over a number of years, Mr. Binder's and TPG's response was to attempt to bury disclosure of what had occurred. No product recall or similar notification to surgeons or patients has been made with respect to the surface roughness manufacturing defect.

231. The facts are as follows: Beginning in late 2004, Exactech began manufacturing "in house" (*i.e.,* at Exactech's Florida facilities) its femoral knee components. The internal design specifications provided by Exactech stated that the non-articulating surface roughness was to be "Ra 125 or better."

232. "Ra" refers to surface "roughness average," a standard measurement of surface finish. A Ra value of 125, for example, corresponds to 3.2 micrometers. A Ra value of 125 indicates a relatively rough surface finish, suitable for applications where high mechanical performance and durability are prioritized over a smooth, polished appearance. A lower Ra value indicates a smoother finish. A higher Ra value indicates a rougher/courser finish. A higher "Ra" number produced greater

surface roughness, which was necessary to obtain adequate fixation with the cement used during surgery so it could adhere and maintain adherence *in vivo*.

233. While TPG and Exactech were aware that a greater surface roughness was needed, until 2021, Exactech's in-house manufacturing process misinterpreted the design specification, resulting in up to 371,986 femoral knee components being manufactured based on a misinterpretation that Ra 125 should be the "maximum," not the "minimum" Ra value for surface roughness. Exactech did not engage in any basic quality control during this period to confirm whether in-house Exactech was actually manufacturing its femoral components in accordance with the intended Ra specifications (it was not), though repeatedly put on notice of surgeon's concerns with aseptic femoral loosening and de-bonding. When this breathtaking long-term manufacturing error was finally identified by Exactech in early 2021, at the same time as the effort to get to the "root cause" of the polyethylene delamination issues discussed herein, Mr. Alvarez (who was deeply involved in both efforts and reported to Mr. Binder) and others sought to bury this manufacturing fiasco from any form of public disclosure. For its part, TPG-designated Board members, though aware of Exactech's quality control problems, did nothing to ensure that proper quality control was implemented, which could have detected this glaring manufacturing error years earlier.

234. By February 16, 2021, Mr. Alvarez had been alerted to the internal confusion at Exactech over the intended specifications for manufacturing the articular side of the femoral component. At the time, Mr. Alvarez was reporting to Mr. Binder on the HSS-related matters, and would shortly thereafter be instructed by Mr. Binder, after the loss of HSS business, to focus further on the delamination issues.

235. What would follow was an effort over a period of months, to bury this manufacturing debacle by Exactech while efforts were made by Mr. Alvarez (at Mr. Binder's direction) to focus attention on the delamination issues. As Exactech disclosed during its bankruptcy, at least 371,986 femoral knee components were manufactured, from late 2004 to November 17, 2021 "in-house" using design specifications for the non-articulating surface roughness of "Ra 125 or better." A substantial portion if not all of the products were manufactured under the incorrect interpretation that the "or better" meant Ra 125 as a maximum, rather than as a minimum (as was intended). Exactech also had outside contractor manufacturers who correctly had interpreted the ambiguous specifications to treat "better" as rougher; thus, implants made by the outside manufacturers did not share the lack of roughness and attendant aseptic loosening or debonding problem. This disparity further complicated an assessment of revision surgeries involving femoral de-

bonding, since Exactech never publicly disclosed its historical femoral component manufacturing error.

236. In a March 31, 2021 Health Hazard Evaluation ("HHE") report issued by Mr. Alvarez, Exactech confirmed that the de-bonding issue likely was caused by a defective design by Exactech (which Exactech internally characterized as "ambiguous"), and that Exactech, as a result, had for years manufactured a surface finish that was too smooth (not with the requisite surface roughness), and resulted in cement not holding once the knee device was implanted in the patient. This femoral aseptic loosening and de-bonding issues had been a major problem for Exactech, as noted *supra*, and it contributed to numerous device failures. The femoral aseptic loosening and de-bonding issue, as alleged herein, had repeatedly been raised to Exactech, its management and its Board as a serious issue that needed to be examined. In Exactech's words, this resulted in "implant loosening or loss of fixation to the bone." While this clearly impacted the safety of the product, and Exactech internally noted in the HHE report, at the time, that 142 complaints had been received "with femoral loosening for any reason" during the period under review and was viewed by Exactech as a "serious" issue, Exactech (with Mr. Alvarez presenting on the "proposed product enhancements," *i.e.,* proposed design changes) falsely and improperly internally determined on April 7, 2021 that "there is no risk

to patient and does not appear to be a compliance issue." Exactech, which at that time was under the control and direction of TPG, was aware of the serious complaints it had received regarding aseptic femoral loosening or de-bonding and attempted to bury this major seventeen (17) year manufacturing and compliance error from public scrutiny. This was the same period during which Mr. Binder, it appears, directed Mr. Alvarez to focus on the delamination issues and closely update Mr. Binder.

237. On June 2, 2021, while Mr. Alvarez allegedly was conducting his investigation into the root cause of the delamination issues, Exactech internally confirmed that "Exactech in house MFG [*i.e.,* manufacturing] made **femorals with the [Ra] 125 as a maximum**, and as such femorals made by Exactech will be reworked to meet the new drawings." (emphasis supplied). The same communication indicated that "Luis [Alvarez] is currently leading a project to revise the prints for all femorals to clarify the backside surface roughness specification…."

238. This glaring specification error involved 17 years of femoral devices (371,986 femoral knee components), manufactured on-site by Exactech from late 2004 until November 17, 2021, when as alleged below, Exactech, then under the control and direction of TPG, surreptitiously changed the design specifications. This change occurred on the last day the FDA was on site conducting an extensive 8 day

inspection of the polyethylene issues. And as alleged herein, the manufacturing defects involving the missing EVOH liners, which also occurred during the same 17 year period (2004-2021), implicated a third-party vendor which failed to include the EVOH liner in numerous vacuum sealed bags as required by specifications.

239. While Exactech appears to have finally changed its "drawings" for the femoral knee device on November 17, 2021, Exactech, then controlled by TPG, did not inform the surgeons who implanted the defective femoral components or any of the many patients who had devices with defective surface finishes implanted in their bodies, exposing them to catastrophic risks as set forth herein. Nor does it appear that the Company made proper disclosure to the FDA of this issue. Exactech did not file a 510(k). Mr. Binder appears to have taken no corrective action on this issue, though he was alerted to the issue by [redacted] and by Dr. Petty no later than March 2019, and was told thereafter that the femoral aseptic loosening and femoral debonding was a major issue being investigated by HSS and problem for Exactech, and that there may well be a direct relationship between that issue and polyethylene delamination.

D. TPG Asserts its Domination and Control to Obstruct Investigations, Including Those by HSS and the FDA.

240. TPG, Mr. Binder, and Exactech had no interest in determining the root cause of the device failures being reported, instead focusing their efforts on fighting

any questions raised about Exactech's faulty devices, delaying and limiting any recalls, and continuing to push the sale of defective devices. TPG has inaccurately contended, for example, that TPG, Mr. Binder, and Exactech did not discover until July 2021 that for the entirety of TPG's ownership, Exactech had been using vacuum packaging of polyethylene that lacked a basic EVOH liner. The EVOH liner is critical to preventing oxidation of polyethylene inserts, a key component in any Exactech knee, hip, ankle or shoulder replacement surgery. [redacted] But at least two Exactech Board members, Mr. Binder and Dr. Petty, had been aware of HSS's complaints since at least 2018. In fact, Mr. Binder had been actively involved in discussions regarding the HSS delamination complaints long prior to 2021. As the record reflects, Mr. Binder himself knew, years before joining Exactech, of the critical role that oxidation played in such polyethylene inserts, and the dangers of accelerated oxidation *in vivo* to polyethylene to patients' health and its relationship to revision surgery. And HSS had urged an Exactech Board member (Dr. Petty) in 2018 and 2019 to examine packaging as a likely root cause.

1. TPG Obstructs the HSS Investigation.

241. TPG principally via Mr. Binder resorted to efforts to obstruct the HSS investigation and mislead surgeons and the FDA, including direct obstruction of

HSS's investigation into premature polyethylene wear, which contributed to further misrepresentations made to surgeons and ultimately the FDA.

242. HSS first raised concerns to Exactech about oxidation of Exactech products in August 2017, prior to the TPG Acquisition. By February 2018, however, when the TPG Acquisition closed, the HSS Biomechanics Lab and a group of HSS physicians had approached Exactech about their observation regarding premature polyethylene wear of Exactech's Optetrak and Opterak Logic insert knee components.[28]

243. By October 2018, with TPG and Mr. Binder in full control of Exactech, Mr. Binder and Exactech sought to undermine and obstruct HSS from publicly disclosing its concerns. Specifically, HSS advised Exactech that it planned to present a PowerPoint at an upcoming October 2018 conference sponsored by the International Society for Technology in Arthroplasty ("ISTA"). The PowerPoint was entitled: "**What Happened? Extreme Delamination and Oxidation in Modern Day Compression Molded Polyethylene**." Among other findings, it

[28] HSS, in addition to being a preeminent surgical institution and Exactech's largest customer, was and remains one of the world's leading independent research institutions in the field of orthopedics. HSS has its own retrieval lab, enabling HSS researchers to routinely conduct retrieval analysis of all implants removed during revision surgery. HSS often publishes such findings for academic purposes in peer-reviewed research papers or journals to educate and inform the medical community of industry trends, product performance, and any product-specific issues observed at the institution.

revealed that "notable surface delamination was found in 27 of the 86 retrieved specimens" or 37% of all Exactech implants at the selected cohort. The presentation also noted that "Oxidation Index values were significantly correlated to polyethylene delamination," which would implicate Exactech's design or manufacturing process. Exactech also became aware of another poster board presentation to be presented at the annual AAHKS conference thereafter in November 2018.

244. Mr. Binder and Dr. Petty thereafter engaged in an egregious and unprofessional attack on HSS and its surgeons, in flagrant breach of their duties, with the goal of silencing HSS and dissuading HSS – through direct threats – to not proceed with its presentations and not otherwise publicize HSS's research on the delamination issue. With Mr. Binder's active direction, Dr. Petty mass emailed several HSS surgeons, attaching a strongly worded letter warning HSS that presenting "**this data…will result in significant damage to both our reputations**," and urged HSS "**to withdraw the presentation" or risk a "public disagreement with HSS…that would be damaging to HSS**" (emphasis supplied).

245. Behind the scenes, Mr. Binder orchestrated the presentation of the contents of the foregoing letter. In an internal email dated October 9, 2018, Mr. Binder commented that "we might even open by saying 'We request that you withdraw this inaccurate and misleading presentation" while adding that the draft

letter itself should "not only be asking questions but providing answers'" (directly implying that Exactech should improperly feed HSS with Exactech's own biased data rather than allow HSS to use its own data). In other internal correspondence with Dr. Petty and others, Mr. Binder crudely described HSS's efforts to inform fellow surgeons of a potential safety concern related to Exactech's devices as a "F*cking hatchet job" while claiming without any scientific evidence or basis, that "a significant correlation between oxidation and delamination does not exist." By the evening of October 10, 2018, after hearing no final word from HSS, Mr. Binder complains that HSS's presentation "will cause us great harm as written." Meanwhile, in an email dated October 9, 2018, HSS surgeon Dr. Charles Cornell, in discussing the topic of polyethylene wear and HSS's findings, directly tells Dr. Petty: "I wonder if it is a post manufacturing issue with either damage to the packaging or some defect in the manufacturing itself." Dr. Petty responds: "[Exactech has] reviewed manufacturing processes over the many years of production and found no process discrepancies," a blatantly false statement since at the time Exactech had never checked to confirm its polyethylene had been packaged in accordance with its specifications and as alleged herein, Exactech internally was aware that packaging certifications provided by suppliers had, in fact, been non-compliant.

246. Mr. Binder's and Dr. Petty's threats to HSS were met with a response by HSS's surgeon-in-chief and Medical Director, Dr. Douglas Padgett, who, in an email called Dr. Petty and Exactech out for trying to directly interfere with research being conducted by an independent research institution. As Dr. Padgett explained: "Respectfully, this needs to stop!....This is quite inappropriate for you and your team to edit this work without direct knowledge or involvement….How do you know that malseating, [*i.e.,* surgical error] is the cause of the observed damage….Let the journal editorial process adjudicate these results." According to Dr. Westrich, a senior surgeon at HSS, also a recipient of Dr. Petty's letter, he had never before seen a company (such as Exactech) press to have such a presentation withdrawn.

247. HSS and Exactech representatives met seven times over seventeen months, until late 2019, to investigate "mutually agreed upon possible factors." Exactech, under the control of TPG, engineered such meetings to avoid agreeing upon a root cause that pinned the blame on Exactech's manufacturing processes. Exactech claimed to have investigated the root cause on its end, but in fact never followed up on the root cause of packaging non-compliance, notwithstanding that HSS raised the packaging issue with Exactech. Consistent with Exactech's historical practice, Exactech instead advanced the false narrative that the polyethylene problems could be due to surgical technique or passed it off to the use of high

viscosity cement, all in an effort to avoid Exactech's own responsibility for these problems. In the meantime, HSS surgeons in the operating room continued to perform revisions identifying that Exactech's polyethylene was failing.

248. On March 24, 2019, HSS for a second time urged Exactech to examine its polyethylene packaging, after Dr. Westrich (of HSS) in an email to Dr. Petty noted: "I just saw a patient (woman in her 50's) that has bilateral Logic knees from a few years ago…[with one knee having] marked synovitis, pain and need[ing] a revision." After noting that they "are both Logic TKR's done the same day with the same implant sizes and the same cement," Dr. Westrich commented: "This leads me to believe there must be a problem in the past with a packaging issue that we have yet to discover." By August 2019, Mr. Binder is copied on an email chain between Exactech distributors and Exactech personnel, where a distributor notes that "Dr. Windsor [of HSS] expressed his concerns about our poly. He has seen a number of referrals of patients done at HSS by other surgeons what he says have 'significant osteolysis' and further observes, "[a]s you can see, and we have discussed, this situation is running rampant throughout the institution [HSS]"

249. In 2020, and early 2021, Exactech and TPG basically did nothing to advance the purported investigation, nor did Exactech (under TPG's control) conduct any follow up investigation into the specific issues raised by Dr. Westrich

and Dr. Cornell with respect to packaging. Instead, Exactech continued to try to suggest that there were many potential root causes, none of which was Exactech's fault.

250. Exactech's delay tactics and efforts to obfuscate, and misdirect, led by Mr. Binder, and the continued incidence of premature delamination at HSS, ultimately led to a rupture in HSS's business relationship with Exactech. Given HSS's status as Exactech's largest customer, this was material adverse financial event for Exactech. On February 9, 2019, HSS made the decision to remove all Exactech PS Knee Implants from its inventory until further notice. On February 17, 2021, HSS "pulled" Exactech's Equinoxe shoulder system product "from the hospital due to" what an Exactech employee described as "*perceived* poly issues." Since HSS had implanted over 15 thousand Exactech molded polyethylene inserts over the prior 20 years, this was a significant blow to Exactech's business.

251. While it appears that Exactech looked at package "dates," it does not appear that any packages were ever opened during this purported "investigation," and while HSS had urged that Exactech examine the packaging issue right in front of Exactech, Exactech appears to have refused to do so. It appears that Exactech concealed material information from HSS, fostering an effort to misdirect HSS. Had Hillman's Certificates of Compliance been examined by Mr. Alvarez, they would

have immediately shown from a sampling that various of the Certificates did not even purport to contain the EVOH liner that had been missing since 2004.

252. HSS's records implied something far more definitively and objectively negative—a structural, product-specific defect—something Exactech well knew even as it publicly falsely declared otherwise. HSS, it appears, also did not have access to the internal Exactech information that its supplier was a local janitorial supply services company that had not been including the required liner for well over a decade, and that Exactech had absolutely no quality control processes in place to detect this elementary product error. Exactech was thus able to continue to withhold relevant factual information from HSS, as well as other surgeons and regulators.

253. Notwithstanding HSS on at least two occasions urging Exactech to examine its polyethylene packaging as a likely root cause of the oxidation problem, Exactech refused to do so. There is no evidence that Mr. Binder, prior to April 2021 (after he learned that HSS was discontinuing its knee replacement business with Exactech over the ongoing delamination issues), took any steps to even check whether any quality control existed at Exactech with respect to its polyethylene packaging to determine whether there had been compliance with the specifications for such packaging. As continuing problems with Exactech's products mounted at HSS, and notwithstanding HSS's repeated efforts to get Exactech to focus on the

fact that it had a material oxidation problem, Exactech, with Mr. Binder and TPG in full control, continued the misdirection efforts that were the hallmark of Exactech's historical practice to try to point blame at every possible source other than Exactech itself.

254. For its part, Exactech did little, if anything from late 2019 through early 2021 in any further investigation of this issue. While Laurent Angibaud and Luis Alvarez had been involved in leading Exactech's efforts, by 2020, Mr. Angibaud assumed other duties and Mr. Alvarez basically did nothing on the matter during COVID (2020) until April 2021 (as discussed herein), when summoned by Mr. Binder after news that HSS has discontinued its use of Exactech's knee products.

255. HSS had been Exactech's largest single institutional customer in the United States, before HSS terminated its use of certain Exactech devices due to the failure rates of such devices and Exactech's conduct. Mr. Binder and TPG tried to conceal this loss of HSS business. Mr. Binder made an effort, without success, to engage HSS to regain such lost business, and was told that HSS had discontinued its business with Exactech due in major part to this unresolved delamination issue. Further, as discussed herein, with problems mounting on other fronts, such as Mr. Binder's, Mr. Schilling's and TPG's knowledge of the surgeon complaints (such as those by [redacted]) regarding Exactech products, Mr. Binder, Mr. Schilling and

TPG in desperation actively explored an early exit from Exactech, whether through a sale of Exactech or an IPO of Exactech. Both exit alternatives failed. The recalls of Exactech's products and the FDA's determination in late 2021 that a larger recall was required, coupled with the loss of HSS business, destroyed any such potential sales or IPO efforts, leading to the onslaught of product liability lawsuits that were filed against Exactech and TPG. It also appears that while HSS had specifically identified aseptic femoral loosening and/or debonding as a potential precursor or contributing cause to the polyethylene delamination and had been specifically examining that as a potential root cause, Exactech apparently did not disclose to HSS the 17 year manufacturing error at Exactech with regard to the femoral knee devices, which Exactech knew was related to the issue of aseptic loosening. [redacted]

2. TPG Controls Exactech's Recall Process

256. [redacted]

257. By July 22, 2021, Michael Crader, Exactech's Chief Quality and Regulatory Clinical Officer, had informed others at Exactech that "[d]uring his [*i.e.*, Alvarez's] investigation he discovered that certifications received over the past 20 years do not mention certification that the EVOH coating is present….This will be a major event…."

258. On July 23, 2021, Mr. Binder held a meeting with Mr. Alvarez and his team to address next steps. By this point, at the latest, Mr. Binder established himself as the key strategist and mastermind behind how Exactech would address any potential recall of Exactech's polyethylene products. By July 25, 2021, Mr. Binder advanced the concept of limiting any recall based on shelf life, in an effort to restrict the recall and allow defective product to continue to be sold. He turned to Mr. Schilling to closely work with him, on behalf of TPG, in orchestrating every step of Exactech's recall process and interactions with the FDA in order to protect TPG's financial interests. For his part, Mr. Schilling, who was trained as a doctor (but did not practice medicine) was acutely aware that Exactech should have done a broad, prompt recall and that it would imperil patients to have delaminated polyethylene in their bodies, but Schilling sided with Binder in instead protecting TPG's financial interests to allow defective product to continue to be sold and

conceal the true facts. TPG effectively had displaced Exactech in all decision-making on the recall process and acted to protect its financial interests.

259. TPG's handprints are on every step of the recall process.

260. Mr. Binder has testified that he considered himself the "leader of the effort of the recall response."

261. On August 4, 2021, Mr. Binder was directly informed that test data suggested that "older poly in bags with EVOH have less oxidation than younger poly in bags without EVOH." Mr. Binder thereafter advanced a recall strategy inconsistent with the data he had received from Exactech's internal testing, and told the FDA the opposite of what he had internally been informed.

262. [redacted] By August 16, 2021, Exactech employees were instructed to report daily to TPG on the progress of data collection relating to the recall. By August 17, 2021, Mr. Binder, in coordination with Mr. Schilling and TPG, had designed a very limited recall plan, which avoided the broader recall that was actually required. Mr. Binder's TPG-led recall strategy failed to provide, *e.g.,* for a Shoulder, Hip (XLE), and Patella recall, nor for the recall of any knee/ankle devices with a shelf life of less than 4 years – all of which

recalls were subsequently required by the FDA. As Mr. Binder was aware at the time in August 2021, as reflected in internal Exactech documents, there was a real risk that the FDA would demand the recall "of all devices packaged in non-EVOH bags" and/or that the FDA would "demand the scrap of all non-EVOH product in inventory." Mr. Binder was well aware of the risk that the FDA would see through the contrived, limited recall and the need to provide a pretextual response to anticipated FDA questions. Mr. Binder coordinated how the misleading responses to anticipated FDA questions would be made, in an effort to buy time to allow defective product to continue to be sold.

263. By August 18, 2021, at the latest, it appears that Mr. Binder and Mr. Schilling had displaced many of Exactech's key regulatory personnel, and TPG loyalists Binder and Schilling, assisted by Messrs. Garrison, Yasskin, Tepatti and Lin took the lead on all aspects of the project. Mr. Binder and Mr. Schilling were well aware that the FDA likely would question Exactech, *inter alia*, as to (i) why Exactech was not recalling all non-conforming devices, (ii) why Exactech was continuing to ship non-conforming devices, (iii) why Exactech was not recalling its shoulder and XLE (hip) devices, and (iv) what Exactech's rationale was for "drawing the line" at 4 years. Despite these known risks, Mr. Binder and TPG moved forward with their recall strategy in an effort to delay and limit any further recalls,

obfuscate and conceal the actual set of facts from the FDA, and facilitate defective product to continue to be sold.

264. For example, on August 19, 2021, Messrs. Binder, Schilling and Lin and took over preparation of key documents, with Messrs. Binder, Schilling and Lin all trying to retroactively spin a false narrative to contend that devices with a shelf life under 4-5 years did not need to be recalled. [redacted] Mr. Lin similarly instructed Dr. Kusuma to re-run a shelf life analysis to obtain contrived results that would artificially narrow the scope of the recall and exclude at least 23,000 additional polyethylene inserts.

265. Furthermore, from August 20, 2021 through August 24, 2021, TPG supervised select members of Exactech's team in around the clock work and exchanged **at least 61 drafts** of a primary PowerPoint Presentation to be submitted to the FDA entitled "Exactech Investigation into Non-Conformance" (*i.e.,* the "FDA Board Deck"). Hundreds of emails show that Defendants Binder, Schilling, Tepatti, Yasskin, and Lin were actively drafting, editing, censoring, and reviewing all aspects

of the FDA Board Deck, wordsmithing what Exactech said or did not say to the FDA. TPG was in complete control of the FDA Board Deck and its contents. An August 21, 2021 email referred to the FDA Board deck as "**the latest deck from TPG**." Critically, an August 23, 2021 email further demonstrated that TPG had final authority, forwarding version 61 of the FDA Board Deck with the comment "**final from TPG blessed deck**."

266. On August 24, 2021, the TPG and Binder-led recall proposal was submitted to the FDA. Within four days, the FDA responded by expressing concerns that Exactech's proposed recall based on shelf-life "may not be based on relevant and reliable data and does not fully characterize the associated risks of the subject device UHMWPE liners for all…devices and all liner shelf-lifes (e.g., [less than] 5 years) that are in non-conforming bags."

267. On February 7, 2022, after being pressed by the FDA, Exactech expanded its recall to all knee and ankle devices regardless of shelf life. In August 2022, the FDA forced Exactech to expand the recall of all its GXL poly products. The Patella and Shoulder poly inserts were not recalled for more than two years, during which hundreds if not thousands of implantation and revision surgeries were conducted by surgeons totally unaware that they were placing defective components into their patients.

3. TPG Otherwise Controls Exactech's Response to the FDA Investigation

268. In September 2021, the FDA had asked Exactech for information regarding various Exactech knee polyethylene inserts where failure had occurred, which Exactech determined to have been implanted by [redacted]. Cognizant of Exactech's typical refrain that the surgeon must have made an error in surgical procedure, [redacted] Again, Mr. Binder cautions, in a November 11, 2021 email, that he did not "want to open ourselves to [redacted] telling them [*i.e.,* the FDA] that he has had no failures with other systems, **true or not**" (emphasis supplied). Both Mr. Binder and Mr. Schilling actively participated in preparing an Exactech response that was critical of [redacted], and dismissive of his complaints. Mr. Binder also instructed Dr. Kusuma (who referred to Mr. Binder, as "Master Yoda"[29]) to be strategic in how to attack [redacted] complaints regarding device failure in responses to the FDA.

29 A reference to the Jedi Master "Yoda" of the movie Star Wars, underscoring that senior Exactech personnel viewed Mr. Binder as directing communications with the FDA on recall issues.

269. At no point between 2017 and 2021 did Mr. Binder or anyone else from Exactech tell [redacted] that the failures of his patients' surgeries with Exactech products were due to his surgical error. [redacted] However, in late 2021, TPG through Mr. Binder and Mr. Schilling falsely tried to spin the opposite narrative to the FDA, blaming [redacted].

270. [redacted]

Had such timely disclosure been made to the FDA, Exactech would have been forced to concede in 2021 that the delamination issue was far more expansive than it had portrayed to the FDA, and that its awareness of the issue had long preceded its claimed discovery of the root cause in late July or August 2021. Mr. Binder would shortly thereafter betray his hostility towards HSS, whose concerns had forced Exactech to initially deal with the delamination issue, claiming in an internal email that the "HSS guys are not our friends."

271. On November 8, 2021, with TPG, Mr. Binder and Mr. Schilling orchestrating Exactech's approach, the FDA arrived on-site at Exactech to begin an eight (8) day investigation of the polyethylene delamination issues. TPG orchestrated how Exactech would handle the inquires made of the Company and its personnel. The on-site investigation concluded on November 17, 2021. Also on November 8, 2021, Exactech internally met and signed off on an "Assessment to Support a Decision Not to Submit a 510(k) for Proposed Changes to the Exactech Cemented Femoral Drawings," *i.e.,* not disclosing to the FDA, which was on-site at the time, that Exactech was finally correcting its femoral design manufacturing instructions. Instead, after seventeen (17) years of Exactech in-house manufacturing femoral components not in accordance with the intended surface "roughness" specifications, the matter was quietly concluded with a perfunctory "memorandum-to-file." Exactech falsely claimed, in its internal paperwork, that the "proposed modifications do not affect the safety or effectiveness of the devices." Exactech should have submitted a 510(k) supplement for the proposed modification, and should have issued a recall and surgeon notification, among other remediation or corrective acts.

272. This surface roughness manufacturing defect and its obfuscation had very important, practical clinical implications. The debonding often does not appear

evident on radiology studies, including even MRIs, so surgeons going in to perform an anticipated polyethylene liner replacement of the recalled liners, were not always prepared to do a much more complex revision involving the femoral component. With a liner replacement, the metal components remain, and it is the polyethylene that is replaced. But when the femoral component needs to be removed, it is more complicated, risky, and a longer procedure requiring additional hardware and necessitating highly skilled revision surgeons. There are many arthroplasty surgeons who only do initial, and simple liner exchanges but are not adept in complex revisions that they refer out to revision specialists. In fact, in a 2024 publication, HSS advised "Even if no evidence is found of implant loosening in the preoperative imaging, intraoperative implant stability must be confirmed at the time of surgery. We have seen numerous examples of debonded femoral components that have normal preoperative imaging but are easily removed at surgery. We believe that weight-bearing pain and/or decreasing flexion range of motion are often associated with femoral component debonding/loosening, so surgeons should proceed with caution when performing isolated liner exchanges in these patients. We encourage recruiting experienced revision surgeons for assistance with these cases. Implant loosening identified at the time of surgery (usually involving the femoral component) should be treated with both-component revision. A planned,

straightforward isolated liner exchange can quickly turn into a much more complex and difficult revision; such operations should only be performed by surgeons at institutions with ready access to equipment and implant inventories capable of managing both-component revision with potential for ligament insufficiency and bone loss." Boettner, *Evaluating and Treating Patients With a Recalled Exactech Knee Replacement: A Consensus Approach*, HSS Journal®: The Musculoskeletal Journal of Hospital for Special Surgery (2024). In other words, when the need for unexpected femoral revisions become evident on the operating room table, special components called "augments," "cones" and "hinges" are required to replace the osteolytic defects (missing bones and holes in bones) and ligament damage, and it is a very complex surgery and dangerous for the surgical patient.

273. The frequency of the respective type of revisions required due to the dual defects in the Exactech knee liner was studied, noting that "more than half of the revisions (56.6%) were due to aseptic mechanical failure. Polymeric wear-related synovitis was detected in 91.4%, and component loosening was found in 3/4 of the revision cases. Isolated femoral implant debonding was found in 15.4%." *Id.* Had surgeons known that in three-fourths of the liner revision surgeries they would have been required to do a full revision, many might have chosen to have a surgical sales representative from a different manufacturer present in the room so that they could

cease using Exactech products and switch to one of the other, more reliable orthopedic manufacturers. When the intended surgery was only a liner replacement, they had to use an Exactech product since only Exactech liners were designed to be compatible with the other components. Thus, by concealing the likelihood of the need for a full revision due to the prevalence of debonding and loosening, TPG and Exactech profited from the sale of the revision liner, and then in most cases the other components. The revision component sales represented a large proportion of Exactech revenue at such time.

274. Despite the enormous clinical impact of the concomitant debonding problem, the 44-page FDA "Establishment Inspection Report," summarizing the investigation by the FDA on-site from November 8-17, 2021, does not reference, however, anyone from Exactech disclosing to the FDA this femoral design "modification" and that Exactech had been improperly manufacturing femoral knee devices at variance to the intended design specifications. [redacted]

275. On November 17, 2021, the last day the FDA was on-site for its investigation, Exactech appears to have quietly finally implemented its covert femoral design "modification," though Exactech did not disclose the modification,

nor the long history of manufacturing non-compliance and product defects, to surgeons, patients, nor to the FDA.

276. The Trust is unaware of TPG-controlled Exactech having made any curative disclosure or related curative conduct or public disclosures on the femoral surface design issue since November 17, 2021. The Trust is also unaware of any recalls being made by such TPG-controlled Exactech Entities for this manufacturing defect, though it appears that thousands of defectively manufactured femoral component devices were implanted prior to November 17, 2021, with defective non-articulating surface roughness.

277. [redacted]

4. The 2023 Regulatory Investigation

278. [redacted] TPG endeavored to create or advance a counterfactual story that suggested, *inter alia*, that TPG and members of Exactech's

Board were not aware of any delamination issues until shortly before the recalls began in 2021 and somehow acted promptly to take corrective action when discovery of the noncompliant packaging was confirmed.

279. [redacted] Further, another of TPG's counsel (who was acting as joint counsel to Exactech) had learned no later than September 2023 that Exactech had been on notice, *inter alia,* by 2012 if not earlier, of the existence of non-compliant certifications from its packaging supplier(s), a fact

implying that a recall should have occurred long prior than even 2018. This information does not appear to have been disclosed to regulators.[30]

E. TPG Directed the Improper and Misleading Product Recall Strategy

280. On January 31, 2020, the FDA 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; (b) lack of or inadequate procedures for design transfer in violation of 21 C.F.R. §820.30(h); (c) lack of or inadequate procedures for design validation in violation of 21 C.F.R. § 820.30(g); and (d) lack of or inadequate design verification procedures in violation of 21 C.F.R. § 820.30(f).

281. Throughout 2021, while under TPG's and Mr. Binder's control, Exactech's internal teams recognized the multiple product development stumbles so central to the FDA findings. For instance, in May 2021, Mike Chados, a senior manager of design quality assurance at Exactech at the time, bemoaned how "the teams" were still "not adequately planning out the timing of the requirements during the design and development phase and pushing things until the end."

[30] The Trustee further believes that after the delamination recall, an Exactech in-house counsel, during document collection, discovered an email communication that indicated that an Exactech employee had raised questions about the adequacy of the packaging certification. The Trustee is continuing to investigate this issue.

282. After the FDA performed its extensive inspection at Exactech from November 8, 2021, to November 17, 2021, the FDA identified other failings with Exactech's packaging of polyethylene components of its hip, knee, and ankle devices, which were known to Exactech, Mr. Binder, Mr. Schilling and others of the TPG Individual Defendants. 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.

283. But, when it now looked more closely, the FDA determined 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." Consequently, "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 requirement."

284. Exactech could not even provide any "documented evidence to substantiate that sample sizes employed as part of shelf-life study protocols were based on a valid statistical rationale." Nonetheless, in approximately 2007, Exactech had extended the purported shelf life of its knee inserts from five to eight years without reporting this extended shelf life as a design or labeling change to the FDA and 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.

285. During this November 2021 inspection, FDA investigators also discovered "that no process validation activities have been conducted [by Exactech] since the manufacturing process was first implemented." Accordingly, FDA investigators concluded "process validation activities have not been conducted for manufacturing processes intended to ensure product specifications to prevent device oxidation." Moreover, following the eight day inspection at Exactech's facilities from November 8-17, 2021, the 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 products from suppliers, including the supplier of vacuum bags used to package UHMWPE components in the inserts or liner components, and

Exactech had no documented evidence to substantiate that sample sizes employed as part of a shelf-life protocol were based on a valid statistical rationale.

286. As the FDA observed in a lengthy report issued in December 2021, EVOH was supposed to be included in Exactech's vacuum packages containing the polyethylene inserts that were to be used, as a key component, in orthopedic replacement surgery. EVOH "provides an oxygen barrier as a component of the bag construction."

287. Indeed, the use of EVOH as an oxygen barrier for packaging was common in the food packaging industry and its utility as an oxidation preventing agent was well established.

288. As observed by the FDA, Exactech's inspection of the package failed in two basic respects: (i) the vacuum bags "do not contain EVOH as required by the packaging drawing" and as a result, **for a period of 17 years**, there was "shipment of nonconforming product to Exactech," and (ii) " Exactech receiving inspection employees accepted the product without verifying for indication of presence of EVOH on certificates of conformance for the vacuum bags. The inspection operator failed to adequately verify that the material certificate of conformance contained the [EVOH] requirement."

289. While the FDA report explains the enormity of the non-compliance in somewhat dry terms, the magnitude and obviousness of this grave manufacturing defect is reflected in the FDA's report.

290. As the FDA noted, "[d]elimiting oxidation on the devices is a requirement intended to prevent adverse effects on the mechanical properties and longevity of the device." As the FDA also noted: "Oxidation can occur both in-vitro and in-vivo environments. Increased oxidation can compromise the ability of polyethylene to withstand mechanical loading which can lead to accelerated wear." "To prevent the oxidation which can cause material degradation and as a result the functionality of the device, the firm is to vacuum pack the liners to protect the material during storing and transportation." Without the EVOH layer, oxygen is transmitted to the polyethylene and degrades mechanical properties of the material.

291. As Exactech finally conceded to the FDA, its packages did not contain the critical EVOH liners (and had not done so for seventeen (17) years), essentially exposing the polyethylene to increased oxidation prior to implantation in the patient. Put another way, a critical damaged Exactech plastic insert, already at risk of fracture or deterioration due to oxidation exposure, had been implanted for years in many thousands of patients, while, as set forth herein, Exactech, TPG and its advisors, including Mr. Binder, worked feverishly to obstruct a prompt discovery of the root

cause of numerous device failures being reported from critical partners such as New York's preeminent HSS, and surgeons across the United States and overseas. The FDA found that "no process validation activities have been conducted since the manufacturing process was first implemented," and that a "total of approximately 1,405,000 device units have been manufactured with the vacuum sealing process since 02/2007 until present."

292. As the record reflects, Exactech had been securing these non-compliant packages, containing the critical polyethylene inserts, from a local Florida distributor named Hillman Supply Company, Inc. (which in turn had out-sourced production to yet other third-party vendors), which specialized in janitorial supplies and was located approximately 15 minutes from Exactech's Florida offices, for approximately 17 years without ever conducting any form of quality control to confirm whether the EVOH inserts were in any of the vacuum sealed packages nor to even check to confirm that the certifications delivered by Hillman even stated that the EVOH liner was in the packages (many of such certifications, it appears, lacked even that statement).

293. TPG, as noted, was acutely aware of Exactech's deficient quality control prior to its acquisition of Exactech. Once TPG acquired Exactech and obtained complete control of the Company, TPG did nothing to rectify such deficient

quality control. The absence of any form of basic quality control (which continued for 3 ½ years after TPG's acquisition of Exactech) included, *inter alia*, the following: (i) Exactech never performed a quality control audit of Hillman; (ii) Exactech never performed a supplier performance review of Hillman; (iii) Exactech never performed a site audit of the third-party manufacturer(s) who manufactured the packaging materials sold by Hillman to Exactech; (iv) Exactech never confirmed whether Hillman was qualified to provide packaging for such liners; (v) Exactech did not confirm whether Hillman itself was ever in possession of any of the packages; (vi) Exactech never confirmed whether the manufacturers of the packages were CGMP or ISO qualified; and (vii) Exactech never confirmed whether Hillman had audited the manufacturing process of the vendors who supplied the packaging to Exactech.

294. It would have been a relatively simple exercise for Exactech to confirm whether any of the packages did or did not contain EVOH, apart from whether the Certificates of Conformance did or did not represent that EVOH was included. The FDA citations alone should have prompted an inspection of processes more broadly. Likewise, the "FDA audit readiness program" Mr. Binder emphasized should have also resulted in attention to these processes that were neglected both before and after TPG's acquisition of Exactech. Even the HSS surgeons suspected packaging was a

problem or root cause in 2018 and again in 2019, and alerted Dr. Petty, yet packaging continued to go unchecked by Exactech until 2021.

295. At no point prior to on or about July 21, 2021, did Exactech take any steps to confirm whether any of the packages contained EVOH, when a test was run using a Differential Scanning Calorimetry device, which confirmed an absence of EVOH. Other even simpler tests had been available historically to Exactech but were not used or employed by Exactech. Exactech had been on notice for a number of years of various red flags that put Exactech on notice of packaging non-conformance issues, but failed to act on such notice.

296. This utter disregard of basic and critical quality control procedures concerning a device intended to be implanted in patients is breathtaking, both in terms of the relative simplicity of confirming that Hillman's packages for years were non-compliant and the known risks that premature oxidation of the polyethylene (something Mr. Binder was well familiar with) posed to the many thousands of patients, who, unwittingly, were being implanted with Exactech devices where premature oxidation *already* had occurred.

297. As Exactech began its initial recall notices in mid-2021, Mr. Binder, Mr. Schilling and TPG were in complete control of the day-to-day decision-making of how to approach such recall issues, and significantly, what would be said – or not

said – to the FDA and others relating to recall issues, when it was to be communicated to the FDA and others, and who would communicate any messaging on behalf of Exactech to the FDA and others.

298. Mr. Binder and Mr. Schilling, at all relevant times with respect to FDA and recall issues, acted to protect the interests of TPG (and its investment in Exactech), for whom Mr. Binder was a consultant and Mr. Schilling a senior employee, not Exactech.

299. Documents, furthermore, suggest that Mr. Binder's control of the recall process was so pervasive, in particular, that by September 2023, TPG in its internal assessment of how to continue its control of the day-to-day management of Exactech through Mr. Binder, noted that the then-CEO of Exactech, Defendant Darin Johnson, found Mr. Binder's "involvement" during 2020-2021 as "overwhelming" and oppressive.

300. As alleged above, during this period during 2021 and thereafter, TPG, both directly and principally through Mr. Binder and Mr. Schilling (assisted by others from TPG), effectively displaced Exactech's role, and exercised complete control and domination over Exactech's interactions with, and positions with the FDA and others on recall issues and other related issues concerning Exactech's device failures.

301. Mr. Binder alone sent, received, or was copied on literally hundreds of emails during this period relating to recall issues where he substantively edited draft communications with the FDA, or directed the positions that he and TPG wanted Exactech to take with respect to the FDA.

302. Mr. Binder made sure to stay in close contact with TPG, and in particular with Defendant Schilling, who along with Mr. Sisitsky, was a key "Point-of-Contact" for Mr. Binder under his "Senior Advisor Agreement" with TPG.

303. In addition, by August 2021, if not earlier, a "Daily wrap-up" call by Defendants Schilling and Kendall Garrison, along with Mr. Lin, a then-Operations Director at TPG Capital, with Exactech to review the recall issues was set up. For his part, Defendant Schilling provided direct feedback and content on specific phrasing within presentations and on an FDA 806 report for major knee and ankle recall.

304. In August 2021, Messrs. Yasskin and Tepatti of TPG appear to have been working on a presentation deck to review concerning recall issues with the FDA. In a private email exchange between them, they discuss dividing slides in a manner confirming that it was TPG that created the slide deck presentation for the FDA and the narrative advancing the Exactech position on the recall issues. An August 21, 2021, email from Exactech states: "[h]ere is the latest deck from TPG."

In response Mr. Binder requests that the deck should be forwarded to "Tepatti and team."

305. Mr. Binder edited all, or virtually all, Exactech responses and other communications to the FDA during such period, with input from Defendant Schilling, ensuring that nothing would be said to the FDA that he, Defendant Schilling and TPG did not personally sign off on. As a result, Mr. Binder and TPG had complete control over Exactech's efforts to delay the investigation, and to try to persuade the FDA that the oxidation delamination issues were not as extensive as they were, and that Exactech's initial "voluntary" recall was adequate, positions that FDA would ultimately reject when it required a more expansive recall.

306. Defendant Schilling would routinely sit in on telephone calls and internal Exactech meetings with Mr. Binder relating to recall issues.

307. By August 2021, if not earlier, the involvement of TPG in the process of orchestrating responses to the FDA on polyethylene delamination issues and trying to obstruct any broader recall by the FDA, was so extensive, that a team of TPG personnel were assigned to assist Mr. Binder in preparing all critical responses.

308. For example, Defendant Schilling reported to Mr. Binder that Mr. Lin, who was assisting in the responses and presentations to the FDA, was "going to begin to pull things together …in line with your comments" and that TPG would

have its "Graphics crew ready for that." Mr. Lin would have extensive involvement in the drafting of a variety of documents relating to the FDA recall issues, and the TPG decision-making as to the limited scope of the recall. TPG even put documents that were being presented by Exactech on TPG's word processing system, to ease the editing of such documents by TPG.

309. Both TPG and Mr. Binder had to sign off on any talking points for communicating with the FDA, with Mr. Binder at times making the presentation to the FDA directly and/or attending meetings with the FDA. For example, Mr. Binder led a presentation on or about September 7, 2021 with the FDA, where, it appears, Mr. Binder represented, falsely, to the FDA that Exactech had taken its "discovery of [the EVOH] nonconformance [issue] very seriously" "conducted detailed analyses with regard to patient safety in defining the scope of the recall," and was "committed to a global action" and disputed the FDA's comments about Exactech's recall efforts. Mr. Binder misrepresented certain facts to the FDA, such as being "surprised by anecdotal reports of [poly] wear."

310. Although Dr. Sharat Kusuma, then the Chief Strategy Officer of Exactech, was listed as a point of contact on various of such Exactech presentations, Dr. Kusuma was required to get prior sign off from Mr. Binder and TPG before communicating with the FDA.

311. As noted, Dr. Kusuma tellingly referred to Mr. Binder as "Master Yoda" in a November 2021 email, where Dr. Kusuma provided Mr. Binder with a draft of a document for editing by Mr. Binder, which appears to have included Exactech's standard false narrative that device failure was mainly due to surgical error. Dr. Kusuma also deferred to Mr. Lin, who routinely would "take the pen" and edit documents, incorporating Mr. Binder's edits and adding those of Mr. Lin.

312. Both Mr. Binder and TPG focused on continuing the false Exactech narrative that device failures were largely due to surgical error, endeavored to delay any further FDA action, and emphasized that Exactech should not take any responsibility for such device errors.

313. At all relevant times during such ongoing discussions with the FDA, all decisions by Exactech as to what was said to the FDA, when it would be said to the FDA, who would make any presentation to the FDA, and all positions by Exactech on recall issues, were ultimately made by Mr. Binder, Defendant Schilling and TPG.

314. TPG and Mr. Binder's control and domination, indeed micromanaging, of the recall process involved misleading conduct throughout, and a continuation of the pre-TPG Acquisition conduct to minimize otherwise severe product defects, try to blame surgeons and/or patients for Exactech device failures, and improperly delay

public disclosure of the recall issues to try to continue to sell defective products prior to a more complete recall was made.

315. While Exactech internally knew (according to its own narrative), at the latest, by July 2021 that it had purchased and sold defective packaging since 2004, it would take until August 2022 for Exactech, under TPG and Mr. Binder's direction, to issue a second recall for GXL liners, which was expanded to include the AcuMatch GXL, MCS GXL, and the Novation GXL Liners.

316. A Hip DHCP Letter sent on August 11, 2022, admitted that the GXL Liners had been packaged in out of specification vacuum bags since 2004, which could lead to accelerated wear, early failure, and osteolysis in patients. However, Exactech's new XLE Liners, which had been on the market since 2018, were not identified as being affected by the August 2022 non-conforming packaging recall—the XLE hip liners would eventually be recalled after the commencement of the Bankruptcy Case, in December 2024.

317. By way of further example, on August 30, 2021, TPG, Mr. Binder and Mr. Schilling directed Exactech to quietly initiate a recall of certain Exactech Knee Devices and Ankle Devices due to accelerated wear of their respective polyethylene tibial inserts. There was no effort to publicize this recall to healthcare providers. It was not sent to medical providers or patients. Instead, it was sent to Exactech

distributors and sales representatives. It would be only much later that surgeons notified patients of the recall and the need to potentially follow up for evaluation.

318. Under the control of Mr. Binder, Mr. Schilling and TPG, a September 15, 2021 "Urgent Field Safety Notice Medical Device Recall," which noted that use of vacuum bags without an EVOH layer may result in elevated transmission of oxygen to the UHMWPE insert packaged therein was not sent to medical providers or patients.

319. As a result of the FDA's rejection of Exactech's recall notices, on February 7, 2022, Exactech was required to send an "URGENT MEDICAL DEVICE CORRECTION," advising health care professionals of the product defect, recall and its clinical significance and expanding an August 31, 2021 recall to include "all knee and ankle arthroplasty inserts packaged in non-conforming bags regardless of label or shelf life." This February 7, 2022, communication was the first time Exactech directly notified health care providers about any problems with its UHMWPE inserts. Mr. Binder and TPG had, through their deceptive and obstructive conduct, facilitated Exactech delay in making such correct disclosure until then.

320. Such course of conduct by Mr. Binder, Mr. Schilling and TPG occurred as well with other recall notices that were sent or required by the FDA ultimately to be send by Exactech.

321. Mr. Binder's, Mr. Schilling's and TPG's hands-on efforts to obstruct the FDA, and their control and domination of Exactech's responses to the recall issues, continued thereafter. In September 2023, despite having already initiated three of the Poly Recalls (which involved recalling over 627,000 units in commerce), Exactech failed another inspection and again did not show adequate procedures to proactively identify and address quality issues, as outlined below.

Figure 7: Citations from the FDA Inspection ended on Sept. 26, 2023 (ID 1038671)

Act/CFR Number	Description of FDA Citation	Quotes from FDA Citation
21 CFR 803.50(a)(1)	An MDR report 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.	"The information included in Complaint CASE-2022-00006275-1 reasonably suggests that your firm's GXL liner, a component of orthopedic hip implants, exhibited accelerated wear due to the use of nonconforming packaging, resulting in the need for revision surgery. The same malfunction is also subject to the recall Z-1734-2022 for the same device. Per the Preamble, in the Medical Devices; Medical User Facility and Manufacturer Reporting, Certification and Registration; Final Rule, 60 Fed. Reg. 63585 (Dec. 11, 1995), Comment 12, a malfunction is reportable if the manufacturer takes or would be required to take an action under sections 518 or 519(g) of the act as a result of the malfunction of the device or other similar devices. We consider a malfunction of such devices likely to cause or contribute to a death or serious injury if it were to recur. **There is no information included for the complaint that rules out that the referenced device malfunction would not be likely to cause or contribute to a death or serious injury if it were to recur**. Your firm became aware of the event on September 1, 2022. However, the corresponding MDR 1038671-2023-00008 was received by the FDA on January 4, 2023, which is beyond the required 30 calendar day timeframe." (Emphasis added.)
21 CFR 820.100(a)	Procedures for corrective and preventive action have not been adequately established.	"Your firm's CAPA procedures, 'Corrective and Preventive Actions', Document #7 01-103-137, and "Quality Data Analysis Review (QDAR)", Document #701-103-161 **do not adequately describe a standardized process for the analysis of quality data** to identify, correct and prevent the recurrence of nonconforming product and other quality problems." (Emphasis added.) "**Your firm has not identified actions needed to correct polyethylene shoulder implants** packaged in vacuum bags that did not meet material specifications or oxygen transmission rate requirements." (Emphasis added.)

F. TPG Continues the Exactech Kickback Strategy

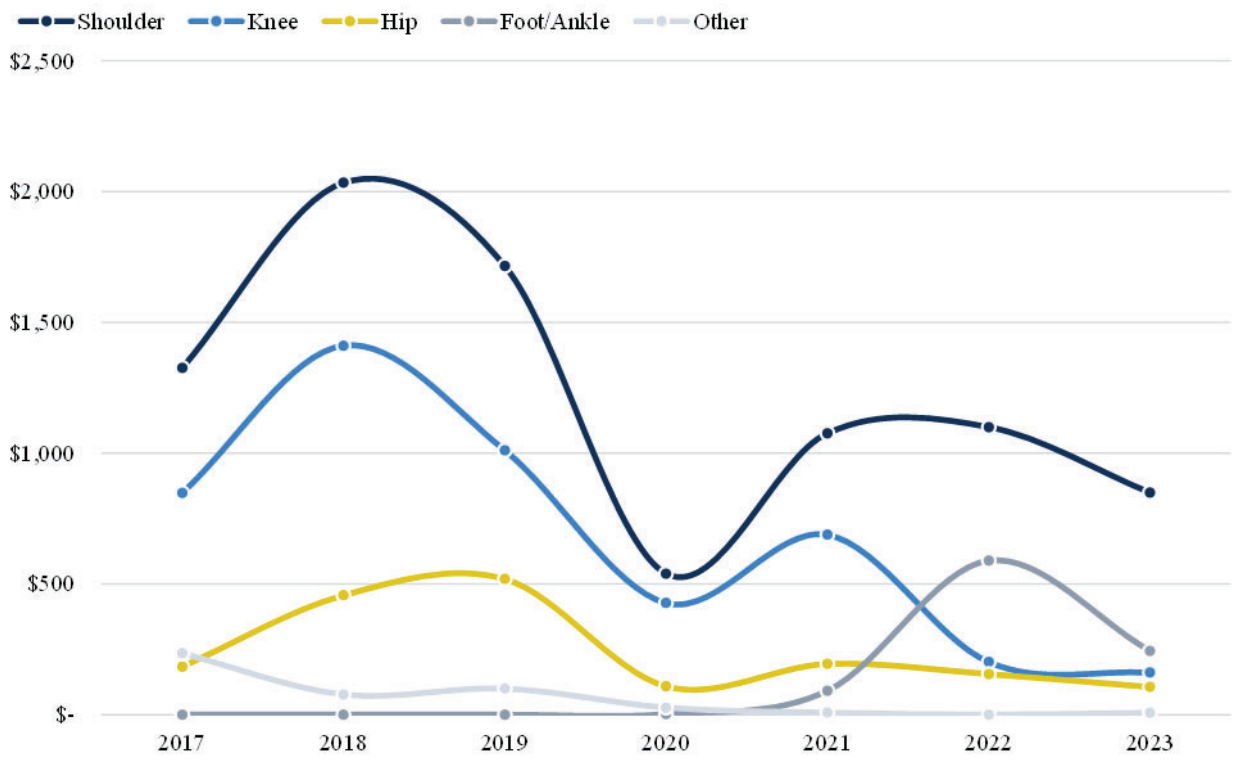
322. Prior to TPG's Acquisition of Exactech, Exactech was investigated and was required to enter into deferred prosecution agreements, corporate integrity agreements, and other agreements related to an improper kickback scheme to physicians. Mr. Binder was familiar with such practices, as when he was CEO of Biomet (prior to joining Exactech), Mr. Binder's former company paid the federal government $26 million to settle a kickback scheme investigation with the DOJ, entered into a Deferred Prosecution Agreement, and thereafter settled yet a second DOJ investigation for corrupt practices overseas and a Qui Tam action. Despite TPG, and Mr. Binder in particular, being well-versed with deferred prosecution agreements, corporate integrity agreements, and DOJ investigations regarding improper payment schemes by orthopedic manufacturers, TPG continued this scheme post-Acquisition.

323. It appears that, notwithstanding the DPA, Exactech continued with such illegal consulting agreements after expiration of the DPA, entering into similar deals and arrangements with doctors, medical professionals and others.

324. As illustrated below, consulting fees paid by Exactech to healthcare providers appear to have peaked in 2018, such that, between the TPG Acquisition Closing Date and the onset of the COVID-19 pandemic in 2020 (the "Pandemic"), consulting fees began declining. Following the onset of the Pandemic, however, it

is worth noting that consulting fees paid in relation to Exactech Shoulder Devices – the Company's largest source of revenues – began rebounding in 2021, remaining at elevated levels, far above those in relation to other Exactech Devices. Given the discretionary nature of consulting fees (unlike that of product royalties) and TPG's ongoing scheme, such volatility implies the continuation of ongoing violative conduct.

Figure 6: Consulting Fees Paid by Exactech, Inc. to Healthcare Providers in the United States ($ in thousands)



325. Notwithstanding Mr. Binder's personal familiarity with problematic consulting arrangements with physicians, according to CMS Open Payment date,

from 2017 to 2023, Exactech paid physicians nearly $60 million, including more than $16 million in consulting fees alone. Further, while TPG owned and controlled Exactech, and Mr. Binder was either Co-Executive Chairman, CEO and/or a Director of Exactech, Mr. Binder and TPG continued to attempt to use such consulting arrangements to incentivize physicians to use Exactech products or chill discussion or deter public criticism the filing of complaints about its products by surgeons who had identified product failures to Exactech or had otherwise raised complaints about defective products.

326. [redacted]

G. TPG Had a Choice: Acknowledge the Defects or Hide the Problems

327. [redacted] had tried repeatedly, without success, to urge Exactech to pull its Logic device off the market. Those requests had included multiple communications with Exactech and its senior management, prior to the TPG Acquisition. [redacted] request to Mr. Binder after the TPG Acquisition was similarly rebuffed.

328. While TPG could have investigated complaints made by [redacted] prior to the February 2018 acquisition, it appears to have elected not to do so. Given that [redacted] reached out directly to Mr. Binder in March 2019, it also is apparent that TPG became aware of [redacted] concerns by March 2019, at the latest.

329. TPG and the Individual Defendants post-Acquisition had a choice. One option was to acknowledge the defects with Exactech's Devices, recall the dangerous products so that more people would not have them implanted in their bodies, warn doctors, hospitals, and patients, and take real steps to identify the root cause of the problems. Or TPG could attempt to continue to hide the problems and blame others and continue to sell defective devices. Unfortunately, TPG chose to conceal the product defects and delay any proper recalls, as discussed herein. By late 2023, TPG, was concerned about its own exposure in the MDL and concerned that federal regulators, who were examining the recalls, thought that based on HSS's delamination complaints, the recalls should have occurred at least three years earlier, in 2018. As a result, TPG made the wrong choice post-Acquisition and, as alleged herein, it directed key aspects of the approach post-Acquisition while trying to conceal, *inter alia*, the actual facts of its role in the recall process. TPG got a brief reprieve after the MDL Court granted its motion to dismiss the veil piercing claim in March 2024, with the MDL Court never having been told by TPG the actual facts

-- that it in fact engineered the entire response to the FDA, directed that various recalls be delayed, and was the puppet master of every decision made on what would and would not be told to the FDA. [redacted] The actual facts with respect to the recall process alleged herein, which were not before the MDL Court, are fatal to TPG on veil piercing, when considered in conjunction with all the other facts pointing to TPG's veil piercing and alter ego liability.

IX. LITIGATION OVER THE PRODUCT DEFECTS

330. As of the Bankruptcy Petition Date, the Company faced lawsuits from claimants harmed by Exactech's defective medical devices, the Alabama Qui Tam Action, and the [redacted], with various cases substantially advanced and trial ready, as of Exactech's Petition Date. For example, the first Bellwether hip case in the Florida state court Master Case was scheduled to go to trial in December 2024, with fact and expert discovery having been completed. And the first Bellwether case in the MDL had undergone significant factual discovery. And, as noted, the Alabama Qui Tam was trial ready as well, it appears, with Exactech's summary judgment motion having been denied.

331. The product liability lawsuits against the Company stem from the various defects (as described in detail above) in the Exactech Devices and non-conforming packaging used for the polyethylene liners and inserts employed in the Exactech Devices manufactured and sold since at least 2004, as well as from inadequate and outdated design specifications and manufacturing processes for these polyethylene components.

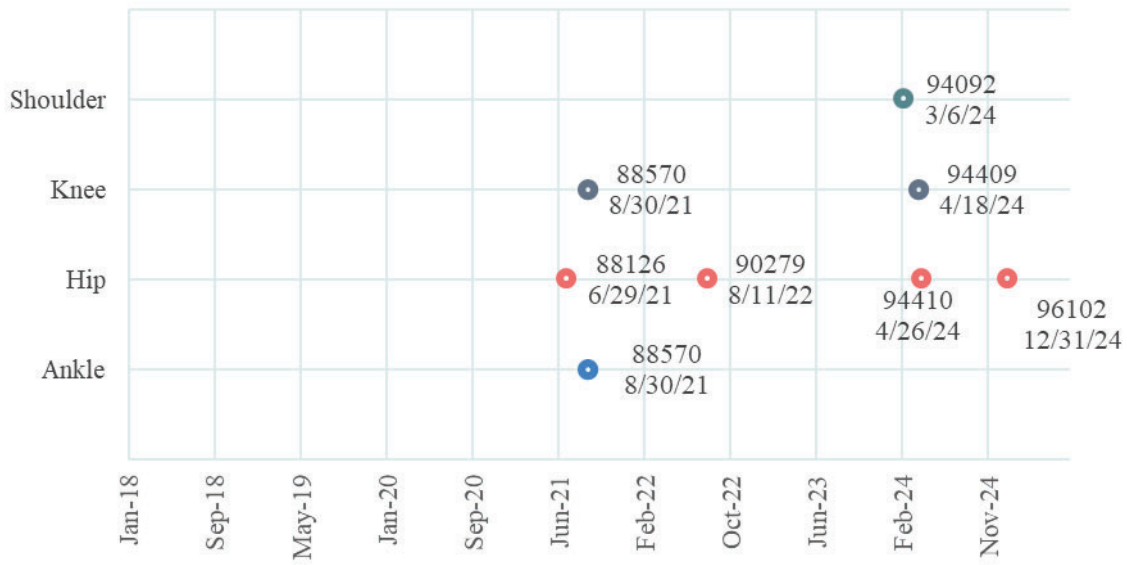
332. As of the Petition Date, the Exactech Entities faced more than 2,500 pending lawsuits filed in multiple federal, state, and non-U.S. courts. Approximately 1,840 pending lawsuits had been consolidated into the MDL. The Florida Master Case included no less than 740 pending lawsuits filed in Florida. By July 2024, over 55 unconsolidated lawsuits had been pending in other state courts, on top of more than 60 foreign actions, among other lawsuits.

333. Along with Exactech and its affiliates, certain TPG entities also were named defendants in the product liability actions, as well as in the [redacted], including TPG, Inc.; Osteon Merger Sub, Inc.; Exactech Osteon Holdings, and Exactech Osteon Holdings II, (collectively, the "TPG Product Liability Defendants").

334. Between the first initiation date of the first polyethene recall on June 29, 2021 through the most recent post-Petition recall on December 31, 2024, the

Company had initiated six recalls of polyethylene components (the "Poly Recalls"). Other recalls would follow, as noted above.

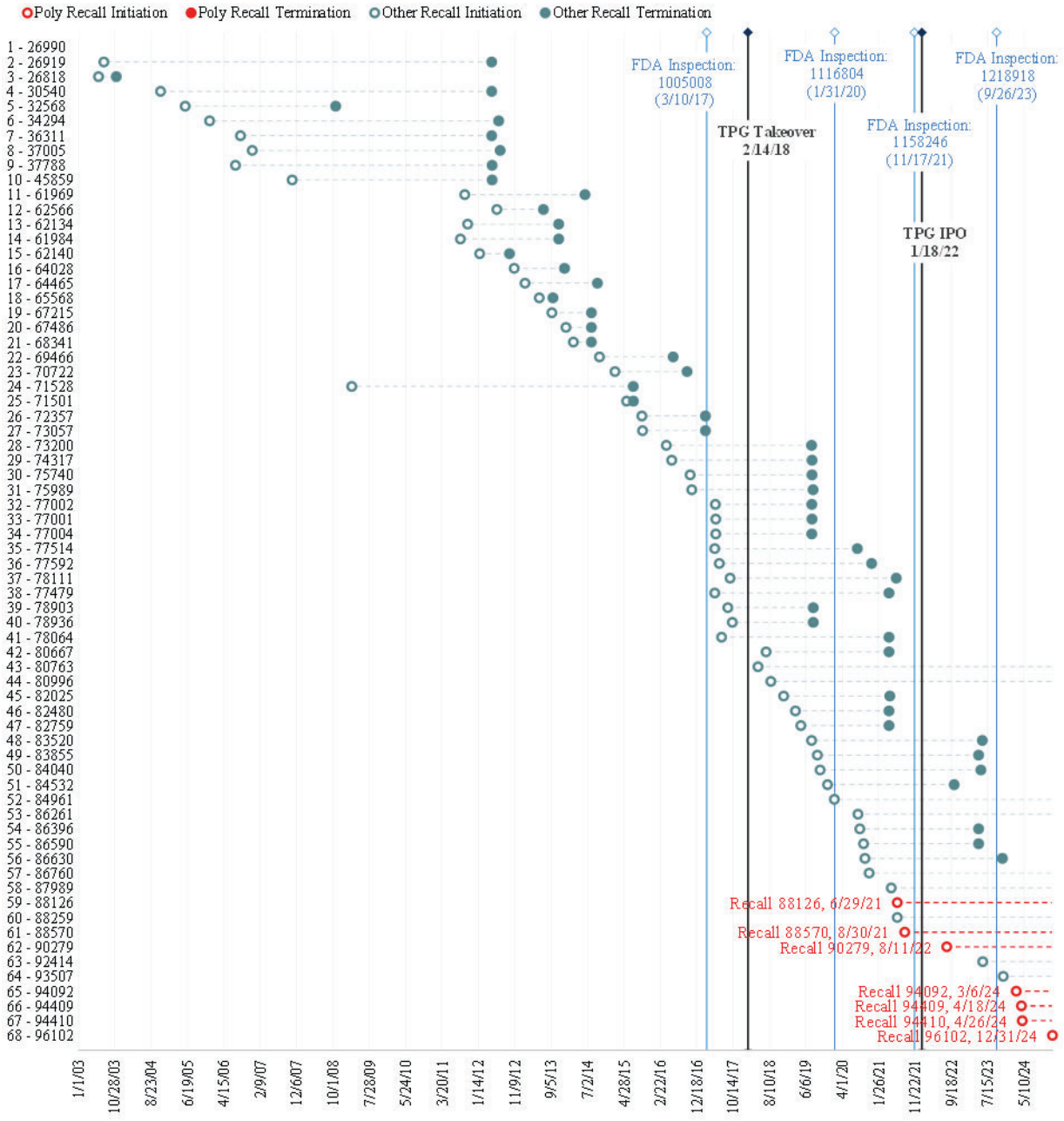
Figure 8: Timeline of Poly Recalls by Initiation Date (Recall ID/Recall Initiation Date)



335. In coordination with the FDA, the Company has recalled over 70 products in connection with the Pre-Petition Poly Recalls, including tibial knee inserts, patellar components, and GXL and conventional polyethylene hip liners, as well as all shoulder glenoids and liners distributed in non-conforming packaging. In the aggregate, nearly 800,000 units were reportedly in commerce worldwide, including hundreds of thousands of units implanted in the United States alone, by the time Exactech initiated the Poly Recalls. While the seven Poly Recalls represent a small fraction of Exactech's 68 recall events, they account for nearly 90% of the

collective number of units recalled by Exactech. As illustrated below, each Poly Recall remains open to this day.

Figure 9: Timeline of Recalls Initiated by Exactech, Inc.



336. As reflected in the summary below, Exactech, despite knowledge of the defective packaging, under the control and direction of Mr. Binder, Mr. Schilling and TPG, continued distributing products that were at risk of failure due to improper packaging as it gradually widened the scope of products being recalled for the same root cause that TPG and the Individual Defendants claim to have "discovered" at the time of the initial Poly Recall in 2021. As set forth above in detail, the serious issues with these products were well known to TPG and the Individual Defendants years earlier. Instead of directing that recalls occur and manufacturing changes be made, these Defendants chose to allow patients to continue to receive these defective products and set the Company on a path that ultimately led to insolvency.

Figure 10: Selected FDA Recall Data for Pre-Petition Poly Recalls

Product Line	Recall Event ID	Exactech Initiation Date	Reported Units in Commerce	Reported Units Implanted/Sold in the US	Manufacturer Reason for Recall
Hip	88126	6/29/2021	89,050	*Undisclosed*	"Risk of edge-loading and premature prosthesis wear is possible in a specific subset of patients with certain implant configurations and surgical implant positioning."
Knee and Ankle	88570	8/30/2021	430,517	147,732	"Inserts were **packaged in vacuum bags that lacked an additional oxygen barrier layer**."
Hip	90279	8/11/2022	107,529	*Undisclosed*	"Specific GXL acetabular polyethylene liners, **packaged in non-conforming bags**, may adversely impact the device

Product Line	Recall Event ID	Exactech Initiation Date	Reported Units in Commerce	Reported Units Implanted/Sold in the US	Manufacturer Reason for Recall
					and contribute to accelerated wear."
Shoulder	94092	3/6/2024	171,322	124,231	"The packaging of these affected UHMWPE humeral liners and glenoids are nonconforming as they do not meet the established packaging specification. They were **packaged in vacuum bags that did not contain an additional oxygen barrier layer** consisting of Ethylene Vinyl Alcohol (EVOH)."
Knee	94409	4/18/2024	N/A	*Undisclosed*	"Exactech is recalling all affected UHMWPE (ultra-high molecular weight polyethylene) knee patella components **packaged in out of specification vacuum bags**."
Hip	94410	4/26/2024	589	*Undisclosed*	"The AcuMatch L-Series 22mm Inner Diameter Bipolar Hip Liner lots were **packaged without the specified ethylene vinyl alcohol (EVOH) layer**. Between 2004 and August 2021, our packaging process utilized two different types of packaging materials: 1) Low Density Polyethylene (LDPE), Nylon, and EVOH, or 2) LDPE and Nylon without EVOH."

Product Line	Recall Event ID	Exactech Initiation Date	Reported Units in Commerce	Reported Units Implanted/Sold in the US	Manufacturer Reason for Recall
Hip	96102	12/31/2024	1575	*Undisclosed*	"This voluntary recall involves specific hip polyethylene liner lots that were **packaged without the ethylene vinyl alcohol (EVOH) layer in the innermost bag**, which is required by our packaging standards. The issue was identified during a review of supplier-provided packaging material certifications. The EVOH layer is intended to mitigate the risk of oxidation, which can lead to device degradation over time. The affected lots were packaged using only Low-Density Polyethylene (LDPE) and Nylon, which does not meet our product specifications or regulatory standards."

337. As the series of Poly Recalls extended over time, liabilities recognized by Exactech in relation to the same surged rapidly. By the end of 2021, Exactech had recognized $16.8 million in relation to the first two Pre-Petition Poly Recalls. This liability, however, became nearly **three times** as large by the end of 2022 ($48.2 million) and roughly **eight times** as large by the end of 2023 ($135.8 million). In 2024, Exactech initiated four additional Poly Recalls in which the Company recalled

over 170,000 units in commerce worldwide, including potentially tens of thousands of units implanted in the United States alone.[31]

338. In addition to this rapid escalation of litigation liabilities, in 2022, Exactech also recognized a $138 million asset impairment that effectively wrote off all the remaining goodwill previously attributed to its Large Joints segment, which comprises the Exactech Knee Devices and Exactech Hip Devices, further exacerbating Exactech's financial insolvency.

X. [redacted]

339. In addition to the Product Liability Actions, Exactech faced [redacted].

340. A qui tam action is a legal action that allows a private individual or individuals known as "relators" to sue on behalf of the government to recover money fraudulently obtained. The government in a qui tam action is the nominal plaintiff, and if the action succeeds, the relators bringing the lawsuit receive a share of the award.

341. While such [redacted] were recently settled, the allegations in such [redacted] are relevant to the Defendants' misconduct alleged herein.

[31] The Trust has not yet received information concerning Exactech's Patella recall, which could make the 170,000 units in commerce recalled worldwide significantly higher.

A. Alabama Qui Tam

342. The Alabama Qui Tam Action was filed by a former employee and two former sales representatives on behalf of themselves, the U.S. federal government, and various states in June 2018, merely months after the closing of the TPG Acquisition.

343. Essentially, this lawsuit alleged violations under the False Claims Act, among others, including that Exactech caused false claims to be submitted for reimbursement from the federal government by selling misbranded knee devices and defective knee devices that were not medically reasonable and necessary. While Exactech claims that it "compl[ied] with its responsibility to investigate the revisions and their causes," the Alabama District Court nonetheless observed that Exactech was "hard-pressed in arguing that its discoveries did not obligate it to report to the FDA."

344. Despite Exactech's repeated settlement attempts, and insistence that a settlement was already being finalized as of July 2024, the Qui Tam claims pending in the Alabama Qui Tam Action – despite numerous efforts by Exactech to avoid or deflect blame – remained pending, and appeared to be trial ready as of the Bankruptcy Petition Date, but for the stay imposed as result of Exactech's bankruptcy filing. A settlement of the Alabama Qui Tam was reached during the pendency of Exactech's bankruptcy.

B. [redacted]

345. [redacted]

346. [redacted]

347. [redacted]

348. [redacted]

XI. TPG LOOKS FOR AN EXIT STRATEGY.

349. Though TPG had purchased Exactech in February 2018, and initially had planned for an exit in 2023 (five years after the TPG Acquisition), soon after the closing, Mr. Binder began to explore a hasty, early exit for TPG. At all relevant times in connection with such potential exits, Mr. Binder consulted with and was directed by TPG.

350. The efforts by TPG to dump its investment in Exactech appear to have been prompted by mounting liability concerns due in large part to the ongoing product liability cases, as well as the risk posed by the Company's continuing to knowingly sell its defective products. As alleged, Exactech may have been insolvent when TPG purchased Exactech in February 2018.

351. By November 2019, notwithstanding headwinds with HSS, issues raised by [redacted], and receipt of the Alabama Qui Tam action, Mr. Binder was pitching the Exactech Board with a "potential IPO story." In all of Mr. Binder's presentations and those of advisors retained by TPG or Exactech, there appears to be an avoidance of any mention or disclosure of the materially negative news that Exactech was facing.

352. By August 2020, Mr. Binder was consulting with outside financial advisors, noting that "we have taken a shot at a high-level potential IPO story circa mid-2021."

353. By April 2021, notwithstanding the loss of HSS's knee business in February 2021 (a critical blow to Exactech), the ongoing Alabama Qui Tam action, and a steady stream of other complaints received by Exactech, Mr. Binder and TPG pushed ahead with a dual track effort to try to sell Exactech or alternatively do an IPO. It appears that TPG and Mr. Binder were determined at this point to unload

Exactech and cut their losses, but failed to take any action to address the mounting data that confirmed the defectiveness of the Company's products, and instead continued to be implanted in more and more patients, thus increasing substantially the liability faced by the Company.

354. An April 2021 "Company Presentation," which Mr. Binder helped prepare, and apparently was used for the potential sale of Exactech's assets, makes no mention nor disclosure of Exactech's ongoing material business challenges, including the loss of HSS's knee business, the ongoing Alabama Qui Tam Action and other escalating complaints that Exactech was receiving. This materially misleading presentation did not result in a sale. By July 13, 2021, Mr. Binder instructed the then-CEO of Exactech to "just simply say the plan is IPO and that there are very few companies out there that would be interested in buying us, including those who already have competing products they would have to integrate."

355. Plans for an IPO ultimately hit a brick wall as well. Exactech prepared and confidentially filed with the SEC a 235-page S-1 on or about April 30, 2021. In the S-1, Exactech did not reference any of Exactech's material business problems, such as the Alabama Qui Tam or the loss of HSS knee business. TPG and Mr. Binder had originally hoped for a potential IPO by mid-2021, but references to any IPO discussion disappear after mid-2021, a period in which TPG, Mr. Binder and Mr.

Schilling were focused on efforts to avoid FDA direction of a broader and more transparent recall.

356. Ultimately, TPG was unable to sell the Company or pursue an IPO, and the problems facing Exactech, which increased significantly under TPG's direction and control, could not be hidden any longer.

XII. THE CURRENT RECORD AS TO TPG CONTROL, INCLUDING INFORMATION WITHHELD BY TPG, WAS NOT BEFORE THE MDL COURT.

357. In the MDL, various plaintiffs included TPG and the Osteon Holdings Entities as defendants alleging in their complaints theories of alter-ego and veil piercing. The MDL Court prematurely dismissed the product liability claims against TPG without the benefit of any discovery from TPG, on an incomplete record. As discussed herein, the record that has now been developed makes clear that the factual assumptions relied upon by the MDL Court were inaccurate. The Trust notes that it appears, based on the Trust's investigation, that TPG did not provide the MDL Court with certain basic facts regarding TPG's control of Exactech, including that TPG's [redacted]

358. For example, critical to the MDL Court's reasoning was its understanding that TPG controlled a *minority* of the Exactech Board; the MDL Court on the record before it at the time was unaware that this understanding was inaccurate (and that TPG had withheld disclosure of relevant facts). The actual

record—including board meeting minutes—reflects that TPG maintained *majority* control of the Exactech Board following the TPG Acquisition. TPG was well aware that this was the case when it sought dismissal of the alter ego/veil piercing claims against it in the MDL. Between 2018 and early 2021, four of the six Exactech directors were from TPG (Defendants Messrs. Binder, Sisitsky, Schilling, and Garrison), and TPG maintained control of the Board up until the bankruptcy sale of Exactech. TPG also appointed the so-called "independent" directors on Exactech's Board, as alleged herein. The MDL Court was not presented with this evidence which came to light via discovery in the bankruptcy proceedings, but was of course at all times known to TPG. Had this information been provided to the MDL Court, it would have seen that TPG exercised complete control of Exactech's Board and day-to-day operations, making key decisions and even directing litigation related to the MDL.

359. The MDL Court also was not told the actual facts as to TPG's role in connection with the 2021 and subsequent recalls, that TPG micro-managed every aspect of the recall process, drafted documents submitted to the FDA, decided when recalls would be made and the scope of such recalls, and otherwise displaced prior Exactech management in the recall process.

360. [redacted]

Exactech and TPG were directed in the MDL on October 17, 2022 to appear before Judge Garaufis for an initial status conference. Immediately after that direction, [redacted]

[redacted]

361. [redacted] was never disclosed to the MDL Court. [redacted] Shortly thereafter, in early March 2023, Kirkland & Ellis entered an appearance on behalf of the TPG entities – including Osteon Holdings and Osteon Intermediate II – in the MDL. But Kirkland & Ellis did not enter an appearance for Exactech. TPG never disclosed to the MDL Plaintiffs that [redacted], even though under case law this was a relevant factor in support of alter ego/veil piercing liability. [redacted]

362. The MDL Court also did not address at all a number of other factors relevant to the alter ego analysis under either state's applicable law that, with the benefit of the further developed record that exists today, support TPG having alter ego/veil piercing liability.

363. One such alter ego factor is whether the parent and the subsidiary file consolidated financial statements and tax returns. The MDL Court did not address

this factor, and the record reflects that while Exactech and TPG Capital filed separate financial statements, TPG reviewed and incorporated Exactech's financial statements into its own financial presentations; TPG reviewed Exactech's presentations to private lenders; and TPG conferred with financial analysts from J.P. Morgan regarding Exactech's financial submissions. The record further reflects that, for years, TPG reviewed Exactech's financials, combing through documents, including Exactech's internal lender presentations and audit reports, recommending actions, and inserting corrections. TPG reviewed led the drafting of Exactech's IPO papers. And Exactech's analysts solicited TPG for comments on Exactech's draft presentations to rating agencies. Further, in presentations that TPG made to Exactech senior management and in SEC filings (*e.g.,* of Osteon Holdings, Inc.), it was clear that TPG maintained complete control over Exactech and its Board.

364. Another alter ego factor not addressed by the MDL Court is whether the daily operations of the parent and subsidiary are kept separate. As detailed herein, daily operations were most certainly not kept separate. TPG personnel regularly attended Exactech Board meetings: Defendant Mr. Tepatti attended at least 28 meetings of the Exactech Board or Exactech's Audit and Compliance Committee, and he and Mr. Yasskin were listed as "required attendees" at some Exactech Board meetings. Exactech Board agendas and draft minutes were sent by Exactech officers

(such as the CEO, Mr. Johnson) to TPG employees (such as Messrs. Yasskin, Tepatti, and/or Lin), who revised them. TPG-affiliated principals and advisors (including the Individual Defendants) holding no official position at Exactech were extensively involved in crafting responses to the FDA and privy to recall discussions and other legal developments. As noted, Mr. Binder's agreement with TPG provided for him to report to three TPG contacts, two of whom served on the Exactech Board with him. TPG personnel controlled Exactech's interactions with the FDA concerning recalls. TPG managed the onboarding of the new directors in 2021. TPG controlled Exactech's capital restructuring and bankruptcy strategy, with Mr. Tepatti and Mr. Yasskin being the primary points of contact for Ropes & Gray and Centerview LLC pre-bankruptcy.

365. Likewise, the MDL Court did not address is whether the parent finances the subsidiary or pays salaries and other expenses of the subsidiary. TPG provided certain directors and officers of Exactech and Osteon Holdings with financial compensation in the form of equity interests in Osteon. [redacted]

[redacted]

366. Another alter ego factor not addressed by the MDL Court is whether the parent and subsidiary fail to observe corporate formalities. The record reflects that some TPG-linked Exactech directors and officers, including some Individual Defendants (*e.g.*, Defendants Messrs. Binder and Garrison), had Exactech email addresses. But other TPG employees conducted Exactech's business using their @tpg.com email address (*e.g.* Messrs. Bolukbasi and Alford). TPG provided services to Exactech through a Master Services Agreement, but TPG also routinely provided informal services to Exactech through various TPG employees and advisors without formalizing statements of work. Through late 2023 there was no effort at Exactech to keep separate Boards, Board minutes, or resolutions. The Boards operated as one in the same, each dominated by TPG.

367. Another alter ego factor not addressed by the MDL Court was whether the parent caused the incorporation of the subsidiary. As alleged above, TPG created and formed each of the Osteon Holdings Entities. TPG also organized the merger of Exactech into Osteon Merger Sub, Inc., structured Exactech as a subsidiary of the

Osteon Holdings Entities and directly controlled the Osteon Holdings entity via TPG VII Partners and TPG VII Osteon Holdings.

368. Based on the information known today, the factual bases for the MDL Court's decision to dismiss claims against TPG were inaccurate and incomplete. Moreover, it is now clear that TPG concealed material information from the MDL Court and the MDL Plaintiffs, including the fact that Exactech and TPG were jointly represented and that the Individual Defendants exercised, on behalf of TPG, complete domination and control of Exactech. TPG and its counsel were obviously aware of the facts set forth above, but actively obfuscated or concealed them from the MDL Court.

COUNTS

COUNT I
DECLARATORY JUDGMENT – TPG IS THE ALTER EGO OF EXACTECH, OR ALTERNATIVELY, OF OSTEON HOLDINGS (AGAINST TPG DEFENDANTS)

369. The Trust restates and realleges the foregoing paragraphs, which are incorporated by reference as if set forth fully herein.

370. As discussed in detail above, following the TPG Acquisition, the TPG Defendants exercised domination and control, *inter alia*, over Exactech and Osteon Holdings through, among other things:

a. controlling four of six seats on Exactech's Board following the TPG Acquisition;

b. controlling four of six seats on the Osteon Holdings Board with those same members following the TPG Acquisition;

c. hand-selecting and appointing "independent" directors in 2021 to falsely give the appearance of independence from TPG;

d. failing to keep corporate formalities between Osteon Holdings and Exactech;

e. managing the Exactech Entities' financial and tax filings;

f. installing TPG's long term outside counsel as counsel for Exactech;

g. designing a bankruptcy strategy to provide TPG with a cheap release;

h. installing key directors and officers in decision-making roles, including, for example, entirely controlling the Company's day-to-day operations and product recall strategy;

i. controlling Exactech's communications with regulators, surgeons, hospitals, patients and the public;

j. routinely failing to observe corporate formalities between itself and Exactech, resulting in an intermingling of business activity, assets, and management; and

k. directing the retention of joint counsel, the law firm of Kirkland & Ellis LLP to represent both TPG and Exactech, while concealing this fact from the MDL Court and the MDL Plaintiffs.

371. The TPG Defendants used their domination and control of Exactech and Osteon Holdings to perpetrate a fraud and for other improper and illegal purposes.

372. As alleged herein, the TPG Defendants' fraudulent, improper and illegal use of the corporate form caused in excess of a billion dollars in damages, and other injury.

373. Failure to disregard the TPG Defendants' and Exactech's and Osteon Holdings' separate forms and pierce the veil shielding TPG from liability for its actions would be fundamentally unfair to Exactech's creditors.

374. Holding the TPG Defendants liable for their actions in, among other things, dominating and controlling Exactech's communications with regulators, surgeons, hospitals, patients and the public, and dominating and controlling Exactech's product recall strategy, is necessary to avoid injustice to Exactech's creditors.

375. No other remedy will be as convenient or as readily available as a declaratory judgment from this Court.

376. Therefore, the Trust is entitled to a declaratory judgment that the TPG Defendants operated as Exactech's and Osteon Holdings' alter ego following the TPG Acquisition, and imposition of damages against the TPG Defendants in an amount to be determined at trial not less than $1 billion.

COUNT II
BREACH OF FIDUCIARY DUTY
(Against Dr. Petty, David Petty, John Schilling, Kendall Garrison, Jeffrey Binder, and Todd Sisitsky (collectively the "Fiduciary Duty Individual Defendants")

377. The Trust restates and realleges the foregoing paragraphs, which are incorporated by reference as if set forth fully herein.

378. As directors and/or officers of Exactech and/or Osteon Holdings, each of the Fiduciary Duty Individual Defendants owe fiduciary duties of care, loyalty, and good faith to the Company. Those fiduciary duties include obligations to exercise good business judgment, to act prudently in the operation of Exactech's business, to discharge their actions in good faith, to act in the best interests of Exactech and its creditors upon the Exactech becoming insolvent, and to put the interests of Exactech and its creditors before their own.

379. The Fiduciary Duty Individual Defendants breached their fiduciary duties of care, loyalty and good faith, and acted with gross negligence and recklessness, for the reasons alleged herein, including, among other things:

a. causing Exactech to continue to market and sell defective products after learning that the Exactech Devices were defective;

b. failing to timely recall defective Exactech Devices upon learning of their defects;

c. breaching statutory and regulatory obligations applicable to the medical device business;

d. acting with an intent to violate applicable law;

e. acting in intentional dereliction of duty;

f. taking steps to protect and further their own interests and TPG's interests over the Exactech Entities' best interests;

g. taking steps to protect and further their own interests and TPG's interests over the Exactech Entities' creditors' best interests while the Exactech Entities were insolvent;

h. taking steps to protect and further the TPG Defendants' interests over the Exactech Entities' best interests;

i. taking steps to protect and further the TPG Defendants' interests over the Exactech Entities' creditors' best interests while the Exactech Entities were insolvent;

j. failing to investigate and inform themselves of the defective product issues with the Exactech Devices;

k. intentionally failing to act in face of a known duty to act;

l. causing the negative effects on the Company and its liabilities on the Exactech Devices by delaying the Poly Recalls;

m. failing to adequately respond to and address longstanding product defects;

n. failing to promptly undertake corrective actions;

o. diluting assets once insolvency and bankruptcy became inevitable;

p. abdicating their decision-making authority to TPG;

q. engaging in a reckless and grossly negligent waste of corporate assets;

r. taking actions designed to benefit the TPG Defendants at the expense of the Exactech Entities; and

s. mismanaging Exactech.

380. In taking the foregoing actions and/or failing to take such actions, the Fiduciary Duty Individual Defendants consistently failed to inform themselves to the degree reasonably necessary about the transactions at issue and the impact of such transactions on the Company.

381. The Fiduciary Duty Individual Defendants consistently failed to exercise reasonable business judgment in approving the foregoing actions and/or inactions.

382. The Trust is entitled to recover damages and against the Fiduciary Duty Individual Defendants, in an amount to be determined at trial not less than $1 billion.

COUNT III
BREACH OF FIDUCIARY DUTY – RED FLAGS
(AGAINST ALL FIDUCIARY DUTY INDIVIDUAL DEFENDANTS)

383. The Trust restates and realleges the foregoing paragraphs, which are incorporated by reference as if set forth fully herein.

384. As directors and/or officers of Exactech and/or Osteon Holdings, each of the Fiduciary Duty Individual Defendants owe fiduciary duties of care, loyalty, and good faith to the Company and to the Company's creditors to the extent that the Company became insolvent. Those fiduciary duties include obligations to exercise good business judgment, to act prudently in the operation of the Exactech Entities' business, to discharge their actions in good faith, to act in the best interests of the Exactech Entities and their creditors upon the Exactech Entities becoming insolvent, and to put the interests of the Exactech Entities and their creditors before their own.

385. The Fiduciary Duty Individual Defendants breached their fiduciary duties of care, loyalty and good faith, and acted with gross negligence and recklessness, for the reasons alleged herein, including, among other things by ignoring and/or not taking prudent actions in the face of red flags, among other things:

t. causing Exactech to continue to market and sell defective products after learning that the Exactech Devices were defective;

u. failing to timely recall defective Exactech Devices upon learning of their defects;

v. breaching statutory and regulatory obligations applicable to the medical device business;

w. failing to investigate and inform themselves of the defective product issues with the Exactech Devices, such as ignoring red flag warnings concerning potential defective packaging of the Exactech Devices;

x. causing the negative effects on the Company and its liabilities on the Exactech Devices by delaying the Poly Recalls;

y. causing the negative consequences of delaying filing of petitions for relief pursuant to the Bankruptcy Code;

z. attempting to suppress HSS from the prompt determination of the root cause of delamination issues;

aa. failing to properly respond when on notice of the inconsistencies between TPG's due diligence regarding Dr. Lemak and what was alleged in the unsealed Alabama Qui Tam Action;

bb. failing to adequately respond to and address longstanding product defects; and

cc. failing to promptly undertake corrective actions.

386. In taking the foregoing actions and/or failing to take such actions, the Fiduciary Duty Individual Defendants consistently failed to inform themselves to the degree reasonably necessary about the transactions at issue and the impact of such transactions on the Exactech Entities, and on the Exactech Entities' creditors, once the Exactech Entities were insolvent.

387. The Fiduciary Duty Individual Defendants consistently failed to exercise reasonable business judgment in approving the foregoing actions and/or inactions.

388. The Trust is entitled to recover damages against Fiduciary Duty Individual Defendants for ignoring and/or not taking prudent actions in the face of red flags in an amount to be determined at trial, not less than $1 billion.

COUNT IV
BREACH OF FIDUCIARY DUTY – INFORMATION SYSTEM
(AGAINST ALL FIDUCIARY DUTY INDIVIDUAL DEFENDANTS)

389. The Trust restates and realleges the foregoing paragraphs, which are incorporated by reference as if set forth fully herein.

390. As directors and/or officers of Exactech and/or Osteon Holdings, each of the Fiduciary Duty Individual Defendants owe fiduciary duties of care, loyalty, and good faith to the Company and to the Company's creditors to the extent that the Exactech Entities became insolvent. Those fiduciary duties include obligations to exercise good business judgment, to act prudently in the operation of the Exactech Entities' business, to discharge their actions in good faith, to act in the best interests of the Exactech Entities and their creditors upon the Exactech Entities becoming insolvent, and to put the interests of the Exactech Entities and their creditors before their own.

391. The Fiduciary Duty Individual Defendants breached their fiduciary duties of care, loyalty and good faith, and acted with gross negligence and recklessness, for the reasons alleged herein, including, by, among other things:

a. not having information systems in place to review medical device specifications and requirements and address defective and potentially defective products, thereby permitting Exactech to continue to market and sell defective products without oversight;

b. not having information systems in place to periodically test packaging for Exactech Devices to ensure that all packaging complied with necessary specifications, such as, for example,

that the packaging included the necessary EVOH layer and, instead, despite red flag warnings of packaging problems, not testing the packaging for more than 17 years;

c. not having information systems in place to periodically test femoral devices, and to have other proper quality control measures in place, to ensure that the surface roughness of femoral devices manufactured in-house by Exactech complied with the intended Ra 125 as a minimum, and instead, despite red flag warnings of femoral debonding and related product defects, failing to monitor or test the surface roughness of over 370,000 femoral devices for 17 years, and permitting such devices to be manufactured in-house with RA 125 as a maximum;

d. not having information systems in place that flagged repeated and potential breaches of statutory and regulatory obligations applicable to the medical device business, resulting in repeated avoidable FDA citations;

e. failing to investigate and inform themselves of product issues with the Exactech Devices, such as ignoring red flag warnings concerning potential defective packaging of the Exactech

Devices and defective manufacturing of Exactech femoral devices, and having no information systems in place to detect such defects;

f. failing to adequately respond to and address longstanding product defects; and

g. failing to promptly undertake corrective actions.

392. In taking the foregoing actions and/or failing to take such actions, the Fiduciary Duty Individual Defendants consistently failed to inform themselves to the degree reasonably necessary about the transactions at issue and the impact of such transactions on the Exactech Entities, and on the Exactech Entities' creditors, once the Exactech Entities were insolvent.

393. The Fiduciary Duty Individual Defendants consistently failed to exercise reasonable business judgment in approving the foregoing actions and/or inactions.

394. The Trust is entitled to damages against the Fiduciary Duty Individual Defendants in an amount to be determined at trial, not less than $1 billion.

COUNT V
AIDING AND ABETTING FIDUCIARY DUTY INDIVIDUAL DEFENDANTS BREACH OF FIDUCIARY DUTY
(Against TPG Defendants, Michael Tepatti, Bennett Yasskin and John Lin (collectively, the "TPG Aiding and Abetting Defendants"))

395. The Trust restates and realleges the foregoing paragraphs, which are incorporated by reference as if set forth fully herein.

396. The TPG Aiding and Abetting Defendants aided and abetted the Fiduciary Duty Individual Defendants breaches of their respective fiduciary duties for the reasons alleged herein, including, among other things:

a. aiding and abetting Exactech's continued marketing and selling of defective products after learning that the Exactech Devices were defective;

b. aiding and abetting failures to timely recall defective Exactech Devices upon learning of their defects;

c. aiding and abetting breaches of statutory and regulatory obligations applicable to the medical device business;

d. aiding and abetting the taking of steps to protect and further the Defendants' own interests over the Exactech Entities' best interests;

e. aiding and abetting the taking of steps to protect and further the Defendants' own interests over the Exactech Entities' creditors' best interests while the Exactech Entities were insolvent;

f. aiding and abetting the taking of steps to protect and further the TPG Defendants' interests over the Exactech Entities' best interests;

g. aiding and abetting the taking of steps to protect and further the TPG Defendants' interests over the Exactech Entities' creditors' best interests while the Exactech Entities were insolvent;

h. aiding and abetting failures to investigate and inform the Exactech Entities' Directors and Exactech Entities' Officers of the defective product issues with the Exactech Devices;

i. aiding and abetting delaying the Poly recalls and that delay's negative effects on the Company and its liabilities on the Exactech Devices;

j. aiding and abetting the suppression of public disclosure of [redacted] complaints and the failure to disclose to the FDA the actual extent and nature of the issues raised by [redacted];

k. aiding and abetting failures to adequately respond to and address longstanding product defects;

l. aiding and abetting failures to promptly undertake corrective actions;

m. aiding and abetting the diluting of assets once insolvency and bankruptcy became inevitable;

n. aiding and abetting the Fiduciary Duty Individual Defendants' abdication of their decision-making authority to TPG;

o. taking actions designed to benefit the TPG Defendants at the expense of the Exactech Entities; and

p. aiding and abetting the mismanagement of Exactech.

397. The Trust is entitled to damages against the TPG Aiding and Abetting Defendants for aiding and abetting the Fiduciary Duty Individual Defendants breaches of their fiduciary duties, and damages in an amount to be determined at trial, not less than $1 billion.

COUNT VI
BREACH OF FIDUCIARY DUTY

OF FORMER DIRECTORS AND OFFICERS FOR PRE-TPG ACQUISITION CONDUCT
(Against Dr. Petty and David Petty)

398. The Trust restates and realleges the foregoing paragraphs, which are incorporated by reference as if set forth fully herein.

399. As directors and/or officers, each of Dr. Petty and David Petty owed fiduciary duties of care, loyalty, and good faith to the Company prior to the TPG Acquisition. Those fiduciary duties include obligations to exercise good business judgment, to act prudently in the operation of the Exactech Entities' business, to discharge their actions in good faith, to act in the best interests of the Exactech Entities and their creditors upon the Exactech Entities becoming insolvent, and to put the interests of the Exactech Entities and their creditors before their own.

400. Dr. Petty and David Petty breached their fiduciary duties of care, loyalty and good faith, and acted with gross negligence and recklessness for their Pre-TPG Acquisition Conduct, for the reasons alleged herein, including, among other things:

a. causing Exactech to continue to market and sell defective products after learning that the Exactech Devices were defective;

b. failing to timely recall defective Exactech Devices upon learning of their defects;

c. breaching statutory and regulatory obligations applicable to the medical device business;

d. acting with an intent to violate applicable law;

e. acting in intentional dereliction of duty;

f. taking steps to protect and further their own interests over the Exactech's best interests, including engaging in a scheme to sell Exactech and profit from such sale while continuing to engage in the scheme set forth herein;

g. taking steps to protect and further their own interests over the Exactech's creditors' best interests while the Exactech were insolvent;

h. concealing from patients, government regulators, hospitals, surgeons, and the public the Exactech Devices' defects;

i. failing to properly investigate and inform themselves of the defective product issues with the Exactech Devices;

j. intentionally failing to act in face of a known duty to act;

k. causing the negative effects on the Company and its liabilities on the Exactech Devices by delaying the Poly Recalls;

l. failing to adequately respond to and address longstanding product defects;

m. failing to promptly undertake corrective actions;

n. engaging in a reckless and grossly negligent waste of corporate assets;

o. causing Exactech to enter into transactions such as the TPG Acquisition and the incurrence of substantial debt at the expense of Exactech and the Exactech's creditors, while profiting themselves; and

p. mismanaging Exactech.

401. In taking the foregoing actions and/or failing to take such actions, Dr. Petty and David Petty consistently failed to inform themselves to the degree reasonably necessary about the transactions at issue and the impact of such transactions on the Exactech Entities, and on the Exactech Entities' creditors, once the Exactech Entities were insolvent.

402. Dr. Petty and David Petty consistently failed to exercise reasonable business judgment in approving the foregoing actions and/or inactions.

403. The Trust is entitled to damages against Dr. Petty and David Petty in an amount to be determined at trial, not less than $1 billion.

COUNT VII
BREACH OF FIDUCIARY DUTY – PERMITTING BREACH OF FIDUCIARY DUTY CLAIMS AGAINST EXACTECH'S FORMER DIRECTORS AND OFFICERS TO LAPSE
(Against All Fiduciary Duty Individual Defendants)

404. The Trust restates and realleges the foregoing paragraphs, which are incorporated by reference as if set forth fully herein.

405. As explained in detail above, Dr. Petty, David Petty, and other of Exactech's Former Directors and Officers breached their fiduciary duties of care, loyalty and good faith, and acted with gross negligence and recklessness, for the reasons alleged herein, including, among other things:

a. causing Exactech to continue to market and sell defective products after learning that the Exactech Devices were defective;

b. failing to timely recall defective Exactech Devices upon learning of their defects;

c. breaching statutory and regulatory obligations applicable to the medical device business;

d. acting with an intent to violate applicable law;

e. acting in intentional dereliction of duty;

f. taking steps to protect and further their own interests over the Exactech Entities' best interests, including engaging in a scheme

to sell Exactech and profit from such sale while continuing to engage in the scheme set forth herein;

g. taking steps to protect and further their own interests over the Exactech Entities' creditors' best interests while the Exactech Entities were insolvent;

h. concealing from patients, government regulators, hospitals, surgeons, and the public the Exactech Devices' defects;

i. failing to properly investigate and inform themselves of the defective product issues with the Exactech Devices;

j. intentionally failing to act in face of a known duty to act;

k. causing the negative effects on the Company and its liabilities on the Exactech Devices by delaying the Poly Recalls;

l. failing to adequately respond to and address longstanding product defects;

m. failing to promptly undertake corrective actions;

n. engaging in a reckless and grossly negligent waste of corporate assets;

o. causing Exactech to enter into transactions such as the TPG Acquisition and the incurrence of substantial debt at the expense

of Exactech and Exactech's creditors, while profiting themselves; and

p. mismanaging Exactech.

406. To the extent, *arguendo*, any breach of fiduciary duty claim Exactech has against the Former Directors and Officers is found to be time-barred, the Fiduciary Duty Individual Defendants breached their fiduciary duties of care, loyalty, and good faith to the Exactech Entities and to the Exactech Entities' creditors by taking no timely action to either bring such breach of fiduciary duty claims against the Former Directors and Officers or to obtain a tolling agreement from the Former Directors and Officers after learning of such scheme by the Former Directors and Officers, thereby permitting those breach of fiduciary duty claims to lapse.[32]

407. The Fiduciary Duty Individual Defendants, alternatively, consistently failed to inform themselves to the degree reasonably necessary about the transactions at issue and the impact of such transactions on the Exactech Entities, and on the Exactech Entities' creditors, once the Exactech Entities were insolvent.

[32] The Trust continues to examine whether the more than $600 million in value transferred to Exactech's shareholders, including the Selling Shareholders, in connection with the TPG Acquisition is subject to clawback on other grounds and reserves all rights as to the Selling Shareholders, the TPG Defendants, the Former Directors and Officers, and the Debtors' Directors and Debtors' Officers in that regard.

408. The Fiduciary Duty Individual Defendants consistently failed to exercise reasonable business judgment in approving the foregoing actions and/or inactions.

409. The Fiduciary Duty Individual Defendants were incapable of making impartial decisions with respect to the actions or inactions taken, and it would have been futile to demand that the Fiduciary Duty Individual Defendants do so.

410. The Trust is entitled to damages in an amount to be determined at trial.

COUNT VIII
STATE LAW ACTUAL FRAUDULENT TRANSFER – MANAGEMENT SERVICES AGREEMENT
(Against TPG Defendants)

411. The Trust restates and realleges the foregoing paragraphs, which are incorporated by reference as if set forth fully herein.

412. As of February 14, 2018, the same day the TPG Acquisition closed, Exactech, Osteon Holdings, Osteon Intermediate I, Osteon Intermediate II (collectively, the "Companies"), and TPG Manager entered into a Management Services Agreement (the "MSA") pursuant to which, *inter alia*, TPG Manager was to provide certain services to the Companies in exchange for an "Annual Fee" of $1 million, paid on a quarterly basis.

413. Eight days later, on February 22, 2018, TPG sent an invoice (the "$5.9 Million Invoice") to Exactech for $5,909,935.00 with the "Description": "2/14/18

Project Osteon Out of Pocket Expenses." Project Osteon was the name TPG used to refer to the TPG Acquisition.

414. As explained in detail above, the Exactech Directors and Exactech Officers prior to the TPG Acquisition had actual knowledge at the time of the TPG Acquisition, and in all events and in the alternative certainly no later than by mid-2019, that there was significant defective product liability in connection with the marketing and sale of the Exactech Devices, that Exactech had misrepresented material facts about its business, its devices, and financial condition prior to the Acquisition, and that Exactech was insolvent and inadequately capitalized at the time of the Acquisition.

415. TPG, Exactech's Directors, and Exactech's Officers caused Exactech to agree to the TPG Acquisition with the actual intent to hinder, delay or defraud Exactech's current and future product liability creditors.

416. The MSA does not provide that Exactech will reimburse TPG for TPG's "Out of Pocket Expenses" in connection with the TPG Acquisition.

417. Within eight days of the closing of the TPG Acquisition and commencement of the MSA, there was no basis for TPG to charge Exactech in excess of $5.9 million for any services rendered.

418. The Exactech Entities' payments to the TPG Defendants pursuant to the MSA should be avoided pursuant to Fla. Stat. § 726.105(1)(a), 6 Del. C. § 1304(a)(1), or other applicable state fraudulent transfer law, and should be recovered by the Trust.

COUNT IX
STATE LAW CONSTRUCTIVE FRAUDULENT TRANSFER – MANAGEMENT SERVICES AGREEMENT
(Against TPG Defendants)

419. The Trust restates and realleges the foregoing paragraphs, which are incorporated by reference as if set forth fully herein.

420. As of February 14, 2018, the same day the TPG Acquisition closed, Exactech, Osteon Holdings, Osteon Intermediate I, Osteon Intermediate II (collectively, the "Companies"), and TPG Manager entered into a Management Services Agreement (the "MSA") pursuant to which, *inter alia*, TPG Manager was to provide certain services to the Companies in exchange for an "Annual Fee" of $1 million, paid on a quarterly basis.

421. Eight days later, on February 22, 2018, TPG sent an invoice (the "$5.9 Million Invoice") to Exactech for $5,909,935.00 with the "Description": "2/14/18 Project Osteon Out of Pocket Expenses." Project Osteon was the name TPG used to refer to the TPG Acquisition.

422. Exactech paid the $5.9 Million Invoice.

423. The MSA does not provide that Exactech will reimburse TPG for TPG's "Out of Pocket Expenses" in connection with the TPG Acquisition.

424. Within eight days of the closing of the TPG Acquisition and the commencement of the MSA, there was no basis for TPG to charge Exactech in excess of $5.9 million for any services rendered, and, in any event, the MSA provided for a $1 million "Annual Fee" for the services TPG Manager was to provide the Companies.

425. At the time the $5.9 Million Invoice was paid by Exactech, purportedly pursuant to the MSA, the Exactech Entities: (i) were insolvent or became insolvent as a result thereof; and/or (ii) were engaged in business or a transaction, or were about to engage in business or a transaction for which any property remaining with the Exactech Entities was an unreasonably small capital.

426. The Exactech Entities received less than the reasonably equivalent value in exchange for the payment of the $5.9 Million Invoice.

427. The TPG Defendants were not good faith transferees, and therefore are not entitled to offset rights under any applicable state law.

428. The Exactech Entities' payments to the TPG Defendants pursuant to the MSA should be avoided pursuant to Fla. Stat. § 726.105(1)(b), 6 Del. C. §

1304(a)(2), or other applicable state fraudulent transfer law, and should be recovered by the Trust.

COUNT X
BREACH OF FIDUCIARY DUTY
– CORPORATE WASTE – MANAGEMENT SERVICES AGREEMENT
(Against Fiduciary Duty Individual Defendants)

429. The Trust restates and realleges the foregoing paragraphs, which are incorporated by reference as if set forth fully herein.

430. As of February 14, 2018, the same day the TPG Acquisition closed, Exactech, Osteon Holdings, Osteon Intermediate I, Osteon Intermediate II (collectively, the "Companies"), and TPG Manager entered into a Management Services Agreement (the "MSA") pursuant to which, *inter alia*, TPG Manager was to provide certain services to the Companies in exchange for an "Annual Fee" of $1 million, paid on a quarterly basis.

431. Eight days later, on February 22, 2018, TPG sent an invoice (the "$5.9 Million Invoice") to Exactech for $5,909,935.00 with the "Description": "2/14/18 Project Osteon Out of Pocket Expenses." Project Osteon was the name TPG used to refer to the TPG Acquisition.

432. Exactech paid the $5.9 Million Invoice.

433. The MSA does not provide that Exactech will reimburse TPG for TPG's "Out of Pocket Expenses" in connection with the TPG Acquisition.

434. Within eight days of the closing of the TPG Acquisition and the commencement of the MSA, there was no basis for TPG to charge Exactech in excess of $5.9 million for any services rendered, and, in any event, the MSA provided for a $1 million "Annual Fee" for the services TPG Manager was to provide the Companies.

435. As directors and/or officers, each of the Fiduciary Duty Individual Defendants owe fiduciary duties of care, loyalty, and good faith to the Company and to the Company's creditors to the extent that the Exactech Entities became insolvent. Those fiduciary duties include obligations to exercise good business judgment, to act prudently in the operation of the Exactech Entities' business, to discharge their actions in good faith, to act in the best interests of the Exactech Entities and their creditors upon the Exactech Entities becoming insolvent, and to put the interests of the Exactech Entities and their creditors before their own.

436. The Fiduciary Duty Individual Defendants breached their fiduciary duties of care, loyalty and good faith, and acted with gross negligence and recklessness, for the reasons alleged herein, including, among other things:

a. causing Exactech to pay TPG's purported $5.9 Million Invoice when Exactech had no obligation to do so under the MSA or otherwise;

b. engaging in a reckless and grossly negligent waste of corporate assets;

c. acting in intentional dereliction of duty;

d. taking steps to protect and further their own interests over the Exactech Entities' best interests;

e. taking steps to protect and further their own interests over the Exactech Entities' creditors' best interests while the Exactech Entities were insolvent;

f. taking steps to protect and further the TPG Defendants' interests over the Exactech Entities' best interests;

g. taking steps to protect and further the TPG Defendants' interests over the Exactech Entities' creditors' best interests while the Exactech Entities were insolvent;

h. diluting assets once insolvency and bankruptcy became inevitable;

i. abdicating their decision-making authority to TPG; and

j. mismanaging Exactech.

437. In causing Exactech to pay TPG's $5.9 Million Invoice when Exactech had no obligation to do so, the Fiduciary Duty Individual Defendants failed to inform

themselves to the degree reasonably necessary about the transactions at issue and the impact of that transaction on the Exactech Entities, and on the Exactech Entities' creditors, once the Exactech Entities were insolvent.

438. The Fiduciary Duty Individual Defendants failed to exercise reasonable business judgment in approving the payment of TPG's $5.9 Million Invoice.

439. The Trust is entitled to judgment the Fiduciary Duty Individual Defendants breached their fiduciary duties, and damages in an amount to be determined at trial for this Count X that is not less than $5,909,935.00.

COUNT XI
ATTORNEY'S FEES AND COSTS
(Against All Defendants)

440. The Trust restates and realleges the foregoing paragraphs, which are incorporated by reference as if set forth fully herein.

441. To the extent allowable by applicable law, the Trust requests that the Court award reasonable attorneys' fees and costs.

RESERVATION OF RIGHTS

The Trust reserves all rights to amend this Complaint as new facts develop or are discovered.

PRAYER FOR RELIEF

WHEREFORE, the Trust prays for relief as follows:

1) On Count I, a declaratory judgment that the TPG Defendants are the alter ego of Exactech and/or Osteon Holdings, and a determination of damages at trial in an amount not less than $1 billion, with pre-judgment interest;

2) On Count II, judgment declaring that the Fiduciary Duty Individual Defendants breached their respective fiduciary duties to the Exactech Entities and the Exactech Entities' creditors once the Exactech Entities became insolvent, and damages in an amount to be determined at trial not less than $1 billion, with pre-judgment interest;

3) On Count III, judgment declaring that the Fiduciary Duty Individual Defendants breached their respective fiduciary duties to the Exactech Entities and the Exactech Entities' creditors once the Exactech Entities became insolvent, and damages in an amount to be determined at trial not less than $1 billion, with pre-judgment interest;

4) On Count IV, judgment declaring that the Fiduciary Duty Individual Defendants breached their respective fiduciary duties to the Exactech Entities and the Exactech Entities' creditors once the Exactech Entities became insolvent, and damages in an amount to be determined at trial not less than $1 billion, with pre-judgment interest;

5) On Count V, judgment declaring that the TPG Aiding and Abetting Defendants aided and abetted the Fiduciary Duty Individual Defendants breaches of fiduciary duties to the Exactech Entities and the Exactech Entities' creditors once the Exactech Entities became insolvent, and damages in an amount to be determined at trial not less than $1 billion, with pre-judgment interest;

6) On Count VI: judgment declaring that Dr. Petty and David Petty breached their respective fiduciary duties to the Exactech Entities and the Exactech Entities' creditors once the Exactech Entities became insolvent, and damages in an amount to be determined at trial not less than $1 billion, with pre-judgment interest;

7) On Count VII, judgment declaring that the Fiduciary Duty Individual Defendants breached their respective fiduciary duties to the Exactech Entities and the Exactech Entities' creditors once the Exactech Entities became insolvent, and damages in an amount to be determined at trial, with pre-judgment interest;

8) On Count VIII:

   a. judgment against TPG finding that Exactech's payment of $5,909,935.00, with pre-judgment interest, in response to the

$5.9 Million Invoice constitutes a fraudulent transfer under Fla. Stat. § 726.105(1)(a), 6 Del. C. § 1304(a)(1), or other applicable state fraudulent transfer law;

b. pursuant to Fla. Stat. § 726.105(1)(a), 6 Del. C. § 1304(a)(1) or other applicable state fraudulent transfer law, avoiding the transfer made to TPG in response to the $5.9 Million Invoice;

c. pursuant to applicable state fraudulent transfer law, entering judgment against TPG, in the amount of the avoided transfer, with pre-judgment interest; and

d. finding that TPG was not a good faith transferee and is not entitled to any offset rights under any applicable state law;

9) On Count IX:

a. judgment against TPG finding that Exactech's payment of $5,909,935.00 in response to the $5.9 Million Invoice constitutes a fraudulent transfer pursuant to Fla. Stat. § 726.105(1)(b), 6 Del. C. § 1304(a)(2), or other applicable state fraudulent transfer law;

b. pursuant to Fla. Stat. § 726.105(1)(b), 6 Del. C. § 1304(a)(2), or other applicable state fraudulent transfer law, avoiding the transfer made to TPG in response to the $5.9 Million Invoice;

c. pursuant to applicable state fraudulent transfer law, entering judgment against TPG, in the amount of the avoided transfer, with pre-judgment interest; and

d. finding that TPG was not a good faith transferee and is not entitled to any offset rights under any applicable state law;

10) On Count X, judgment declaring that the Fiduciary Duty Individual Defendants breached their respective fiduciary duties to the Exactech Entities for corporate waste and related misconduct, and damages in an amount to be determined at trial, with pre-judgment interest;

11) On Count XI, judgment awarding attorney's fees and costs; and

12) Awarding such other and further relief as this Court may deem just and proper.

Dated: January 30, 2026
Wilmington, Delaware

Feburary 5, 2026

HOGAN♦McDANIEL

By: */s/ Daniel K. Hogan*
Daniel K. Hogan (#2814)
1311 Delaware Avenue
Wilmington, Delaware 19806
Telephone: (302) 656-7540
Facsimile: (302) 656-7599
Email: dkhogan@dkhogan.com

-and-

BROWN RUDNICK LLP
David J. Molton (*pro hac vice forthcoming*)
Sigmund S. Wissner-Gross (*pro hac vice forthcoming*)
D. Cameron Moxley (*pro hac vice forthcoming*)
Brown Rudnick LLP
7 Times Square
New York, New York 10036
Telephone: (212) 209-4800
DMolton@BrownRudnick.com
SWissner-Gross@BrownRudnick.com
DMoxley@BrownRudnick.com

- and -

Eric R. Goodman (*pro hac vice forthcoming*)
Brown Rudnick LLP
601 Thirteenth Street NW, Ste. 600
Washington, D.C. 20005
Telephone: (202) 536-1700
EGoodman@BrownRudnick.com

Counsel to Ellen K. Reisman, Trustee, on behalf of the Exactech Settlement Trust, a Delaware Trust