IN THE UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF LOUISIANA

GERALDINE BILLUPS Plaintiff, VERSUS **EXACTECH, INC.** Defendants.	**Civil Action No.:** **Judge:** **Magistrate Judge:**

COMPLAINT AND JURY DEMAND

TO THE HONORABLE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF LOUISIANA AND THE JUDGES THEREOF:

NOW COMES Plaintiff, Geraldine Billups, a person of the full age of majority, through undersigned counsel, and brings this action against Exactech, Inc. for personal injuries suffered as a proximate result of the implantation of an Exactech Knee Replacement System, and alleges as follows:

THE PARTIES

1. Plaintiff, Geraldine Billups, is a citizen and resident of Metairie, Jefferson Parish, Louisiana.

2. Defendant, Exactech, Inc. is a Florida corporation with its principal place of business at 2320 NW 6th Court, Gainesville, Florida 32653.

JURISDICTION AND VENUE

3. This Court has subject matter jurisdiction over this case pursuant to diversity jurisdiction under 28 U.S.C. § 1332 because the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs, and there is complete diversity between the parties.

4. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because all or a substantial part of the events or omissions giving rise to this claim occurred in this District. Venue is also proper in this Court pursuant to 28 U.S.C. § 1391 because Defendants have sufficient minimum contacts with the State of Louisiana and intentionally availed themselves of the market within Louisiana through the promotion, sale, marketing, and distribution of their products.

NATURE OF THE CASE

5. Plaintiff, Geraldine Billups, files this Complaint against Exactech, Inc. ("Exactech" or "Defendant") for damages deemed just and proper arising from the injuries suffered by Plaintiff as a direct and proximate result of Defendant's manufacturing, designing, testing, assembling, device packaging, quality control, storing, distributing, supplying, warranting and/or unfair and deceptive marketing, advertising and selling the Optetrak Total Knee Replacement System containing a defective polyethylene tibial insert packaged in a non-conforming bag, hereinafter referred to as "defective insert", and the defective Optetrak posterior stabilized knee implant containing a finned tibial tray component (hereinafter referred to as "defective tibial tray").

6. Defendant, directly or through its agent, distributor and/or employees designed, assembled, manufactured, packaged, labeled, distributed, marketed, warranted, and sold the defective insert and defective tibial tray for use as components of the Optetrak Knee Replacement System throughout the United States and, specifically, Louisiana.

7. The Optetrak Knee Replacement System was manufactured, marketed, and sold by Defendant during the years 2004 to 2022 containing defective inserts stored in out-of-specification, non-conforming bags, which lacked a protective barrier necessary to prevent air from reaching the insert during storage, thereby causing premature wear, and resulting in the necessity for surgical revisions. Furthermore, the tibial tray was defective due to the way it was designed as a finned

tibial tray. Plaintiff was implanted with a finned tibial tray in 2006, a component of the Optetrak Knee Replacement System.

8. Although Defendant had obtained FDA 510(k) clearance under the Medical Device Amendments of 1976 to the Food Device Cosmetic Act (MDA) for sale and distribution of the Optetrak Knee Replacement System during the years 2004-2022, this type of clearance did not involve clinical testing by the FDA for safety and effectiveness or quality control of the Optetrak Knee Replacement System or any of its components.

9. Exactech retained sole responsibility for safety and effectiveness of the Optetrak Knee Replacement System, specifically during the times when it was marketed and sold with the defective insert and/or defective tibial tray, including quality control procedures.

FACTUAL BACKGROUND

10. In 2006, Plaintiff sought treatment at Ochsner Medical Center for knee pain. At the recommendation of the orthopedic surgeon, she underwent knee replacement surgery on her right knee with an Optetrak Knee Replacement System, including the defective insert and defective tibial tray.

11. In 2008, less than two years after her knee replacement surgery, Plaintiff developed loosening of the device and pain in her right knee. On October 28, 2008, Plaintiff underwent a surgical revision of her right knee due to "failed right total knee with a loose tibial component." At the time of surgery, it was discovered that Plaintiff's right knee was also infected and, therefore, the Optetrak Knee Replacement System and its components were removed while Plaintiff underwent treatment for the infection.

12. Plaintiff continued treatment for the infection until February 3, 2009, when another Optetrak Knee Replacement System was implanted in her right knee at Ochsner Medical Center,

along with another defective insert. At that time, unbeknownst to Plaintiff, Defendant had introduced a new finned tibial tray, FIT, to replace the defective tibial tray due to numerous reports of loosening and bone loss that were not reported by Defendant to the FDA, or disclosed to the orthopedic surgeons or to the general public, including Plaintiff.

13. Plaintiff continued to have pain and instability in connection with her Optetrak Knee Replacement System and, in October 2012, it was determined that the device had again loosened and failed, and that, therefore, she was required to undergo another revision. On October 18, 2012, surgery was once again performed on Plaintiff's right knee. At this re-revision, another defective insert was implanted in Plaintiff's knee.

14. Plaintiff continued to have difficulty with her right knee, and, in March 2021, she switched her care to Tulane Medical Center. At Tulane, on March 25, 2021, Plaintiff underwent another revision due to loosening and bone loss related to the defective insert. As a result of this revision surgery, Plaintiff's popliteal artery was severed, and Plaintiff continues to suffer from medical complications and risks.

15. In total, Plaintiff was subjected to three consecutive premature failures of her right knee replacements resulting in five additional procedures:

Date	Reason	Surgery
06/08/2006		Primary TKA surgery
10/28/2008	Loosening	Removal surgery with antibiotic spacer
02/03/2009		Revision TKA implantation
10/18/2012	Loosening	Revision TKA, partial
03/25/2021	Loosening	Revision TKA, complete
03/23/2021	Complication	Popliteal artery and vein repairs

THE DEFECTIVE INSERT

16. On August 30, 2021, Exactech issued a partial recall of the Optetrak polyethylene inserts implanted between 2004 and 2022, labeled with a certain limited shelf life. That partial recall stated that "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

17. Then, on February 7, 2022, Defendant expanded its recall, regardless of shelf-life, and issued an "Urgent Medical Device Correction" which 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 "nonconforming") 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, https://www.exac.com/wp-content/uploads/2022/04/Exactech-DHCP-letter.4.6.2022.pdf

18. On March 17, 2022, in response to the recall, Ochsner Medical Center advised all of their patients who had been implanted with an Optetrak, including Plaintiff, that Exactech had issued a recall of all of its polyethylene inserts, including the ones implanted in Plaintiff. According to Ochsner:

> "Exactech learned that one of the packaging layers for the plastic insert has been out of specification and may allow oxygen from the air to diffuse into the plastic insert prior to it being implanted in your knee. If a large amount of oxygen diffuses into the plastic insert while it's being stored and before it is implanted, this can lead to a process called oxidation, which can cause the plastic to wear out earlier than expected or to become damages after it is implanted into the patient's body."

Exactech also reported in its notification letter that:

> "Premature wear of the plastic insert of your knee replacement can lead to the need for additional surgery (also known as revision surgery)."

See attached Exhibit 1.

19. Upon information and belief, Defendant knew, or should have known, that between 2004 and 2022, when Plaintiff underwent implant surgery and revisions, the defective insert was being packaged in bags that did not comply with its own specifications for protection. This defective packaging caused increased release of tibia-femoral wear debris from the polyethylene inserts implanted in Plaintiff. And this, in turn, increased the particle burden, which contributed to loosening and bone loss documented in her successive failed knee replacement procedures.

20. Furthermore, upon information and belief, Defendant knew, or should have known, of the premature wear of the defective inserts based on patient complaints reported in the Australian Orthopaedic Association National Joint Replacement Registry demonstrating significantly higher overall revision rates due to loosening, bone loss and pain occurring with the Optetrak Knee Replacement System.

21. Plaintiff could not, by the exercise of reasonable care, have discovered the dangers related to the defective insert prior to February 7, 2022, when Defendant issued a recall of the defective insert and notified the healthcare providers and patients.

THE DEFECTIVE TIBIAL TRAY

22. Defendant manufactured and sold the Optetrak Knee Replacement System with the defective tibial trays. The tibia tray was marketed as a component that anchors to the patient's tibia and connects to the artificial knee.

23. Defendant designed, marketed, advertised, and sold the defective tibial tray to Ochsner Medical Center for implantation in Plaintiff's right knee replacement surgery on June 8, 2006.

EXACTECH VIOLATIONS

24. Upon information and belief, Defendant received numerous reports of adverse events relating to injuries caused by the defective tibial tray but failed to report these events in violation of FDA's requirements in reporting adverse events. 21 U.S.C. § 352(t).

25. Upon information and belief, Defendant engaged in a "silent recall" wherein it replaced the defective tibial trays with a different designed tray. Concurrent with this strategy, Defendant also engaged in a campaign of misinformation wherein any incidents of early failures were blamed on surgeons or patients rather than the defective tibial tray.

26. Based on information and belief, Defendant's Optetrak Knee Replacement Systems with their defective inserts and/or defective tibial trays are considered adulterated pursuant to 21 U.S.C. § 351 because, among other things, they failed to meet established performance standards, and/or methods, facilities, or controls used for their manufacture, packaging, storage, or installation, and are not in conformity with federal requirements in accordance with Current Good Manufacturing Practices ("cGMP") for medical devices. *See* 21 U.S.C. § 351; 21 C.F.R. § 820, *et seq.*

27. Based on information and belief, Defendant's Optetrak Knee Replacement Systems with a defective insert and/or defective tibial tray are considered misbranded because, among other things, they are dangerous to health when used in the manner prescribed, recommended, or suggested in the labeling thereof. *See* 21 U.S.C. § 352.

28. Had Defendant complied with the federal requirements regarding cGMP, Defendant's knee implant devices would have been manufactured properly and would not have resulted in injuries to Plaintiff.

EQUITABLE ESTOPPEL AND *CONTRA NON VALENTEM*

29. Plaintiff incorporates by reference the allegations of the preceding paragraphs of the Complaint as if fully set forth at length herein.

30. Plaintiff invokes the doctrine of *contra non valentem* as she could not discover the defects and unreasonably dangerous condition of Defendant's defective tibial tray and defective insert.

31. Defendants are estopped from relying on any prescription limitations by virtue of their acts of fraudulent concealment, affirmative misrepresentations and omissions, which include Defendant's intentional concealment from Plaintiff, Plaintiff's health care professionals and the general public that the Optetrak Knee Implant System was unreasonably dangerous and carried serious risks causing injuries.

32. Defendant breached its duty to disclose that the Optetrak Knee Implant System was unreasonably dangerous and carried with it the serious risk of early failure, injury and revision surgery.

33. Defendant breached its duty to notify, inform, or disclose to Plaintiff, Plaintiff's health care professionals or the general consuming public that Defendant's Optetrak Knee Implant System was causing high incidences of injuries and that its use carried with it the serious risk of developing the injuries Plaintiff has suffered and complained of herein.

CAUSES OF ACTION

COUNT I – STRICT LIABILITY – UNREASONABLY DANGEROUS IN COMPOSITION

34. The Optetrak Knee Implant System containing the defective insert and/or defective tibial tray was unreasonably dangerous as manufactured, packaged, distributed, marketed and/or sold by the Defendant, as defined in the Louisiana Products Liability Act ("LPLA"), Louisiana Revised Statute 9:2800.55.

35. The defective components in the Optetrak Knee Replacement System were a substantial factor in causing Plaintiff's injuries.

36. Defendant is strictly liable for the defective condition of the Optetrak Knee Replacement System; the distribution, marketing, and/or sale of the defective insert and/or the defective tibial tray; and the injuries sustained by Plaintiff.

COUNT II – STRICT LIABILITY – UNREASONABLY DANGEROUS IN DESIGN

37. Defendant had a duty to design and package the defective insert in a manner that did not present an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff.

38. The designs of the defective tibial tray and the packaging of the defective insert were unreasonably dangerous for its expected, intended, and/or foreseeable uses, functions, and purposes, as defined in the Louisiana Products Liability Act, Louisiana Revised Statute 9:200.56.

39. The defective tibial tray was not reasonably safe as designed, distributed, marketed, delivered and/or sold by Defendant.

40. The design defects in the defective tibial tray and defective insert and its packaging existed when the device left the Defendant's control.

41. Plaintiff's physicians implanted the defective tibial tray and defective insert in the manner in which they were intended and recommended to be used, making such use reasonably foreseeable to Defendant.

42. The defective tibial trays and the defective inserts and packaging were defective in design and unreasonably dangerous when it entered the stream of commerce and received by Plaintiff, and the foreseeable risks exceeded or outweighed the purported benefits associated with the device.

43. Feasible, safer, alternative designs and packaging providing the same functional purpose were available to the Defendant at the time the defective tibial tray and the defective insert were designed, packaged, and offered for sale in the market.

COUNT III – STRICT LIABILITY-UNREASONABLY DANGEROUS BECAUSE OF INADEQUATE WARNING

44. Defendant failed to provide adequate warnings with reasonable care regarding dangers in the use and handling of the defective tibial tray and defective insert, as defined in the Louisiana Products Liability Act, Louisiana Revised Statute 9:2800.57.

45. Defendant had a duty to distribute, market, and/or sell the Optetrak Knee Replacement System with adequate warnings that did not present an unreasonable risk of harm or injury to users and patients exposed to their danger, including Plaintiff.

46. The warnings that accompanied the Optetrak Knee Replacement System, with the defective tibial tray and/or defective insert, and its packaging were inadequate, thereby making the product not reasonably safe for its expected, intended, and/or foreseeable uses, functions, and purposes.

47. In particular, Defendant failed to adequately disclose the danger of the defective tibial tray, particularly when used with a size three femur in combination with a size three tray, as in Plaintiff's implant surgery, given its propensity to undergo substantial early failure due to component loosening, tissue damage, bone loss, osteolysis, other complications, as well as the need for revision surgery.

48. Defendant knew of the defective insert's increased risk of harm to the Plaintiff and other consumers and that warnings would have been feasible and effective in preventing plaintiff's injuries.

COUNT IV – UNREASONABLY DANGEROUS BECAUSE OF NON-CONFORMITY TO EXPRESS WARRANTY

49. At the time Defendant applied for the 510(k) premarket approval of its Optetrak Knee Replacement System with the defective insert, Defendant warranted that all components would be supplied, properly packaged according to specifications, and Defendant would conduct package validation testing. Defendant failed to perform the package testing over the course of sales from 2004 through 2022.

50. Defendant warranted that it would comply with 21 CFR Part 820 of the FDA regulations for Current Good Manufacturing Practice (cGMP) requirements to ensure safety and effectiveness of its medical devices, including packaging of finished devices under subpart K and L (subsection 130, 140, 150 of part 820). Defendant violated this warranty.

51. Defendant, in its marketing and advertising, warranted less polyethylene wear from the Optetrak as compared to other manufacturers' devices. Defendant breached this warranty.

52. Defendant was both manufacturer and seller of the Optetrak Knee Replacement System and warranted against redhibitory defects regarding defective components when used. Because Defendant was in bad faith and failed to reveal the defects, Defendant is liable for reimbursement of the expenses, damage, and attorneys' fees under Louisiana Civil Code Article 2345.

COUNT V – VIOLATION OF LOUISIANA UNFAIR TRADE PRACTICE AND CONSUMER PROTECTION LA. R. S. 51:1401 *ET SEQ*

53. In order to obtain a commercial advantage, Defendant was engaged in disseminating inaccurate, false, and/or misleading information about the Optetrak Knee Replacement System to health care professionals in the State of Louisiana, including Plaintiff's physicians and medical providers, with a reasonable expectation that such information would be used and relied upon by physicians and medical providers throughout the State of Louisiana, including but not limited to:

a. false representations regarding the duration and survival of the components lasting longer than other knee implants because of proprietary use of materials and processes to give superior wear characteristics; and

b. promotional materials of successful outcomes with survival rates of 15 to 20 years despite adverse event reports.

54. Plaintiff was a consumer of Defendant's defective insert and defective tibial tray and was wrongfully billed and charged as a result.

DAMAGES

55. By reason of the foregoing acts, omissions and conduct committed by Defendant, Plaintiff sustained serious personal injuries, severe pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses, and she 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. Accordingly, Plaintiff is seeking compensatory and special damages, including attorneys' fees and costs, and all other available remedies under the law.

JURY DEMAND

56. Plaintiff respectfully demands a trial by jury of all claims that are so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, Geraldine Billups, prays for damages together with costs, judicial interest and any other relief deemed appropriate under the law.

Respectfully submitted,

GERTLER LAW FIRM, LLP

Dated: May 19, 2022

/s/ Louis L. Gertler .
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