UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

IN RE: EXACTECH POLYETHYLENE ORTHOPEDIC PRODUCTS LIABILITY LITIGATION MARYELIZABETH DAVIS, Plaintiff, v. EXACTECH, INC. and EXACTECH U.S., INC., Defendants.	MDL No. 3044 Case No. 22-MD-03044 (NGG) (MMH) **DIRECT FILED COMPLAINT PURSUANT TO PRACTICE AND PROCEDURE ORDER NO. 2**

COMES NOW Plaintiff MARYELIZABETH DAVIS ("Plaintiff"), by and through the undersigned attorneys, and brings this action against EXACTECH, INC. ("EXACTECH") and EXACTECH U.S., INC. ("EXACTECH U.S.") (hereafter collectively as "Defendants"), for personal injuries suffered as a proximate result of the implantation of a now-recalled Exactech Truliant Posterior Stabilized Knee System (hereafter as "Truliant Device") and alleges as follows:

NATURE OF THE ACTION

1. This is an action for damages relating to Defendants' development, designing, testing, assembling, manufacturing, packaging, monitoring, labeling, preparing, distribution, marketing, supplying, storage, and/or selling of the Truliant Device.

2. Thousands of patients, like Plaintiff MARYELIZABETH DAVIS have been, and/or will be, required to undergo extensive revision surgery to remove and replace defective Truliant Devices in connection with a recent recall of these devices which first revealed to patients and surgeons that the polyethylene components within the prosthesis prematurely degrades over time causing an inflammatory response resulting in bone necrosis and osteolysis. The recall notice admits that the recall and problems arose from failure to properly package the

polyethylene insert component of the Truliant Device.

3. As a result of Defendants' failure to properly package the Truliant Device prior to distribution, the polyethylene liner prematurely degraded and Plaintiff MARYELIZABETH DAVIS required revision surgery due to severe pain, swelling, and instability in the knee and leg. These injuries were caused by early and preventable wear of the polyethylene insert and resulting component loosening and/or other failures causing serious complications including tissue damage, osteolysis, permanent bone loss and other injuries.

4. Recipients of the Truliant Device, like Plaintiff MARYELIZABETH DAVIS, have been required to undergo revision surgeries well before the estimated life expectancy of a knee implant and at a much higher rate than should reasonably be expected for devices of this kind and have suffered pain and disability leading up to and subsequent to the revision surgery.

5. Despite knowledge that the Truliant Device was defective and resulted in premature failures and accompanying complications, Defendants only first issued a nationwide recall of their implant products on February 7, 2022, advising that "most of our inserts since 2004 were packaged in out-of-specification… vacuum bags that are oxygen resistant but do not contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) that further augments oxygen resistance."

6. As a direct and proximate result of the defective nature of Defendants' Truliant Device surgically implanted in Plaintiff which necessitated premature removal, Plaintiff MARYELIZABETH DAVIS suffered and will continue to suffer serious personal injuries, including pain, impaired mobility, rehabilitation, medical care, loss of enjoyment of life, and other medical and non-medical sequelae.

7. Plaintiff MARYELIZABETH DAVIS brings this action for personal injuries suffered as a proximate result of failure of the Truliant Device. Plaintiff accordingly seeks compensatory and punitive damages, and all other available remedies provided to Plaintiff under the law as a result of injuries she sustained due to Defendants' negligent, reckless, and wrongful conduct.

JURISDICTION & VENUE

8. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy exceeds Seventy-Five Thousand Dollars ($75,000.00), exclusive of interest and costs, and because there is complete diversity of citizenship between Plaintiff and all Defendants.

9. This matter is being filed directly in the Eastern District of New York, in MDL No. 3044, pursuant to Practice and Procedure Order No. 2 (Doc. No. 69, "Direct Filing Order"). In the Direct Filing Order, the Court allows for the direct filing of complaints by individuals, like Plaintiff, who allege total joint replacement failure and injury due to accelerated polyethylene wear in Exactech devices.

10. Absent the Direct Filing Order, this Complaint would otherwise have been originally filed in the state of Pennsylvania.

11. Defendants are subject to personal jurisdiction because at all relevant times they have engaged in substantial business activities in the state of Pennsylvania. At all relevant times Defendants transacted, solicited, and conducted business in Pennsylvania through their employees, agents, and/or sales representatives, and derived substantial revenue from such business in Pennsylvania. Defendants' contacts with the state of Pennsylvania are sufficient to confer personal jurisdiction over them to the full extent of the Constitution and applicable law.

12. Venue is otherwise proper in the Southern District of pursuant to 28

U.S.C. § 1391 because Plaintiff is a citizen and resident of Pike County, Pennsylvania, and a substantial part of the events or omissions giving rise to the claim occurred, including that her implantation surgery occurred and damages accrued in this district.

THE PARTIES

13. Plaintiff MARYELIZABETH DAVIS is a resident and citizen of Shohola, Pennsylvania.

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

15. Defendant EXACTECH, INC. develops, manufactures, packages, stores, distributes, markets, and sells orthopedic implant devices, including Truliant Devices and related surgical instrumentation throughout the United States, including in and throughout the United States and the state of Pennsylvania.

16. Defendant EXACTECH, INC. manufactured the Truliant Device implanted in Plaintiff MARYELIZABETH DAVIS.

17. At all times relevant to this action, Defendant EXACTECH, INC. tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Truliant Device in interstate commerce and throughout the State of Pennsylvania and generated substantial revenue as a result.

18. Defendant EXACTECH U.S., INC., a wholly owned subsidiary of Defendant EXACTECH, INC., is a domestic Florida corporation with its principal place of business located at 2320 NW 66th Court, Gainesville, Florida 32653.

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

20. EXACTECH U.S., INC. is engaged in the business of designing, developing, testing, assembling, selecting, manufacturing, packaging, labeling, preparing, distributing,

marketing, supplying, warranting, selling, and introducing Defendants' products, including Truliant Devices, into commerce throughout the United States and the State of Pennsylvania.

21. Upon information and belief, the Truliant Devices manufactured by Defendant EXACTECH, INC. were distributed by Defendant EXACTECH U.S., INC. throughout the United States, including Pennsylvania and the Hospital for Special Surgery in New York, New York where Plaintiff MARYELIZABETH DAVIS received her implant.

22. At all times relevant to this action, Defendant EXACTECH U.S., INC., tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, stored, promoted, advertised, marketed, distributed, and/or sold the Truliant Device in interstate commerce and throughout the State of Pennsylvania and generated substantial revenue as a result.

FACTUAL BACKGROUND

23. Upon information and belief, the Truliant product was introduced in the United States in 2017.

24. At all times material hereto, Defendants designed, developed tested, assembled, selected, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, warranted, and/or sold the Truliant Device to hospitals in many states, including to Hospital for Special Surgery in New York, New York.

25. Defendants obtained 510(k) clearance from the Food and Drug Administration ("FDA") for various knee system devices and components between 1994 and 2017 including under the names: Optetrak, Optetrak Logic, and Truliant.

26. 510(k) clearance is distinct from the FDA's pre-market approval ("PMA") process in that clearance does not require clinical confirmation of safety and effectiveness and as such the manufacturer retains all liability for the assertions of safety and effectiveness.

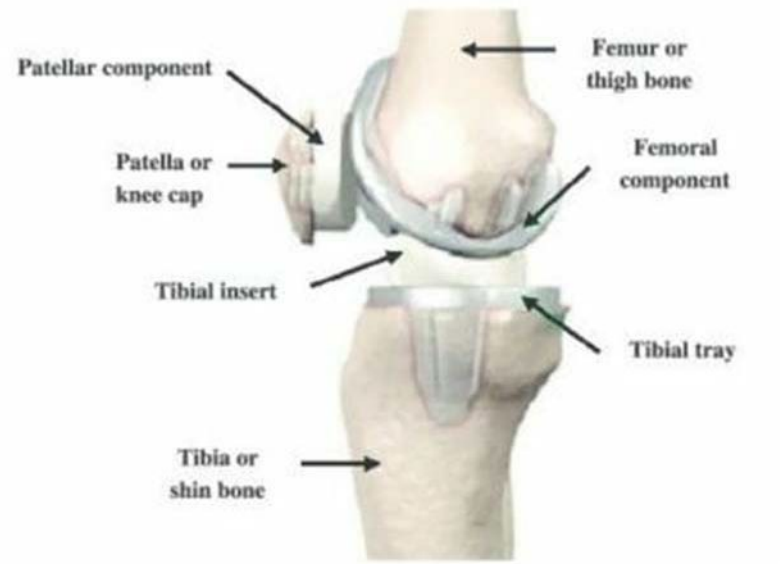
27. 510(k) clearance only requires the manufacturer to notify the FDA under section 510(k) of the Medical Device Amendments of 1976 to the Food Device Cosmetic Act (MDA) of its intent to market a device at least 90 days prior to the device's introduction on the market, and to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then "clear" the new device for sale in the United States.

28. All the component parts comprising Plaintiff's Optetrak Device were cleared for marketing by the FDA pursuant to 510(k) process or were marketed without receiving either 510(k) clearance or PMA approval by the FDA.

29. The Truliant Knee System is classified as a knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis. It features a mix of polyethylene and metal-based components.

30. According to Defendants, the device "introduces novel implants and instruments to make the total knee procedure, easier, faster, and more consistent, improving patient satisfaction for a more diverse population requiring total knee replacements."

31. The Truliant Device is comprised of the following parts: a patellar cap, femoral component, tibial insert, and tibial tray, as shown:



32. The patellar cap and tibial insert are made of polyethylene.

33. Defendants touted the Truliant Device as being first-in-class in their product brochures.

34. In their marketing materials, Defendants promised that knee implants had excellent long-term clinical outcomes; for example, it claims that "surgeons and patients can have every confidence in the performance and longevity of the Truliant knee system."

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

36. However, Exactech Devices have performed poorly when compared to their competitors. For example, the Australian Orthopaedic Association, a preeminent, internationally recognized orthopedic implant registry, has identified the Truliant as an implant with a higher-than-expected rate of revision.

37. According to the 2020 Australian National Joint Replacement Registry, the rate of revision for a total knee replacement utilizing an Truliant tibial component with an Truliant-CR

femoral component was 8.5% at ten years and 10.2% at ten years when implanted with an Truliant-PS femoral component which far exceeds international guidelines for accepted revision rates.

38. Per the recommendations established by the International Benchmarking Working Group and applied by the Australian Orthopaedic Association, the Truliant Devices do not qualify for a "superiority benchmark" or even a "non-inferiority benchmark."

39. At all times relevant, Defendants have been aware of a high rate of early failures associated with their knee implants, including their Truliant Devices.

40. Upon information and belief, by 2012, Defendants had further clinical evidence that Truliant Devices were failing at a rate higher than promoted. Reports in the Manufacturer and User Facility Device Experience (MAUDE) indicate instances of revision due to "loose tibial component," "aseptic loosening," "pain and visible loosening," "polyethylene deformation," "polyethylene worn," and "pain, limited mobility, knee swelling and sensitivity" due to "loose" joint.

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

42. Upon information and belief, the complaints of early onset failures continued in 2014. Some examples include "revision due to tibial loosening," "tibial loosening," "revision of Truliant knee components due to tibial loosening," "revision due to pain and loosening," "revision of Truliant knee components due to aseptic loosening," several reports described as

"revision of knee components due to tibial loosening," and "revision of Truliant knee components reportedly due [to] aseptic loosening."

43. The general practice in orthopedic implant surgeries, and with Exactech implants specifically, is for the sales representative of the manufacturer, in this case Exactech's authorized representative and agent, hereinafter "the sales rep," to be present at the time of surgery to provide implant components to the surgeon, relieving the hospital of the responsibility for having on stock all potential sizes and components that may be needed in surgeries. This practice includes the original implant surgery and any revision surgery.

44. The sales reps of Exactech observed many instances of premature failures of the Exactech knee implants with plain evidence upon revision of polyethylene debris that needed to get removed, a/k/a "debrided," visible bone loss, osteolysis, and/or plainly loose components that were easy to remove due to lack of fixation. Often these sales reps would take the component from the surgeon to return to the company for inspection and analysis.

45. The sales reps of Exactech were under a duty to report these findings to the engineering and medical departments of Exactech who were under a duty to then do an investigation, analyze the removed component when available, also known as "retrieval analysis" and honestly and thoroughly report such findings to the FDA and the surgeons.

46. Despite Defendants' knowledge of early onset failures of the Truliant Device, Defendants continued to manufacture, promote, and distribute the Optetrak and Truliant Devices without alerting surgeons, patients, or the FDA of the potential increased risks of early onset failures.

47. Defendants never changed the labeling, marketing materials or product inserts to adequately and accurately warn patients or physicians of the associated increased risks of early failure due to loosening and/or polyethylene wear.

48. Not until August 30, 2021, did Defendants take some action and issue a partial recall of all Optetrak All-polyethylene tibial components, including the OPTETRAK All-polyethylene CC Tibial Components; OPTETRAK All-polyethylene CR Tibial Components; OPTETRAK All-polyethylene CR Tibial Sloped Components; OPTERAK All-polyethylene PS Tibial Components; OPTETRAK HI-FLEX PS Polyethylene Tibial Components; OPTETRAK Logic All-polyethylene CR Tibial Components; OPTETRAK Logic All-polyethylene CRC Tibial Components; OPTETRAK Logic All-polyethylene PSC Tibial Components; OPTETRAK Logic Modular PS Tibial Components; OPTETRAK Logic RBK PS Tibial Components; TRULIANT CR Tibial Inserts; TRULIANT CRC Tibial Inserts; TRULIANT PS Tibial Inserts; and TRULIANT PSC Tibial Inserts.

49. In issuing the August 2021 recall, Defendants stated "inserts were packaged in vacuum bags that lacked an additional oxygen barrier layer." *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=189266

50. According to the FDA website:

> Exactech began notification to distributors and sales representatives on about 08/30/2021 via letter titled "URGENT MEDICAL DEVICE RECALL." Actions being taken by Exactech included removing all Knee and Ankle UHMWPE products labeled with an 8-year shelf life and not packaged in EVOH/Nylon bags. This will be performed in a phased approach over the next 12 months. Phase 1: immediately return all knee and ankle UHMWPE devices labeled with an 8-year shelf life that will be 5 years old or older by 08/31/2022 not packaged in EVOH/Nylon bags. Phase 2: between 05/31/2022 to 08/31/2022, returning all remaining knee and ankle UHMWPE devices labeled with an 8-year shelf life not packaged in EVOH/Nylon bags.

Id.

51. Despite initial communications with distributors and sales representatives, Defendants did not issue any communications to surgeons, who had implanted Optetrak Device with a recalled polyethylene component, or to patients who had received an Truliant Device with a recalled polyethylene component until months later in February 2022.

52. On February 7, 2022, Defendants issued an "Urgent Medical Device Correction" in which it informed health care professionals that:

> After extensive testing, we have confirmed that most of our inserts manufactured since 2004 were packaged in out-of-specification (referred to hereafter as "non-conforming") vacuum bags that are oxygen resistant but do not contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) that further augments oxygen resistance. **The use of these non-conforming bags may enable increased oxygen diffusion to the UHMWPE (ultra-high molecular weight polyethylene) insert, resulting in increased oxidation of the material relative to inserts packaged with the specified additional oxygen barrier layer. Over time, oxidation can severely degrade the mechanical properties of conventional UHMWPE, which, in conjunction with other surgical factors, can lead to both accelerated wear debris production and bone loss, and/or component fatigue cracking/fracture, all leading to corrective revision surgery.**

See Exactech Urgent Medical Device Correction dated February 7, 2022.

53. The "Urgent Medical Device Correction" went on to further state that Defendants were expanding the recall to include all knee arthroplasty polyethylene inserts packaged in non-conforming bags regardless of label or shelf life. The components subject to the recall now included: OPTETRAK®: All-polyethylene CR Tibial Components, All-polyethylene PS Tibial Components, CR Tibial Inserts, CR Slope Tibial Inserts, PS Tibial Inserts, HI-FLEX® PS Tibial Inserts; OPTETRACK Logic®: CR Tibial Inserts, CR Slope Tibial Inserts, CRC Tibial Inserts, PS Tibial Inserts, PSC Tibial Inserts, CC Tibial Inserts; and TRULIANT®: CR Tibial Inserts, CR Slope Tibial Inserts, CRC Tibial Inserts, PS Tibial Inserts, PSC Tibial Inserts. *Id.*; *see also*

Exactech Urgent Medical Device Correction dated April 7, 2022 *available at* https://www.exac.com/wp-content/uploads/2022/04/Exactech-DHCP-letter.4.6.2022.pdf.

54. It is estimated that a total of 147,732 inserts implanted in the United States since 2004 were produced with non-conforming packaging. *Id.*

55. Defendants further acknowledged the original Optetrak knee system has shown statistically significant higher overall revision rates compared to other total knee arthroplasties in the Australian, United Kingdom and New Zealand joint registries. *Id.*

56. Specifically, reasons for revision associated with polyethylene wear, including loosening, lysis, and pain, were increased three-to seven-fold with the Optetrak total knee replacement combination of the Optetrak-PS/Optetrak according to the 2021 Australian National Joint Replacement Registry with revision diagnoses related to accelerated polyethylene wear possibly related to the non-conforming packaging. *Id.*

57. Implanting surgeons were advised in the February 2022 notice to contact patients previously implanted with recalled components and to schedule an evaluation if the patient is experiencing any new or worsening knee swelling, pain while walking, inability to bear weight, grinding or other noise, instability, or any new symptoms of clicking in the knee. *Id.*

58. Furthermore, Defendants advised surgeons that revision surgery should be considered for patients who exhibit premature polyethylene wear. *Id.*

59. Based on Defendants' own representations, since 2004, Defendants manufactured, promoted, and distributed the Optetrak Device, and later the Truliant Device, without ensuring the polyethylene components were properly packaged to prevent or minimize oxidation. At no point, until August 2021, did Defendants first modify the packaging in an effort to address this defect.

60. In approximately 2017 – 2018, Exactech, Inc. was in the process of being acquired by the Private Equity Group TPG Capital which in February 2018 successfully completed a merger agreement. As a result, TPG acquired all the issued and outstanding common stock of Exactech. In connection with the transaction, Exactech's founders, CEO, and certain other management shareholders exchanged a portion of their shares in the transaction, for new equity securities in the post-closing ownership of the Company. *See* https://www.exac.com/exactech-announces-completion-of-merger-with-tpg-capital/

61. Disclosure of knowledge of the improper packaging and excessive premature failure rates could have harmed this transaction.

62. At all times relevant to this action, Defendants were aware of their knee implants' propensity to undergo substantial early polyethylene wear consisting of the degradation and breakdown of the plastic chemicals causing toxicity to the tissue and bone and component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery and its attendant complications in patients.

63. At all times relevant to this action, Defendants failed to acknowledge the manufacturing defects in the Truliant Device due to poor and inadequate quality assurance procedures and due to a wanton and reckless disregard for public safety. Defendants also failed to implement or utilize adequate safeguards, tests, inspections, validation, monitoring, and quality assessments to ensure the safety of the Truliant Device.

64. At the time the Truliant Device was manufactured and sold to patients, including Plaintiff, the device was defectively manufactured, packaged, unreasonably dangerous, and did not conform to the federal regulations subjecting patients to unreasonable risks of injury.

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

66. During the course of manufacturing and distributing the Truliant Device, Defendants failed in several ways, including, without limitation, by:

a. Failing to conduct adequate mechanical testing, including oxygen-resistance or other wear testing for the components, subassemblies, and/or finished Truliant Device;

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

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

d. Failing to identify and/or note the significance of any testing that resulted in failure of the Truliant Device;

e. Failing to take corrective actions to eliminate or minimize further failures of the Truliant Device;

f. Failing to adequately explain packaging specifications for the components, subassemblies, and/or finished Truliant Device;

g. Failing to perform adequate quality control before the components, subassemblies, and/or finished Truliant Device were distributed;

h. Failing to properly address reports from their sales representatives who reported their observations while attending revision surgeries where

evidence of polyethylene debris and osteolysis was apparent and noted by the surgeons and the sales representatives themselves;

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

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

67. On or before the date of Plaintiff's initial knee replacement surgery, Defendants knew or should have known the Truliant Device was failing and causing serious complications after implantation in patients. Such complications included, but were not limited to, catastrophic polyethylene wear including the deposition of plastic particulate wear debris throughout the knee, a high rate of component loosening, and overall early system failure resulting in tissue destruction, osteolysis, and other injuries causing severe pain, swelling, instability and dysfunction in the knee and leg necessitating revision surgery.

68. Defendants, as manufacturers of orthopedic devices, know that each surgery, especially a revision surgery, is always more complicated than an initial knee replacement surgery and is fraught with serious risks of infection, anesthesia errors, dislocations, and other serious complications that should be avoided.

69. Defendants, however, ignored reports of early failures of their Truliant Device and failed to promptly investigate the cause of such failures or issue any communications or warnings to orthopedic surgeons and other healthcare providers.

70. Before the date of Plaintiff's initial knee replacement surgery, Defendants knew or should have known that the Truliant Device was defective and unreasonably dangerous to patients, that the product had an unacceptable failure and complication rate, and that the product had a greater propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients.

PLAINTIFF-SPECIFIC ALLEGATIONS

71. On December 30, 2014, Plaintiff MARYELIZABETH DAVIS underwent a left knee replacement surgery and was implanted with a Truliant Device at the Hospital for Special Surgery in New York, New York.

72. Following the surgery, Plaintiff began experiencing worsening symptoms, including, but not limited to polyethylene particulate debris-induced extensive synovitis, osteolysis, effusion, instability, pain and discomfort. Plaintiff received a recall letter from the Hospital for Special Surgery regarding her Exactech Truliant Device, and her physician confirmed that she was implanted with a now-recalled device.

73. Plaintiff underwent a left knee revision surgery on July 7, 2022 at the Hospital for Special Surgery in New York, New York and was implanted with a Zimmer Persona device.

74. Plaintiff has not yet undergone any additional revision surgeries on her left knee as of today.

75. Plaintiff continues to experience pain and discomfort on a daily basis in her left knee, which limits her daily activities and quality of life.

76. As outlined above, Defendants, through their affirmative misrepresentations and

omissions, actively and fraudulently concealed from Plaintiff and Plaintiff's health care providers the true and significant risks associated with the Truliant Device and the need to vigilantly do diagnostic procedures to promptly diagnose the insidious process of the toxic polyethylene particles degrading and causing osteolysis.

77. Defendants know that after the one-year checkup following a total knee arthroplasty, patients are not typically expected to return for monitoring absent problems. Thus, Defendants knew that unless they informed surgeons to call their patients back for periodic radiologic monitoring, polyethylene chemical degradation and attendant osteolysis could be occurring unchecked until it reached the stage of severe bone loss.

78. As a direct, proximate, and legal consequence of the defective nature of the Truliant Device as described herein, Plaintiff MARYELIZABETH DAVIS has suffered and continues to suffer permanent and debilitating injures and damages, including but not limited to pain, swelling, effusion, knee popping, knee giving away, difficulty walking, antalgic gate, and other injuries presently undiagnosed, which all require ongoing medical care.

79. As a further direct, proximate and legal consequence of the defective nature of the Truliant Device, Plaintiff has sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; and pain and suffering.

TOLLING OF STATUTE OF LIMITATIONS, FRAUDULENT CONCEALMENT, & ESTOPPEL

80. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.

81. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial of the facts as alleged herein by Defendants. Plaintiff has been kept ignorant of vital information essential to the pursuit of these claims, without any fault or lack of diligence on Plaintiff's part.

82. Defendants were under a continuing duty to disclose the true character, quality and nature of the Truliant Device and components identified herein, to the Plaintiff as well as her physicians. Because of their concealment of the true character, quality and nature of the Truliant Device to Plaintiff, Defendants are estopped from relying on any statute of limitations defense.

83. As a result of Defendants' unlawful and fraudulent concealment of the effects of the Truliant Device, the running statute of limitations has been suspended with respect to claims that Plaintiff could bring. Plaintiff had no knowledge of Defendants' unlawful conduct, or any of the facts that might have led to the discovery of Defendants' wrongdoing, until shortly before the Complaint was filed.

84. The breakdown and wear of polyethylene, a plastic, leads to the release of toxic compounds, including chemical additives and nanoplastics. *See* Rillig, Matthias C. *et al.*, "The Global Plastic Toxicity Debt," *Environ. Sci. Technol.* 2021, 55, 2717-2719.

85. All plastics contain additional chemicals or additives and may contain impurities such as catalyst residues, unreacted monomers or breakdown products which possess toxic properties that can adversely affect human health. *Id.*

86. A comparison of muscle tissue from patients implanted with ceramic liners versus polyethylene liners during total hip arthroplasty demonstrated decreased osteolysis and capsule atrophy as well as less structural change to the muscles. *See* Hernigou, Phillippe *et al.*, "Ceramic-on-ceramic THA Associated with Fewer Dislocations and Less Muscle Degeneration by Preserving Muscle Progenitors," *Clin Orthop Relat Res* (2015) 473:3762-3769.

87. In patients who develop osteolysis, there is osteolysis-associated reduced bone regenerative capacity with a decrease in mesenchymal stem cells (MSCs) that is accompanied by reduced muscle mass and increased fatty degeneration. *Id.*

88. For polyethylene implants with resulting osteolysis, a "possible mechanism was evaluated by an experimental study demonstrating that contact PE (polyethylene) particles inhibit the osteogenic activity of osteoprogenitor cells… which may result in reduced periprosthetic bone regeneration." *Id.*

89. To date, most plastic chemicals remain unknown and the toxic hazards of potentially thousands of chemicals humans are exposed to remain unknown, and thus, unregulated. *See* Zimmerman, Lisa *et al.*, "Plastic Products Leach Chemicals That Induce *In Vitro* Toxicity under Realistic Use Conditions," *Environ. Sci. Technol.* 2021, 55, 11814-11823.

90. Plastics contain several thousand extractable chemicals which induce *in vitro* toxicity. *Id.*

91. "Our study highlights that plastic products leach chemicals triggering toxicity… the prevalent antiandrogenicity is an indicator for the leaching of endocrine-disrupting chemicals relevant for human health. Our results also show that many more chemicals are migrating from plastics than previously known." *Id.*

92. Furthermore, gamma-sterilized ultra-high molecular weight polyethylene contains macroradicals that will react with available oxygen in air or dissolved in bodily fluids. Kurtz, Steven M., *UHMWPE Biomaterials Handbook*, "Packaging and Sterilization of UHMWPE" (2016).

93. By virtue of Defendants' recall notice and representations on their website, Defendants describe a process by which sterilization of the tibial insert is achieved by gamma radiation in a reduced oxygen environment by use of oxygen barrier packaging. *See* "Optimizing Polyethylene Materials to the Application: When it Comes to Manufacturing Methods, Hips are Not Knees," *available at* https://www.exac.com/optimizing-polyethylene-materials-to-the-application/ (March 14, 2017).

94. "Gamma sterilization… initiate[s] a complex cascade of chemical reactions in the polymer, which ultimately result[s] in oxidation and subsequent degradation of material properties." *See UHMWPE Biomaterials Handbook.*

95. To the extent it is claimed that Plaintiff suffered symptoms prior to undergoing revision surgery, the statute of limitations is tolled because development of osteolysis and bone loss are latent conditions caused by years of exposure to the unknown, toxic properties of polyethylene that could not be appreciated until the time of revision surgery.

96. Furthermore, Plaintiff exhibited due diligence but did not possess technical, scientific, or medical knowledge and information sufficient to ascertain the cause of her injuries until after Defendants initiated a recall process of the Truliant Device in April of 2022 and when Plaintiff received the recall letter from Hospital for Special Surgery in 2022 advising her that the implant she received was subject to the recall and/or spoke with her physician regarding the recall of her Truliant Device.

97. Defendants, through their affirmative misrepresentations and omissions, actively and fraudulently concealed from Plaintiff and Plaintiff's healthcare providers the true and significant risks associated with the Truliant Device.

98. Following implantation of the Truliant Device, Plaintiff and Plaintiff's healthcare providers relied on Defendants' continued representations that the Truliant Device had excellent long-term clinical outcomes.

99. Defendants made these representations with knowledge of their falsity given their knowledge of reports of high failure rates.

100. As early as 2007, the Australian Joint Registry identified the Truliant Device as having a higher than anticipated rate of revision.

101. According to the Australian Joint Registry published in 2007, use of the Truliant-PS femoral component with an Truliant tibial component resulted in a 6.23% revision rate at three years and 6.64% revision rate at four years. The Registry identified use of these components as "Individual Primary Total Knee Prostheses with higher than anticipated revision rates either alone or in combination."

102. The cumulative rate of revision with use of the Truliant-PS femoral component and an Truliant tibial component continued to increase. Data from the 2008 and 2009 Australian Joint Registry demonstrated a revision rate of 6.7% and 7.0% at five years, respectively.

103. By 2010, the use of the Truliant-PS femoral component and Truliant-PS tibial components were "identified and no longer used" as a result of a 21% cumulative revision rate at five years. This rate increased to 22.7% the following year.

104. Identification of problems with the Truliant-PS tibial component continued to grow. According to the 2015 registry data, "[t]she Truliant PS all-polyethylene prosthesis has a cumulative percent revision of 19.4% at seven years."

105. Defendants themselves have acknowledged, "[e]very Exactech Truliant TKR polyethylene component combination demonstrated statistically significant increased revision rates compared to other TKR systems," citing 2021 Australian Registry data, however, data demonstrating high rates of premature failure were available to Defendants as early as 2007.

106. The Truliant Device had similarly high failure rates as documented in the United Kingdom National Joint Registry. In 2015, the revision rate for the Truliant Device was 5.02% at seven years and 6.92% at ten years. In 2016, the revision rate for the Truliant Device was 5.15% at seven years and 7.79% at ten years. In 2017, the revision rate for the Truliant Device was 5.23% at seven years and 7.45% at ten years. In 2018, the revision rate for the Truliant CR was 5.53% at seven years and 7.61% at 10 years.

107. The failure rates for the Truliant Device in the UK Registry were consistently higher compared to other knee replacement devices.

108. Defendants sold these implants worldwide and had a duty to monitor the international registries to assess how their prostheses were faring. Unfortunately, since the United States does not have a single payer health system, there is no national registry and doctors in the Unites States are not privy to nor expected to be aware of such data from other continents.

109. Defendants never informed physicians of the high failure rates associated with the Truliant Devices reported annually in the international registries.

110. Although clinical evidence demonstrated that Truliant Devices were failing at a rate higher than promoted with instances of excessive revision rates due to device loosening and

polyethylene wear, Defendants failed to initiate a recall of similar devices, such as Truliant Devices, earlier or issue any communications to healthcare providers that patients should be monitored.

111. Furthermore, earlier disclosure of these failure rates could have impacted the sale of the company to private equity.

112. Had Defendants not actively and fraudulently concealed evidence of growing reports of premature device failures, Plaintiff would have obtained radiological intervention at an earlier time.

113. Such intervention would have led to an earlier diagnosis of bone loss and earlier removal of the Truliant Device thereby reducing damage to bone and tissue.

114. As a result of Defendants' actions, Plaintiff and Plaintiff's healthcare providers were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified herein, and that those risks were the result of defects in the product due to Defendants' acts, omissions, and misrepresentations.

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

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

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

CAUSES OF ACTION

FIRST CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – DEFECTIVE MANUFACTURING

118. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows:

119. Prior to Plaintiff's initial knee surgery, and at all times relevant this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Truliant Device for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

120. Defendants had a duty to manufacture the Truliant Device in a manner that prevents unreasonable risk of harm or injury to users and patients, including Plaintiff.

121. Defendants had a duty to distribute, market, and/or sell the Truliant Device without manufacturing and related packaging defects to prevent an unreasonable risk of harm or injury to users and patients, including Plaintiff.

122. The Truliant Devices manufactured by Defendants were not reasonably safe for their expected, intended, and/or foreseeable uses, functions, and purposes.

123. The Truliant Devices were not reasonably safe as manufactured, packaged, distributed, marketed and/or sold by Defendants.

124. The defects in manufacture of the Truliant Device were a substantial factor in causing Plaintiff's injuries.

125. At all times herein mentioned, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Truliant Device, which was implanted in Plaintiff, such that it was

dangerous, unsafe, and defective in manufacture. The defects in manufacture include but are not limited to:

a. Failure to package the polyethylene components of the Truliant Device in vacuum bags that contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) as to prevent the components from undergoing increased oxidation and causing patients to experience substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery;

b. The materials used to package the Truliant Device were of an inferior grade or quality;

c. That the Truliant Device as manufactured differed from Defendants' intended specifications;

d. That Defendants failed to measure and/or test an adequate number of samples of Truliant Devices on an ongoing basis;

e. That Defendants failed to take corrective actions to eliminate or minimize further failures of the Truliant Device;

f. That Defendants failed to perform adequate quality control or other such testing on the polyethylene inserts used in the Truliant Device to ensure they complied with required specifications and were not prematurely degrading while stored;

g. Failing to select appropriate third-parties to package the polyethylene inserts used in the Truliant Device;

h. Failing to properly supervise and monitor the packaging of the polyethylene inserts used in the Truliant Device;

i. That Defendants failed to exercise sufficient quality control to ensure the polyethylene inserts in the Truliant Device were safe for implantation in users and patients and would not degrade abnormally under average and regular use; and

j. That Defendants violated applicable state and federal laws and regulations; and in all other ways.

126. Defendants knew or reasonably should have known and been aware that the Truliant Devices were defectively manufactured.

127. The manufacturing defects in the Truliant Device existed when the device left Defendants' control.

128. Plaintiff's physicians implanted the Truliant Device in the manner in which it was intended and recommended to be used, making such use reasonably foreseeable to Defendants.

129. The Truliant Device as tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold by Defendants reached Plaintiff without substantial change in its condition.

130. As alleged herein, Defendants knew or had reason to know that the Truliant Device caused an increased risk of harm to the Plaintiff and other consumers due to the device's propensity to undergo substantial early polyethylene wear, component loosening, and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients.

131. The manufacturing defects of the Truliant Device presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when used and operated for the purposes intended by Defendants.

132. The manufacturing defects of the Truliant Device presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when they were used and operated in a manner that was foreseeable to Defendants.

133. Plaintiff could not, by the exercise of reasonable care, have discovered the manufacturing defect and perceived its dangers or avoided injury.

134. Defendants are strictly liable for the defective manufacture of the Truliant Device; the distribution, marketing, and/or sale of the defectively manufactured Truliant Device; and the injuries sustained by Plaintiff.

135. By reason of the foregoing acts, omissions, and conduct committed by Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

136. By reason of the foregoing acts, omissions and conduct committed by Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, and physical disability that will require continued and additional medical treatment.

137. As a direct, proximate and legal consequence of the defective nature of the Truliant Device as described herein Plaintiff MARYELIZABETH DAVIS has suffered and continues to suffer permanent and debilitating injures and damages, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening; soft tissue

damage; bone loss; and other injuries presently undiagnosed, which all require ongoing medical care.

138. As a further direct, proximate, and legal consequence of the defective nature of the Truliant Device, Plaintiff has sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; and pain and suffering.

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

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

SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – DEFECTIVE DESIGN AND UNREASONABLY DANGEROUS PRODUCTS

140. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows:

141. Prior to Plaintiff's initial knee surgery, and at all times relevant this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Truliant Device for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

142. Defendants had a duty to design and package the Truliant Device in a manner that did not present an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff.

143. Defendants had a duty to distribute, market, and/or sell the Truliant Device with a design that did not present an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff.

144. The design of the Truliant Device and corresponding packaging is defective and not reasonably safe for its expected, intended, and/or foreseeable uses, functions, and purposes.

145. The Truliant Device and corresponding packaging are not reasonably safe as designed, distributed, marketed, delivered and/or sold by Defendants.

146. The defective design of the Truliant Device and packaging received by Plaintiff's implanting surgeon were a substantial factor in causing Plaintiff's injuries.

147. At all times relevant to this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Truliant Device, which were implanted in Plaintiff, such that it was dangerous, unsafe, and defective in design. The defects in the design include but are not limited to:

a. That the Truliant Device has propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients;

b. Failure to design the packaging for the polyethylene components of the Truliant Device in vacuum bags that contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) as to prevent the components from undergoing increased oxidation and causing patients to experience substantial early polyethylene wear, component loosening and/or other

failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery;

c. That the materials used within the Truliant Device and packaging were of an inferior grade or quality than advertised and promoted by Defendants;

d. Defendants failed to conduct adequate testing, including wear or other testing, on components, subassemblies and/or the finished Truliant Device as packaged and distributed;

e. Defendants failed to test an adequate number of samples of Truliant Devices on an ongoing basis;

f. Defendants failed to take adequate steps to specifically identify failure modes with the Truliant Device with clarity and to suggest methods to monitor, avoid, and/or prevent further failures;

g. Defendants failed to identify and/or note the significance of any testing that resulted in failure of the Truliant Device;

h. Defendants failed to take corrective actions to eliminate or minimize further failures of the Truliant Device;

i. Defendants failed to adequately design packaging specifications for the components, subassemblies, and/or the finished Truliant Device;

j. The polyethylene material used in the Truliant Device in conjunction with the inferior vacuum bags caused and/or contributed to the devices having a higher failure rate than other similar devices available at the time the Truliant Devices were put on the market;

k. The polyethylene material used in the Truliant Device in conjunction with the inferior vacuum bags caused and/or contributed to the devices having a shorter effective lifetime than other similar devices available at the time the Truliant Devices were put on the market;

l. Defendants' method of designing the polyethylene insert and packaging increased the risk of users and patients suffering from pain, discomfort, injury and the need for revision surgery; and

m. That Defendants violated applicable state and federal laws and regulations; and in all other ways.

148. Defendants knew or reasonably should have known and been aware that the Truliant Devices and packaging were defectively designed.

149. The design defects in the Truliant Device and packaging existed when the device left Defendants' control.

150. Plaintiff's physicians implanted the Truliant Device in the manner in which it was intended and recommended to be used, making such use reasonably foreseeable to Defendants.

151. The Truliant Device as tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold by Defendants reached Plaintiff without substantial change in its condition.

152. As alleged herein, Defendants knew or had reason to know that the Truliant Device caused an increased risk of harm to the Plaintiff and other consumers due to the device's propensity to undergo substantial early polyethylene wear, component loosening, and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients.

153. The Truliant Device and packaging as designed carried risks that were outweighed by any utility of the design of the device and packaging because when paired together the implant, the Truliant Device was dangerous to an extent beyond that which would be contemplated by the ordinary consumer. At no time did Plaintiff have reason to believe that the Truliant Device and the packaging in which it was received were in a condition not suitable for proper and intended use.

154. The Truliant Device and packaging were defective in design and unreasonably dangerous when it entered the stream of commerce and was received by Plaintiff, because the foreseeable risks exceeded or outweighed the purported benefits associated with the device.

155. Feasible safer alternative designs providing the same functional purpose were available to Defendants at the time the Truliant Device was designed and packaged and offered for sale in the market.

156. For example, Defendants could have utilized vacuum bags containing a secondary barrier layer containing ethylene vinyl alcohol (EVOH) as to prevent the polyethylene components from undergoing increased oxidation according to their own admissions.

157. The design defects of the Truliant Device and corresponding packaging presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when used and operated for the purposes intended by Defendants.

158. The design defects of the Truliant Device and corresponding packaging presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when they were used and operated in a manner that was foreseeable to Defendants.

159. Plaintiff could not, by the exercise of reasonable care, have discovered these design defects and perceived its dangers or avoided injury.

160. Defendants are strictly liable for the defective design of the Truliant Device; defective design of the packaging of the Truliant Device; the distribution, marketing, and/or sale of the Truliant Device; and the injuries sustained by Plaintiff.

161. By reason of the foregoing acts, omissions and conduct committed by Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

162. By reason of the foregoing acts, omissions and conduct committed by Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, and physical disability that will require continued and additional medical treatment.

163. As a direct, proximate, and legal consequence of the defective nature of the Truliant Device as described herein, Plaintiff has suffered and continues to suffer permanent and debilitating injures and damages, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening; soft tissue damage; bone loss; and other injuries presently undiagnosed, which all require ongoing medical care.

164. As a further direct, proximate, and legal consequence of the defective nature of the Truliant Device, Plaintiff has sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; and pain and suffering.

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

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and

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

THIRD CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – FAILURE TO WARN

166. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows:

167. Prior to Plaintiff's initial knee surgery, and at all times relevant this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Truliant Device for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

168. Defendants had a duty to provide adequate warnings regarding the Truliant Device in a manner that did not present an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff.

169. Defendants had a duty to distribute, market, and/or sell the Truliant Device with adequate warnings that did not present an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff.

170. The warnings that accompanied the Truliant Device and corresponding packaging were defective thereby making the product not reasonably safe for its expected, intended, and/or foreseeable uses, functions, and purposes.

171. The Truliant Device and corresponding packaging are not reasonably safe as labeled, distributed, marketed, delivered and/or sold by Defendants.

172. Inadequate labeling accompanying the Truliant Device and packaging received by Plaintiff's implanting surgeon was a substantial factor in causing Plaintiff's injuries.

173. At all times relevant to this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Truliant Device, which was implanted in Plaintiff, such that it was dangerous, unsafe, and defective.

174. The Truliant Device was defective and unreasonably dangerous when it entered the stream of commerce and was received by Plaintiff, because the warnings in the instructions for use, operative techniques, directions, marketing and promotional materials, advertisements, white papers, and other communications provided by Defendants or its sales force to physicians and patients with or about the Truliant Device failed to adequately convey the potential risks and side effects of the Truliant Device and the dangerous propensities of the device, which risks were known or were reasonably scientifically knowable to Defendants.

175. In particular, Defendants failed to adequately disclose the device's propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, bone loss, osteolysis, and other injuries as well as the need for revision surgery in patients.

176. Defendants consciously disregarded the increased risks of harm by failing to adequately warn of such risks; unlawfully concealing the dangerous problems associated with implantation of the Truliant Device; and continuing to market, promote, sell and defend the Truliant Device until the very recent recall.

177. Defendants knew or reasonably should have known and been aware that the Truliant Devices and packaging contained inadequate warnings.

178. The inadequate warnings for the Truliant Device existed when the device left Defendants' control.

179. Plaintiff's physician implanted the Truliant Device in the manner in which it was intended and recommended to be used, making such use reasonably foreseeable to Defendants.

180. The Truliant Device as tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold by Defendants reached Plaintiff without substantial change in its condition.

181. As alleged herein, Defendants knew or had reason to know that the Truliant Device caused an increased risk of harm to the Plaintiff and other consumers due to the device's propensity to undergo substantial early polyethylene wear, component loosening, and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients.

182. The Truliant Device that was labeled, manufactured, distributed, and sold by Defendants to Plaintiff was in a defective condition that was unreasonably dangerous to any user or ordinary consumer of the device, including Plaintiff.

183. The labeling defects of the Truliant Device and corresponding packaging presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when used and operated for the purposes intended by Defendants.

184. The labeling defects of the Truliant Device and corresponding packaging presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when they were used and operated in a manner that was foreseeable to Defendants.

185. Plaintiff could not, by the exercise of reasonable care, have discovered these defects and perceived its dangers or avoided injury.

186. Defendants failed to issue new warnings or initiate a recall in a timely manner as to help minimize the damage and bone loss occurring in patients, including Plaintiff.

187. Defendants are strictly liable for providing inadequate warnings accompanying the Truliant Device and packaging of the Device; the distribution, marketing, and/or sale of the Truliant Device; and the injuries sustained by Plaintiff.

188. By reason of the foregoing acts, omissions, and conduct committed by Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

189. By reason of the foregoing acts, omissions and conduct committed by Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, and physical disability that will require continued and additional medical treatment.

190. As a direct, proximate and legal consequence of the defective nature of the Truliant Device as described herein, Plaintiff has suffered and continues to suffer permanent and debilitating injures and damages, including but not limited to, significant pain and discomfort; gait impairment; poor balance; difficulty walking; component part loosening; soft tissue damage; bone loss; and other injuries presently undiagnosed, which all require ongoing medical care.

191. As a further direct, proximate and legal consequence of the defective nature of the Truliant Device, Plaintiff has sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; and pain and suffering.

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

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

FOURTH CAUSE OF ACTION
NEGLIGENCE

193. Plaintiff incorporates by reference each and every paragraph of this complaint as if set forth herein.

194. Plaintiff will show that the serious risk of failure of the Truliant Device and other related injuries are the direct and proximate result of breaches of obligations owed by Defendants to Plaintiff, including defects in design, marketing, manufacturing, distribution, instructions and warnings by Defendants, which breaches and defects include but are not limited to the following:

a. Failure to instruct and/or warn of the serious risk of loosening of and failure of the Truliant Device resulting in injuries;

b. Failure to adequately instruct and/or warn healthcare providers, including those healthcare providers who implanted the Truliant Device in Plaintiff, of the serious risk of loosening of the tibial baseplate and failure of the Truliant Device resulting in injuries;

c. Manufacturing, producing, promoting, creating, and/or designing the Truliant Device without adequately testing it;

d. Failing to provide adequate warning of the dangers associated with the Truliant Device;

e. The defects in designing, researching, developing, manufacturing, marketing, promoting and selling a medical device when it knew or reasonably should have known of the high risk of loosening and failure;

f. Defendants' liability under Pennsylvania law as a result of its design, development, manufacture, marketing, labeling and sale of a medical device which is in defective condition and is unreasonably dangerous;

g. The continued production and sale of Truliant Devices given the propensity of the medical device to loosen and fail at high rates resulting in subsequent surgery and injuries;

h. Providing inaccurate labeling and inadequate warnings and instructions with the Truliant Device;

i. Other breaches and defects which may be shown through discovery or at trial; and

j. Generally, the failure of Defendants to act with the required degree of care commensurate with the existing circumstances.

195. At all times relevant, Defendants had a duty to exercise reasonable care in the design, manufacture, sale and/or distribution of the Truliant Device into the stream of commerce, including a duty to assure that the Truliant Device did not pose a significantly increased risk of bodily harm to its users. Defendants breached this duty.

196. Defendants owed a duty to follow the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers of the Truliant Device, and otherwise distributing the Truliant Devices. Defendants breached this duty.

197. Defendants owed a duty of care to provide adequate warnings and instructions to the physicians, providers, suppliers, patients, distributors, or other end users of the Truliant Device. Defendants breached this duty.

198. Defendants performed inadequate evaluation and testing on the Truliant Device where such evaluation and testing would have revealed the propensity of the Truliant to detach, disconnect and ultimately fail causing pain, swelling, instability and other complications and injuries that Plaintiff has experienced.

199. Prior to and after the date of Plaintiff's initial knee replacement surgery in which the Truliant Device was implanted, Defendants were on notice that the Truliant Device caused serious complications, including the complications that Plaintiff suffered here.

200. Defendants had a duty to perform post-marketing testing of the Truliant Device; investigate the root cause of these complications; suspend sales and distribution; and warn physicians and patients of the propensity of Truliant Device to fail. Defendants breached this duty.

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

202. Defendants knew or should have known that the Plaintiff could foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

203. As a direct and proximate result of Defendants' breaches, Plaintiff suffered serious physical and mental injury, harm, damages, including but not limited to past, present and future medical expenses and economic loss and will continue to suffer such harm, damages and economic loss in the future.

FIFTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

204. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows:

205. Prior to Plaintiff's initial knee surgery, and at all times relevant this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Truliant Device for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

206. Defendants owed a duty to orthopedic surgeons, other healthcare providers, and to consumers of the Truliant Device, including Plaintiff, to accurately and truthfully represent the risks of the Truliant Device. Defendants breached their duty by misrepresenting and/or failing to adequately warn Plaintiff's orthopedic surgeon, the medical community, Plaintiff, and the public about the risks of the Truliant Device, including the device's propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients, which Defendants knew or in the exercise of diligence should have known.

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

208. Defendants, as the designers, manufacturers, sellers, promoters, and/or distributors of the Truliant Device knew, or reasonably should have known, that the patients implanted with Truliant Device would suffer early failure and require revision surgery because the information disseminated by Defendants and relied upon by health care professionals and

consumers, including Plaintiff, was materially inaccurate, misleading, or otherwise false.

209. Defendants failed to exercise reasonable care to ensure that the information they disseminated to health care professionals and consumers concerning the quality and longevity of the Truliant Device was accurate, complete, and not misleading. As a result, Defendants disseminated information to health care professionals and consumers that was materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Plaintiff.

210. Among Defendants' numerous misrepresentations and misleading omissions are Defendants' assurances that the Truliant Device was safe, had an excellent performance record, and did not have a greater propensity to undergo substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients.

211. Despite their knowledge of serious problems with the Truliant Device, Defendants urged their sales representatives to continue marketing the Truliant Device, and distributed medical literature, white papers, non-peer reviewed studies, and other communications to surgeons in an effort to mislead them and the general public about the risks associated with the Truliant Device and instead create the image and impression that the Truliant Device was safe.

212. Defendants made such statements even after they became aware of numerous and serious complications with the Truliant Device. Defendants did not reveal (and instead concealed) their knowledge of numerous and serious complications and other bad data.

213. Defendants made these representations with the intent to induce reliance thereon, and to encourage purchase and implantation of the Truliant Device.

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

215. Misrepresentations spanned a number of years, but also include the critical time period of 2017 – 2018 when the company was in the process of being acquired by the Private Equity Group TPG Capital which in February 2018 successfully completed a merger agreement. As a result, TPG acquired all of the issued and outstanding common stock of Exactech. In connection with the transaction, Exactech's founders, CEO and certain other management shareholders exchanged a portion of their shares in the transaction, for new equity securities in the post-closing ownership of the Company. *See* https://www.exac.com/exactech-announces-completion-of-merger-with-tpg-capital/

216. Full disclosure of the magnitude of the problem with the polyethylene failure might have negatively impacted the merger prospects and the merger may have been one of the reasons the problems were concealed.

217. Nevertheless, after the merger in 2018, it still took four years for Defendants to reveal the product defects and their health consequences to the medical community and to the patients, including Plaintiff, even though the key officers of Exactech generally continued with their roles in the newly merged company.

218. Defendants failed to exercise ordinary care in making their representations concerning the Truliant Device and, in the manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce of the Truliant Device.

219. By reason of the foregoing acts, omissions and conduct committed by Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, physical

disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

220. By reason of the foregoing acts, omissions and conduct committed by Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, and physical disability that will require continued and additional medical treatment.

221. As a direct and proximate result of Defendants' acts and omissions, including Defendants' negligent misrepresentations regarding the Truliant Device, Plaintiff MARYELIZABETH DAVIS was implanted with the Truliant Device and was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

222. As a further direct, proximate and legal consequence of Defendants' acts and omissions, including Defendants' negligent misrepresentations regarding the Truliant Device, Plaintiff has sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; and pain and suffering.

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

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

SIXTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

224. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows:

225. Prior to Plaintiff's initial knee surgery, and at all times relevant this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Truliant Device for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

226. Defendants expressly warranted the Truliant Devices, including the Truliant Posterior Stabilized Knee System, were safe and effective orthopedic devices.

227. Defendants promised that the Truliant Device had excellent long-term clinical outcomes and that "surgeons and patients can have every confidence in the performance and longevity of the Truliant knee system."

228. At the time Defendants manufactured, marketed, sold and/or distributed the Truliant Devices, they knew that the devices were intended for human use, and that Plaintiff was a foreseeable user of the Truliant Device.

229. The express warranties represented by Defendants were a part of the basis for Plaintiff's use of the Truliant Device, and she and her surgeon relied on these warranties in deciding to use the Truliant Device.

230. At the time of the making of the express warranties, Defendants had knowledge of the purpose for which the Truliant Devices were to be used and warrantied the same to be in all respects safe, effective, and proper for such purpose.

231. The Truliant Devices do not conform to these express representations as demonstrated by the fact that Plaintiff's implant failed prematurely due to polyethylene wear of the tibial insert which necessitated her to undergo revision surgery.

232. At the time Defendants marketed, sold and/or distributed the Truliant Devices, Defendants expressly warranted that the total knee replacement systems, including all of their component parts, were safe and merchantable for their intended use.

233. Plaintiff MARYELIZABETH DAVIS and her implanting physician reasonably relied upon Defendants' express warranties.

234. Plaintiff MARYELIZABETH DAVIS used the Truliant Device for its intended purpose and in a reasonable foreseeable manner.

235. The Truliant Devices manufactured and sold by Defendants, did not conform to Defendants' express representations because the Truliant Device caused serious injury to Plaintiff when used as recommended and directed.

236. As a direct and proximate result of Defendants' acts and omissions, including breach of express warranty, Plaintiff MARYELIZABETH DAVIS was implanted with the Truliant Device and was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

237. As a further direct, proximate and legal consequence of Defendants' acts and omissions, including breach of express warranty, Plaintiff has sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; and pain and suffering.

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

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

SEVENTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY

239. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows:

240. Prior to Plaintiff's initial knee surgery, and at all times relevant this action, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Truliant Device for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

241. Defendants impliedly warranted, through its marketing, advertising, distributors, and sales representatives, that the Truliant Device was of merchantable quality, and fit for the ordinary purposes and uses for which it was sold.

242. In fact, the Truliant Device was not of merchantable quality nor fit for the ordinary purposes and uses for which it was sold and did not meet the expectations of consumers.

243. The Truliant Device manufactured and supplied by Defendants was not of merchantable quality and was not fit for the ordinary and/or particular purpose for which it was intended as physicians and patients would expect the components to be properly packaged and stored as to avoid premature degradation of component materials.

244. Plaintiff and/or her physician reasonably relied upon the skill and judgment of Defendants as to whether the Truliant Device was of merchantable quality and safe for its intended and particular use and purpose.

245. Contrary to such implied warranties, the Truliant Device was not of merchantable quality or safe for its intended and particular use and purpose, because Defendants failed to package the polyethylene components of the Truliant Device in vacuum bags containing a secondary barrier layer containing ethylene vinyl alcohol (EVOH) as to prevent the components from undergoing increased oxidation and causing patients to experience substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery.

246. As a direct and proximate result of Defendants' acts and omissions, including breach of implied warranties, Plaintiff MARYELIZABETH DAVIS was implanted with the Truliant Device and was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

247. As a further direct, proximate and legal consequence of Defendants' acts and omissions, including breach of implied warranties, Plaintiff has sustained and will sustain future damages, including but not limited to cost of medical care; rehabilitation; home health care; loss of earning capacity; mental and emotional distress; and pain and suffering.

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

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, and severally, as follows:

a. Judgment in favor of Plaintiff and against all Defendants, for damages in such amounts as may be proven at trial;

b. Compensation for both economic and non-economic losses, including but not limited to medical expenses, loss of earnings, disfigurement, pain and suffering, mental anguish, and emotional distress, in such amounts as may be proven at trial;

c. Punitive and/or exemplary damages in such amounts as may be proven at trial;

d. Attorneys' fees and costs;

e. Interest; and

f. Any and all further relief, both legal and equitable, that the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury.

DATED this 6th day of April 2023.

Respectfully submitted,

/s/A. Renee Preston
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