Fabrice N. Vincent (State Bar No. 160780)
LIEFF CABRASER HEIMANN & BERNSTEIN, LLP
275 Battery Street, 29th Floor
San Francisco, CA 94111-3339
Telephone: 415.956.1000
Facsimile: 415.956.1008

Wendy R. Fleishman (*pro hac vice forthcoming*)
Kelly McNabb (*pro hac vice forthcoming*)
LIEFF CABRASER HEIMANN & BERNSTEIN, LLP
250 Hudson Street, 8th Floor
New York, New York 10013-1413
Telephone: 212.355.9500
Facsimile: 212.355.9592

Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

DANIEL BROSNAN and ROBERTA BROSNAN,

Plaintiffs,

v.

ZIMMER, INC.; ZIMMER US, INC.; and ZIMMER BIOMET HOLDINGS, INC., f/k/a ZIMMER HOLDINGS,

Defendants.

Case No. 18-cv-5948

COMPLAINT FOR DAMAGES

(1) Negligence
(2) Strict Products Liability – Design Defect
(3) Strict Products Liability – Manufacturing Defect
(4) Strict Products Liability – Failure to Warn
(5) Negligent Misrepresentation
(6) Breach of Implied Warranty
(7) Violation of California Competition Law
(8) Punitive Damages
(9) Loss of Consortium

JURY TRIAL DEMANDED

Plaintiffs DANIEL BROSNAN and ROBERTA BROSNAN ("Plaintiffs"), by their undersigned attorneys, brings this Civil Action Complaint against Defendants ZIMMER INC., ZIMMER US, INC., and ZIMMER BIOMET HOLDINGS, INC. f/k/a Zimmer Holdings, Inc. (collectively, the "Zimmer Defendants" or "Zimmer" or "Defendants") upon information and belief, investigation and personal knowledge, and at all times hereinafter mentioned, allege as follows:

NATURE OF THIS ACTION

1. This products liability action relates to the design, development, manufacture, testing, marketing, promotion, distribution, and sale of Zimmer's defective hip implant components known as the Zimmer VerSys Hip System Femoral Head 12/14 Taper ("Zimmer VerSys femoral head") and the Zimmer M/L Taper Prosthesis ("Zimmer M/L Taper") (collectively, the "Defective Devices" or "the Products" or "Zimmer hip joint implant products").

2. The Products were surgically implanted in Plaintiff Daniel Brosnan's left hip on January 26, 2015.

3. On March 31, 2017, Mr. Brosnan required revision surgery of his left hip because the Products were causing metal debris to be released into his hip causing adverse local tissue reaction and elevated metal ions in his blood (a condition known as metallosis) and therefore, were defective. This surgery caused Plaintiff to suffer significant injuries, including great pain and agony that restricted his ability to engage in activities of daily living as well as the physical activities that he enjoys.

PARTIES

4. Plaintiffs Daniel Brosnan and Roberta Brosnan are citizens and residents of Lakeport, Lake County, California. They are married to one another and were married at all times relevant to this action.

5. Defendant Zimmer Biomet Holdings, Inc. formerly known as Zimmer Holdings, Inc. is a Delaware corporation with its principal place of business at 345 East Main Street, Warsaw, Indiana, 46580-2746. At all relevant times, Zimmer Biomet Holdings, Inc. was the publicly traded holding company with wholly owned subsidiaries that it controlled, including Zimmer, Inc. and Zimmer US, Inc., which designed, manufactured, marketed, supplied and sold to distributors, physicians, hospitals, patients and medical practitioners the Products to be surgically implanted in patients throughout the United States, including in the State of California.

6. On April 24, 2014, Zimmer Holdings, Inc. entered into an agreement to acquire Biomet, Inc., and was renamed Zimmer Biomet Holdings, Inc.

7. Defendant Zimmer, Inc. is a Delaware corporation with its principal place of business at 1800 West Center Street, Warsaw, Indiana, 46581-0708.

8. Zimmer, Inc. is a wholly owned subsidiary of Defendant Zimmer Biomet Holdings, Inc.

9. Defendant Zimmer, Inc. solicits business within the State of California and derives substantial revenue from goods used and sold in the State of California.

10. At all times mentioned in this Complaint, Defendant Zimmer, Inc. designed, testing, manufactured, packaged, and sold the Zimmer VerSys femoral head and Zimmer M/L Taper generally for use in hip replacement surgeries, including Mr. Brosnan's surgery.

11. Defendant Zimmer US, Inc. is a Delaware corporation with its principal place of business at 345 East Main Street, Warsaw, State of Indiana.

12. Defendant Zimmer US, Inc. is a wholly-owned subsidiary of Zimmer Biomet Holdings, Inc.

13. At all times mentioned in this Complaint, Defendant Zimmer US, Inc. sold hip implants, including the Zimmer VerSys femoral head and Zimmer M/L Taper that were used in Mr. Brosnan's surgery.

14. At all relevant times, each and all of the Defendant Zimmer entities regularly sold and shipped the Products into the State of California, and in particular, provided the Products to Healdsburg District Hospital, in Healdsburg California, and to Plaintiff's implanting surgeon, Dr. Dr. Michael Bollinger, in Sebastopol, California, for implantation into human patients, including Plaintiff Daniel Brosnan.

15. At all relevant times, Zimmer Defendants represented that the subject orthopedic prosthetic hip components, and specifically the Products at issue in this lawsuit, were safe, fit for use, free from defects and suitable for implantation into human patients, including Plaintiff Daniel Brosnan.

16. At all relevant times, each of the Defendants and their directors and officers acted within the scope of their authority. At all relevant times each Defendant was responsible for each other's actions and inactions; and, each Defendant acted on behalf of each other Defendant.

17. At all relevant times, Defendants possessed a unity of interest between themselves and Zimmer, and Zimmer exercised control over its subsidiaries and affiliates. As such, each Defendant is responsible individually, as well as jointly and severally, and therefore each is liable to Plaintiffs for Plaintiffs' injuries, losses and damages.

JURISDICTION AND VENUE

18. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiffs and Defendants, and because Plaintiffs allege an amount in controversy in excess of $75,000, exclusive of interest and costs.

19. The Court has personal jurisdiction over Defendants because at all relevant times Defendants engaged in substantial business activities in the State of California. At all relevant times, Zimmer Defendants transacted, solicited, and conducted business in California through their employees, agents, and/or sales representatives, and derived substantial revenue from such business in California.

20. Venue is proper in this District pursuant to 28 U.S.C. § 1391(a) because a substantial portion of the wrongful acts upon which this lawsuit is based occurred in this District. Venue is also proper pursuant to 28 U.S.C. § 1391(c) because Defendants are all corporations that have substantial, systematic, and continuous contacts in the Northern District of California and are all subject to personal jurisdiction in this District.

FACTUAL ALLEGATIONS

I. DANIEL BROSNAN

21. On or about January 26, 2015, Plaintiff Daniel Brosnan underwent a total hip arthroplasty of his left hip with insertion of the Products, specifically the Zimmer® M/L Taper Hip Prosthesis Femoral Stem 12/14 Neck Taper, Lot 62356550/Ref. 7711-16; and the VerSys® Hip System Femoral Head 12/14 Taper, Lot 62741042/Ref. 8018-36-03. The surgical procedure was performed by Michael Bollinger, M.D., at Healdsburg District Hospital in Healdsburg, California.

22. At the time that Plaintiff underwent his total left hip arthroplasty, he received defective, dangerous, hazardous and unsafe products designed, manufactured, developed, tested, promoted, distributed and sold by the Zimmer Defendants.

23. Following the total left hip arthroplasty, Plaintiff Daniel Brosnan began experiencing significant pain and discomfort in his left side.

24. Diagnostic work-up in December 2016 showed his cobalt serum level elevated and a large pseudotumor.

25. Mr. Brosnan was referred to the University of California San Francisco (UCSF) for further evaluation given continuing swelling and pain. Dr. Eric Hansen at UCSF felt that Mr. Brosnan's recently elevated cobalt/chromium levels [*Chromium 1.6; Cobalt 10.*2] and large fluid collection around the joint were likely the underlying cause of the persistent swelling and irritation due to metal ions potentially due to taper/trunnion issues. Due to this, Dr. Hansen suggested a revision surgery to debride the pseudotumor caused by adverse reaction to the metallic debris fretting off the prosthesis; replace the cobalt chrome ball with a ceramic ball; and to replace the hip system liner.

26. Prior to his revision surgery, Mr. Brosnan suffered from daily pain and difficulty sleeping, causing a restriction of his normal activities.

27. Based upon these findings and in light of worsening symptoms, Plaintiff underwent a complex revision surgery of his left prosthesis on March 31, 2017, performed by Eric Hansen M.D., at University of California San Francisco, in San Francisco, California.

28. Intra-operatively, upon removal of the femoral head, there was a large amount of black corrosion of both taper and the opening of the femoral head where the two parts join as part of the prosthetic hip system.

29. Pathology from the revision surgery was consistent with aseptic lymphocytic vasculitis-associated lesion (ALVAL)—a complication that has appeared in a subset of patients with metal-on-metal total hip arthroplasties.

30. Following revision surgery, Mr. Brosnan's cobalt levels have decreased. Mr. Bronson continued to suffer from pain and recurrent hip dislocations due to extensive abductor

damage. He ultimately had four dislocations and required another revision of his left hip on January 1, 2018.

31. As a result of the defective hip implants, Plaintiff's well-being has suffered and will continue to suffer. Mr. Brosnan and his wife, Roberta Brosnan have expended and will continue to expend money for his care.

32. Spouse Plaintiff Roberta Brosnan has lost the society and love and affection of her beloved spouse.

II. BACKGROUND ON ARTIFICIAL HIPS AND HIP REPLACEMENT DEVICES

33. The human hip joint consists of two parts: a ball and a socket. A portion of the pelvic bone forms a cup-shaped socket; the ball at the top of the thigh bone fits into it. The ball is surrounded with cartilage which, in a healthy hip joint, allows the ball to move smoothly within the socket. Conditions such as osteoarthritis and avascular necrosis can cause degeneration of the hip joint such that hip replacement is required. A hip implant is designed to replicate the human anatomy—that is, the relatively simple ball and socket structure of the human hip joint. Total hip replacement surgery involves implanting an artificial ball and socket into the patient.

34. The artificial hip implantation process requires a surgeon to insert a metal cup with a smooth lining into the patient's diseased pelvic socket. The lining (known as a liner) serves the same purpose as natural cartilage: allowing for smooth movement of the ball portion of the thigh bone. The diseased or degenerated ball part of the thigh bone is then removed and replaced by a metal or sometimes ceramic ball mounted onto a thin metal stem. The metal stem is then fit into the thigh bone. Finally, the ball is placed securely into the pelvic socket that has been fitted with the artificial metal cup, where it should move easily, without friction or pain to the patient.

35. Total hip replacement is most commonly used to treat joint failure caused by osteoarthritis. Other indications include rheumatoid arthritis, avascular necrosis, traumatic arthritis, protrusion acetabuli, certain hip fractures, benign and malignant bone tumors, arthritis associated with Paget's disease of the bone, ankylosing spondylitis and juvenile rheumatoid arthritis. The aims of the procedure are pain relief and improvement in hip function. Hip

replacement is usually considered only once other therapies, such as pain medications, have failed.

36. Total hip arthroplasty ("THA"), or total hip replacement, is a common medical procedure performed on more than 420,000 patients in the U.S. each year. It is designed to help relieve pain and improve joint function in people with severe hip degeneration due to arthritis or trauma. Traditional devices to replace degenerative hips utilize implantable metal or ceramic heads fitting into a modular metal-backed polyethylene bearing. One concern that historically plagues successful THAs is the wear of the bearing. As the THA becomes more common among younger patients who want to maintain a physically active lifestyle, alternative bearing surfaces such as cross-linked polyethylene, ceramic-on-ceramic and metal-on-metal have been developed to address the issue of wear.

III. ZIMMER M/L TAPER and the VERSYS 12/14 FEMORAL HEAD

37. The Zimmer M/L Taper prosthesis is a femoral implant comprised of Tivanium® Ti-6Al-4V alloy that is used for hip replacements.

38. The Zimmer VerSys femoral heads are manufactured with Zimaloy® cobalt-chromium-molybdenum alloy.

39. During hip replacement surgery, the damaged portions of the hip joint are removed and replaced with an integrated system of products, which includes the femoral stem and neck. The Zimmer VerSys femoral head is used in connection with the M/L Taper.

40. The Zimmer M/L Taper is used with a spray coating called a "Circumferential Plasma Spray" intended to facilitate surgical placement. The device components, together with the acetabular cup are intended to be used in patients with adequate bone stock, like Plaintiff Brosnan.

41. The Zimmer M/L Taper was approved pursuant to a 510(k) on or about October 22, 2003, and Zimmer proceeded to sell the components to be used together with the Zimmer VerSys femoral head.

42. Zimmer introduced the M/L Taper as part of a modular system that had a modular stem and neck components that were intended to offer the orthopedic surgeon more options in the

operating room. The three failure modes were considered when developing and manufacturing this modular neck and stem system:

a. Proximal implant strength;

b. Fretting and corrosion; and,

c. Junction stability.

43. The Zimmer VerSys femoral heads were first tested in 1996 by Zimmer to be used with cobalt chromium tapers and with titanium alloy tapers. According to Zimmer, there was not significant fretting or corrosion using either form of taper.

44. Plaintiff Daniel Brosnan's cause for revision was metal-related pathology.

45. Defendant Zimmer, Inc. and Zimmer US, Inc. failed to disclose the greater risk of wear, metal debris and corrosion associated with these devices prior to Mr. Brosnan's implant surgeries and continuously through his revision surgery. Zimmer, Inc.'s and Zimmer US, Inc.'s continued fraud worsened Mr. Brosnan's outcome.

46. Zimmer, Inc. and Zimmer US, Inc. used its distributors and its sales representatives to communicate with the doctors, such as Dr. Bollinger and the doctors at Healdsburg District Hospital.

47. In particular, Zimmer, Inc.'s sales representative, Colby Leonelli, was present during Mr. Brosnan's implant surgery on January 26, 2015 and, upon information and belief, Mr. Leonelli was reasonable for detailing Dr. Bollinger and provided, or failed to provide, Dr. Bollinger with information, including the benefits and risks, about the Products.

48. Zimmer, Inc. and Zimmer US, Inc. provided distributors and sales representatives with all marketing and sales materials. Zimmer, Inc. and Zimmer US, Inc. trained all distributors and sales representatives on the Zimmer products, including the Products at issue in this Complaint, including the risks and benefits of the Zimmer products. At all relevant times, Zimmer, Inc. and Zimmer US, Inc. directed and controlled the activities of the distributors and sales representatives of Zimmer products, including the Products at issue in this Complaint.

49. Prior to Mr. Brosnan's implanting surgery on January 26, 2015 and continuing through his revision surgery on March 31, 2017, Zimmer, Inc. and Zimmer US, Inc. and its sales

representatives, specifically Colby Leonelli, intentionally or negligently failed to accurately describe the risks of fretting and corrosion, release of metal debris and metal ions into the surrounding tissue and the blood associated with the use of the M/L Taper and the VerSys femoral head to Dr. Bollinger and other surgeons at Healdsburg District Hospital.

50. Prior to Mr. Brosnan's implanting surgery on January 26, 2015 and continuing through his revision surgery on March 31, 2017, Zimmer, Inc. and Zimmer US, Inc. did not include a warning of an increased risk of corrosion when the M/L Taper was paired with a VerSys femoral head in the "Warnings" or "Precautions" sections of the Products' package inserts.

51. The statements made by Zimmer sales representatives, including Colby Leonelli, as directed by Zimmer, Inc. and Zimmer US, Inc., and contained in Zimmer, Inc. and Zimmer US Inc.'s written literature, instructions for use, package insert, and advertisements were false and misleading because the Products had an increased rate of failure because of mechanically assisted crevice corrosion (i.e. fretting and corrosion).

52. In fact, the M/L Taper stem has a greater prevalence (4.9%) of mechanically assisted crevice corrosion ("MACC") than all other Zimmer stem types,[1] with a significantly higher prevalence found in patients with M/L Taper style stem and total hip arthroplasty performed in 2009 and between 2009-2012 (when Mr. Pride's prosthetic was implanted). Hussey, D.K. & McGrory, B.J., Ten-Year Cross-Sectional Study of Mechanically Assisted Crevice Corrosion in 1352 Consecutive Patients with Metal-on-Polyethylene Total Hip Arthroplasty, J. Arthroplasty, 1-6 (2017), incorporated by reference herein.

53. Dr. Bollinger relied on the information provided by Zimmer, Inc., Zimmer US, Inc., and its sales representatives acting as Zimmer agents, including Colby Leonelli. Had

[1] MACC is a term given to a complex interaction of crevice corrosion, initiated by changes in local chemistry within crevices, and fretting, which disrupts the protective oxide layer on the taper. "MACC produces cobalt (Co) and chromium (Cr) ions, fretting products, and corrosive debris that may cause adverse local tissue reaction (ALTR)." Hussey, D.K. & McGrory, B.J., Ten-Year Cross-Sectional Study of Mechanically Assisted Crevice Corrosion in 1352 Consecutive Patients with Metal-on-Polyethylene Total Hip Arthroplasty, J. Arthroplasty, 1-6 (2017) (incorporated by reference herein). Patient outcome worsens the longer the defective hip prosthetic devices are implanted, due to increased tissue damage caused by the metal debris in the surrounding tissue and ALTR. *Id.*

Zimmer disclosed the accurate information about this particularly dangerous failure mode—increased rate of MACC (i.e., fretting and corrosion)—Plaintiff and his surgeon, Dr. Bollinger, would not have used these components.

54. Despite their knowledge of the serious injuries associated with use of these Products, Zimmer, Inc. and Zimmer US, Inc. engaged, and continue to engage, in a marketing and advertising program which, as a whole, by affirmative and material misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the use of the these Products were safe.

55. At all relevant times, Zimmer, Inc. and Zimmer US, Inc. knew or should have known that the M/L Taper when paired with the VerSys femoral head were not safe for the patients in whom it was implanted, including Plaintiff, because of the unacceptable failure rate.

56. Notwithstanding the knowledge of predicted failures with the defective devices, Zimmer, Inc. and Zimmer US, Inc. continue to sell these devices for implantation in patients.

57. Plaintiff Daniel Brosnan has not only suffered physical injuries, he has endured and continues to endure an unacceptable increase in the risk of severe pain and disability, with or without a costly and painful additional revision surgery. The revision surgery was invasive and painful and was necessitated by these defective devices. It is unknown what the long term effects are of the increased metal ion levels in Mr. Brosnan's blood and tissue. However, Mr. Brosnan lost a good amount of muscle tissue in and around his pelvis and abductors.

58. Mr. and Mrs. Brosnan have had to expend large sums of money for care. Plaintiffs will in the future have expenses as a result of the injuries and damages he suffered as a result of Zimmer's omission and misconduct.

IV. VIOLATIONS OF FEDERAL REGULATIONS

59. The Medical Device Amendments of 1976 ("MDA") to the Food Device Cosmetic Act ("FDCA") established the current regulatory framework for medical device approval.

60. According to the U.S. Supreme Court in *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 346 (2001), the Supreme Court explained that: "[s]ection 510(k) submissions must include the following: 'Proposed labels, labeling, and advertisements sufficient to describe the

device, its intended use, and the directions for its use,' 21 CFR § 807.87(e) (2000); and must include "[a] statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement," § 807.87(f); "[a] statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted," § 807.87(k); and "any additional information regarding the device requested by the [FDA] Commissioner that is necessary for the Commissioner to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution," § 807.87(l). Here, the Zimmer M/L Taper and the VerSys femoral head were cleared pursuant to this 510(k) process.

61. The FDCA requires cleared medical devices to be demonstrated to be safe and effective for each intended use. *See* 21 U.S.C. § 360e(c)(2)(A)(v). Not only is the medical device itself part of the 510(k) process, but so is the labeling and packaging that comes with it.

62. Pursuant to federal law, a device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular manner, or if it is dangerous to health when used in the manner prescribed, recommended, or suggested in the labeling thereof. *See* 21 U.S.C. §352.

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

64. Pursuant to federal law, manufacturers are required to comply with FDA regulation of medical devices, including FDA requirements for records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any of its medical devices may have caused or contributed to death or serious injury, or if the devices have malfunctioned in a manner likely to cause or contribute to death or serious injury. Federal law also mandates that the FDA establish regulations requiring a

manufacturer of a medical device to report promptly to FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. *See* 21 U.S.C. §360(i).

65. Pursuant to FDA regulation, adverse events associated with a medical device must be reported to FDA within 30 days after the manufacturer becomes aware that (a) a device may have caused or contributed to death or serious injury, or (b) that a device has malfunctioned and would be likely to cause or contribute to death or serious injury if the malfunction was to recur. Such reports must contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. In addition, manufacturers are responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event. *See* 21 CFR §803.50.

66. Pursuant to federal regulations, manufacturers of medical devices must also describe in every individual adverse event report whether remedial action was taken with regard to the adverse event, and whether the remedial action was reported to FDA as a removal or correction of the device. *See* 21 CFR §803.52.

67. Pursuant to federal regulations, manufacturers must report any reportable Medical Device Reporting ("MDR") event or events, including a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health, to the FDA within 5 business days after becoming aware of such event or events. *See* 21 CFR §803.53.

68. Pursuant to federal regulations, device manufacturers must report promptly to FDA any device corrections and removals and must also maintain records of device corrections and removals. FDA regulations require submission of a written report within ten working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, or to remedy a violation of the Act caused by the device which may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported, the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device

report numbers. Manufacturers must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal, and provide a copy of all communications regarding the correction or removal. *See* 21 CFR §806.

69. Pursuant to federal regulations, manufacturers must comply with specific quality system requirements promulgated by FDA. These regulations require manufacturers to meet design control requirements, including but not limited to conducting design validation to ensure that devices conform to defined user needs and intended uses. Manufacturers must also meet quality standards in manufacture and production of the devices. Manufacturers must establish and maintain procedures for implementing corrective actions and preventive actions, and investigate the cause of nonconforming products and take corrective action to prevent recurrence. Manufacturers are also required to review and evaluate all complaints and determine whether an investigation is necessary. Further, manufacturers are required to use statistical techniques, where necessary, to evaluate product performance. *See* 21 CFR §820.

70. Pursuant to federal regulations, a manufacturer must report to the FDA any new indications for use of a device, labeling changes, or changes in the performance or design specifications, circuits, components, ingredients, principle of operation or physical layout of its devices. Federal regulations require that: "A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification." *See* 21 CFR §814.

71. Specifically, it is believed that with respect to the Zimmer M/L Taper and Zimmer VerSys femoral head, Defendants failed to timely report adverse events; failed to timely conduct failure investigations and analyses; failed to timely report any and all information concerning product failures and corrections; failed to timely and fully inform FDA of unanticipated adverse effects, increases in the incidence of adverse effects, or device failures necessitating a labeling, manufacturing or device modification; failed to conduct necessary design validation; and sold a misbranded and adulterated product.

72. Zimmer's violation of the FDCA statutes and accompany regulations, as discussed above, directly caused or significantly contributed to the use of the M/L Taper and the VerSys

Femoral Head; and, generally, and directly caused or significantly contributed to the use of these Defective Devices in Plaintiff and Zimmer's misconduct in this regard thus directly caused or contributed to Plaintiff's injuries and damages.

CLAIMS FOR RELIEF

CLAIM ONE

NEGLIGENCE

73. Plaintiffs adopt and re-alleges the allegations contained in the above paragraphs as if set forth fully herein.

74. At all times mentioned in this complaint, Zimmer had a duty to properly manufacture, compound, test, inspect, package, distribute, market, examine, maintain, and prepare for use and sell its above-mentioned hip joint implant products.

75. In placing the Products onto the market, Zimmer was careless, reckless and negligent by virtue of the following acts or omissions, which are listed herein as illustrative and not exhaustive:

a. Failure to adequately and properly design and manufacture the aforesaid Products; there were alternative safer designs of the hip prosthetic components that had a much lower incidence of fretting, corrosion, release of metal ions, metallosis, and adverse tissue reactions, specifically using a ceramic femoral head with the M/L Taper;

b. Distributing the products when Zimmer knew, or in the exercise of reasonable care should have known, that its hip joint implant products were of such a nature that if such products were not properly manufactured, compounded, tested, inspected, packaged, distributed, marketed, examined, and/or sold, such products were likely to cause serious injury in patients;

c. Negligently and carelessly manufacturing, packaging, distributing, recommending, displaying, selling, examining and failing to examine its above-mentioned hip joint implant products that such were dangerous and unsafe for the user and for the purpose for which the products were intended;

d. Failing to adequately and properly test and inspect the products before placing them on the market;

e. Failing to have adequate or appropriate quality controls over the design and/or manufacturing process;

f. Failing to warn the public in general, Dr. Michael T. Bollinger, and the medical community and the patients, such as Daniel Brosnan in particular, of the risks and dangers associated with the use of its products;

g. Failing to take reasonably prompt steps to withdraw the products, notify learned intermediaries such as physicians, or otherwise remove the products from the stream of commerce as soon as the defects therein were discovered; and

h. Zimmer failed to adequately disclose the fretting and corrosion caused by these devices to the medical community, to the medical journals and to the medical community at large who depended on Zimmer for accurate and truthful information about its products so that the physicians could make appropriate judgments and choices of products for their patients;

i. And, as the information increased that there was an increasing risk of failure, Zimmer failed to disclose it to the medical community and the patients who had been implanted with these devices that there was a previously undisclosed increased rate of corrosion, fretting and the release of metal debris and metal ions.

76. The Zimmer Defendants were negligent in carrying out the manufacturing, retailing, design, wholesaling, testing, advertising, promotion, marketing, sales and/or distribution of the Products.

77. The personal injuries sustained by Daniel Brosnan were caused by the latent effects of his exposure to and implantation with the defective, dangerous, hazardous and unsafe products designed, manufactured, distributed and supplied by Zimmer, which defects were not discovered by the Plaintiff and could not have been discovered through the exercise of reasonable diligence by Plaintiff until, at the earliest, in or about December 2016, when he received blood and other test results evidencing adverse local tissue reaction surrounding his hip implant and metallosis.

78. As a proximate result of the above-mentioned carelessness and negligence of Zimmer, Zimmer's Products caused severe and permanent injuries to Plaintiff's body and thereby proximately caused Plaintiffs to sustain the injuries and damages as alleged in this Complaint.

79. As a further proximate cause of Zimmer's negligence, Plaintiffs were required to and did employ physicians and surgeons to examine, treat, and care for Mr. Brosnan, and did incur medical, hospital, pharmaceutical, and incidental expenses, and will continue to incur such medical, hospital, pharmaceutical and incidental expenses in the future. In addition, Zimmer's conduct proximately caused Daniel Brosnan to live under a continued likelihood of increased risk of developing medical problems associated with the presence of metal ions in his body, and attendant emotional stress that constantly is present.

80. By reason of the foregoing, Plaintiff Daniel Brosnan has been severely and permanently damaged; has sustained economic losses; and will be required to incur additional medical expenses in the future to care for himself as a result of the injury and damages he has suffered; and Plaintiff Roberta Brosnan has lost the society, comfort and consortium of her beloved husband..

81. The foregoing was caused without any negligence on the part of Plaintiffs contributing to these injuries and damages.

82. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest and costs.

83. Defendants' conduct as alleged above was malicious, intentional and outrageous willful and conscious disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiffs and as such, warrants an imposition of punitive damages.

CLAIM TWO

STRICT LIABILITY: DEFECTIVE DESIGN

84. Plaintiffs adopt and re-alleges the allegations contained in the above paragraphs as if set forth fully herein.

85. Prior to Mr. Brosnan's total hip arthroplasty, Zimmer, as the designer, manufacturer, retailer, wholesaler, fabricator, supplier, and/or distributor of the Products were

under a strict duty not to design, manufacture, distribute, market or otherwise place into the stream of commerce a product that was defective, dangerous, hazardous or otherwise unsafe to human health.

86. As a direct and proximate result of Zimmer's placing the defective hip implant products onto the market, Plaintiff was implanted with these defective products.

87. Zimmer is strictly liable to Plaintiffs for manufacturing, designing, retailing, distributing, wholesaling, modifying, fabricating, supplying and/or placing on the market and in the flow of commerce, defective products knowing that the Products would be used by the public and particularly by the recipients without inspection. The Products were not fit for their intended purpose; the risks inherent in the design of the Products outweighed the benefits; and the Products were more dangerous than Plaintiff or his doctor anticipated. All of these defects proximately caused the injuries and damages to Plaintiff as alleged.

88. Zimmer's Products were defective, unsafe and unreasonably dangerous for use in hip arthroplasty surgery and caused and will continue to cause grievous and debilitating bodily injury when used for such purposes.

89. The defective condition of Zimmer's above-mentioned hip joint implant products existed when the product left the manufacturer's control.

90. Zimmer's above-mentioned hip joint implant products reached Plaintiff and his surgeons without substantial change.

91. Zimmer knew that its hip joint implant products were to be used by the user without inspection or testing for defects in the product.

92. Plaintiff was injured by the defect in the product. The product as composed caused fretting and corrosion at the juncture where the taper met the femoral head. That resulted in the release of metal ions and debris into the surrounding tissue causing Plaintiff to suffer an adverse tissue reaction, due to the death of the tissue from the metal ions. Had Zimmer sold Plaintiff's surgeon a safer, alternative design existed, then Plaintiff would never have been injured by this dangerous and defective set of products, designed and sold to be used together.

93. Zimmer knew and had reason to know that there were safer alternative products available on the market at the time the defective Products were sold in this case. In fact, Zimmer manufactured and sold Zimmer hip prosthetic devices that were to avoid any problem consistent with metallosis due to the implant failure.

94. Plaintiff neither knew, nor had reason to know, at the time of the use of Zimmer's Products, or at any time prior to such use, of the existence of the above-described defect or that there were other, safer hip implants available on the market at the time of his total hip arthroplasty.

95. As a direct and proximate result of being implanted with Zimmer's defective, dangerous, hazardous and unsafe hip implant products, Plaintiff Daniel Brosnan has been severely and permanently damaged; has sustained economic losses; and will be required to incur additional medical expenses in the future to care for himself as a result of the injury and damages he has suffered and Plaintiff Roberta Brosnan has lost the society, comfort and consortium of her beloved husband. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

96. Defendants' conduct as alleged above was malicious, intentional and outrageous and constitutes a willful and conscious disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiffs and as such, warrants an imposition of punitive damages.

CLAIM THREE

STRICT LIABILITY: MANUFACTURING DEFECT

97. Plaintiffs adopt and re-alleges the allegations contained in the above paragraphs as if set forth fully herein.

98. Prior to Plaintiff's total hip arthroplasty, Zimmer, as the designers, manufacturers, retailers, wholesalers, fabricators, suppliers, and/or distributors of the hip joint implant products were under a strict duty not to design, manufacture, distribute, market or otherwise place into the stream of commerce a product that was defective, dangerous, hazardous or otherwise unsafe to human health.

99. As a direct and proximate result of Zimmer's placing the said defective hip implant products into the market, Plaintiff was implanted with same.

100. The hip joint implant products implanted into Plaintiff, as manufactured, deviated from Zimmer's design and/or internal quality standards.

101. Zimmer is strictly liable to Plaintiffs for manufacturing, designing, retailing, distributing, wholesaling, modifying, fabricating, supplying and/or placing on the market and in the flow of commerce, defective products knowing that the products would be used by the public and particularly by the recipients without inspection. The hip joint implant products were not fit for their intended purpose and/or the risks inherent in the design of the hip joint implant products outweighed the benefits and/or the hip joint implant products were more dangerous than Plaintiff anticipated. All of these defects proximately caused the injuries and damages to Plaintiff as alleged herein.

102. Zimmer's above-mentioned hip joint implant products were defective, unsafe and unreasonably dangerous for use in hip arthroplasty surgery and caused and will continue to cause grievous and debilitating bodily injury when used for such purposes.

103. The defective condition of Zimmer's above-mentioned hip joint implant products existed when the product left the manufacturer's control.

104. Zimmer's above-mentioned hip joint implant products reached Plaintiff and his surgeons without substantial change.

105. Zimmer knew that its hip joint implant products were to be used by the user without inspection for defects in the product.

106. Plaintiff was injured by the manufacturing defect in the product. The product as manufactured caused fretting and corrosion at the juncture where the taper met the femoral head. That resulted in the release of metal ions and debris into the surrounding tissue causing Plaintiff to suffer an adverse tissue reaction, due to the death of the tissue from the metal ions. Had Zimmer sold Plaintiff's surgeon a safer, alternative design, then Plaintiff would never have been injured by this dangerous and defective set of products, designed, manufactured, and sold to be used together.

107. Zimmer knew and had reason to know that there the hip joint implant products were defectively manufactured at the time it sold and distributed the products.

108. Plaintiff neither knew, nor had reason to know, at the time of the use of Zimmer's products, or at any time prior to such use, of the existence of the above-described manufacturing defect or that there were other, safer hip implants available on the market at the time of his total hip arthroplasty.

109. As a direct and proximate result of being implanted with Zimmer's defective, dangerous, hazardous and unsafe hip implant products, Plaintiff Daniel Brosnan has been severely and permanently damaged; has sustained economic losses; and will be required to incur additional medical expenses in the future to care for himself as a result of the injury and damages he has suffered; and Plaintiff Roberta Brosnan has lost the society, comfort and consortium of her beloved husband. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

110. Defendants' conduct as alleged above was malicious, intentional and outrageous and constitutes a willful and conscious disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiffs and as such, warrants an imposition of punitive damages.

CLAIM FOUR

STRICT LIABILITY: FAILURE TO WARN

111. Plaintiffs adopt and re-alleges the allegations contained in the above paragraphs as if set forth fully herein.

112. At the time the hip joint implant products were supplied to Plaintiff, the products were defective as a result of Zimmer's failure to adequately test for safety, and to give adequate warnings, labeling, or instructions regarding the development of medical problems associated with the presence of metal ions in Plaintiff's body and/or intended users as described herein and other dangers which might be associated with the use of the hip joint implant.

113. Zimmer's above-mentioned hip joint implant products were defective, unsafe and unreasonably dangerous for use in hip arthroplasty surgery and caused and will continue to cause grievous and debilitating bodily injury when used for such purposes.

114. The defective condition of Zimmer's above-mentioned hip joint implant products existed when the product left the manufacturer's control.

115. Zimmer's above-mentioned hip joint implant products reached Plaintiff and his surgeons without substantial change.

116. Zimmer failed to adequately test the hip joint implant products before marketing them to consumers such as Plaintiff, failed to disclose to Plaintiff that such testing had not been done, and which testing would have disclosed the magnitude of the potential risks associated with the use of the hip joint implant.

117. Zimmer failed to warn of the increased incidents of fretting and corrosion, or that the pre-market data demonstrated a greater probability of failure than was initially described to FDA or implant physicians, including Dr. Bollinger. Zimmer's failure to warn was willful and malicious in that Zimmer's conduct was carried out with a conscious disregard for the safety and the rights of Plaintiff.

118. Specifically, prior to Mr. Brosnan's implanting surgery on January 26, 2015 and continuing through his revision surgery on March 31, 2017, Zimmer, Inc. and Zimmer US, Inc. did not include a warning of an increased risk of corrosion when the M/L Taper was paired with a VerSys femoral head in the "Warnings" or "Precautions" sections of the Products' package inserts.

119. As a direct and proximate result of being implanted with Zimmer's defective, dangerous, hazardous and unsafe hip implant products, Plaintiff Daniel Brosnan has been severely and permanently damaged; has sustained economic losses; and will be required to incur additional medical expenses in the future to care for himself as a result of the injury and damages he has suffered; and Plaintiff Roberta Brosnan has lost the society, comfort and consortium of her beloved husband. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

120. Defendants' conduct as alleged above was malicious, intentional and outrageous and constitutes a willful and conscious disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiffs and as such, warrants an imposition of punitive damages.

CLAIM FIVE

NEGLIGENT MISREPRESENTATION

121. Plaintiffs adopt and re-alleges the allegations contained in the above paragraphs, specifically paragraphs 44-55, as if set forth fully herein.

122. Zimmer, Inc. and Zimmer US, Inc., as the designers, manufacturers, and sellers of the Products had knowledge of material facts about the quality, safety, and effectiveness of the Products that was superior to the knowledge that Plaintiff and Plaintiff's surgeon possessed or could have possessed. Zimmer's knowledge that the Zimmer M/L Taper and the Zimmer VerSys femoral head, when used together, were associated with an increased risk of corrosion and fretting was not available to the public or medical community. This is so because Zimmer, Inc. and Zimmer US, Inc. had exclusive knowledge about, and possession, of the following:

a. Pre-market documents, including the Design History and Risk Management Files. These files are required for medical devices that can cause or contribute to death, serious illness, or injury and document that medical device manufacturers are complying with design controls. The files include information about: the design inputs, which are the product requirements that include the physical and performance characteristics of the device that are used as a basis for device design; design outputs—known as the product specifications, which are broadly speaking the "blueprints" for the product; design verifications and validations, which are the test protocols and test reports to confirm the products meet the design requirements and specifications and conform to user needs and intended uses; engineering change orders, which are intended design changes; internal audit reports of the Design History File; and device/design failure modes and effects analysis, which identifies possible failures in a design or manufacturing process.

b. Regulatory submissions. This includes premarket notification and all communications related to the clearance from and to the FDA; letters to file regarding modifications to the Products that are not reported to the FDA; and correction and removal reports to the FDA, which is any correction or removal of a medical device if the correction or removal was initiated to reduce a risk to health posed by the device.

c. Post-market surveillance. This includes complaint files with documents that are not in the public domain; corrective and preventive action files with documents that are not in the public domain such as Health Hazard Evaluations and verifications or validation reports, which are used to identify and investigate product and quality problems, and full Medical Device Reports that report adverse events.

123. Zimmer, Inc. and Zimmer US, Inc. have a special relationship with implanting surgeons, and thus a duty to doctors that significantly exceeds the duty between ordinary buyers and sellers, for the following reasons:

a. Doctors, such as Dr. Bollinger, rely on information from medical device manufacturers and they expect this information to be truthful. For this reason, Zimmer, Inc. and Zimmer US, Inc. knew or should have known that surgeons rely on information provided by Zimmer, Inc. and Zimmer US, Inc.

b. Zimmer, Inc. and Zimmer US, Inc. affirmatively tell doctors to rely on Zimmer. For example, in the Zimmer M/L Taper Hip Prosthesis Surgical Techniques guide,[2] Zimmer, Inc. expressly states "[t]his documentation is intended exclusively for physicians and is not intended for laypersons." It directs physicians to "refer to the package inserts for important product information, including, but not limited to, contraindications, warnings, precautions, and adverse effects." Nowhere in the package insert does Zimmer, Inc. or Zimmer US, Inc. warn or disclose that the Products are associated with an increased risk of corrosion and fretting, or that the patients' metal ion levels should be monitored for early detection of corrosion that can lead to adverse local tissue reaction, which kills the tissue and muscle surrounding the hip prosthesis, worsening the patient's outcome the longer the device is implanted. Because Zimmer directs doctors to rely on this information, Zimmer, Inc. and Zimmer US, Inc. knew or should have known that surgeon's rely on this information.

c. Zimmer Inc. and Zimmer US, Inc. knew or should have known that Dr. Bollinger specifically, the surgeon who performed Mr. Brosnan's surgery, relied on Zimmer.

[2] *Available at* http://www.zimmerbiomet.com/content/dam/zimmer-biomet/medical-professionals/000-surgical-techniques/hip/zimmer-ml-taper-hip-prosthesis-surgical-technique.pdf, incorporated by reference herein.

This is so because Zimmer Inc. and Zimmer US, Inc. representative Colby Leonelli was in the operating room during Mr. Brosnan's initial total hip replacement surgery for the specific purposes of providing expert information about the Zimmer Products to Dr. Bollinger.

124. Zimmer, Inc. affirmatively misrepresented that "the M/L Taper Hip Prosthesis met performance requirements and is as safe and effective as the predicate devices." *See* Zimmer Inc. Summary of Safety and Effectiveness.[3] In fact, the M/L Taper stem has a greater prevalence (4.9%) of mechanically assisted crevice corrosion ("MACC") than all other Zimmer stem types, with a significantly higher prevalence found in patients with M/L Taper style stem and total hip arthroplasty performed in 2009 and between 2009-2012. Hussey, D.K. & Bollinger, B.J., Ten-Year Cross-Sectional Study of Mechanically Assisted Crevice Corrosion in 1352 Consecutive Patients with Metal-on-Polyethylene Total Hip Arthroplasty, J. Arthroplasty, 1-6 (2017) (incorporated as referenced herein).

125. In addition to this affirmative misrepresentation, Zimmer, Inc. and Zimmer, US, Inc. failed to disclose that the Zimmer M/L Taper and the Zimmer VerSys femoral head, when used together, were associated with a higher prevalence of metallosis, trunnionosis, high cobalt and/or chromium levels, corrosion, pseudotumors, adverse tissue reaction and/or necrotic tissue, and required patients to monitor metal ion levels accordingly and undergo revision surgery as compared to competitor hip implant devices. Zimmer Inc. and Zimmer US, Inc. omitted this material information from its written literature, advertisements, the Zimmer M/L Taper Hip Prosthesis Brochure,[4] the Zimmer M/L Taper Hip Prosthesis Surgical Technique guide,[5] Zimmer, Inc.'s M/L Taper Hip Prosthesis website,[6] the Products package inserts, and Zimmer, Inc.'s

[3] *Available at* https://www.accessdata.fda.gov/cdrh_docs/pdf3/K032726.pdf, incorporated by reference herein.

[4] *Available at* http://www.zimmerbiomet.com/medical-professionals/hip/product/ml-taper-hip-system.html, incorporated by reference herein.

[5] *Available at* http://www.zimmerbiomet.com/content/dam/zimmer-biomet/medical-professionals/000-surgical-techniques/hip/zimmer-ml-taper-hip-prosthesis-surgical-technique.pdf, incorporated by reference herein.

[6] *Available at* http://www.zimmerbiomet.com/medical-professionals/hip/product/ml-taper-hip-system.html, incorporated by reference herein.

Summary of Safety and Effectiveness, and other information, submitted to the FDA for 510(k) clearance.[7]

126. Zimmer, Inc. and Zimmer US, Inc. knew or should have known that its affirmative misrepresentation and concealments were false. This is so because Zimmer, Inc. and Zimmer US, Inc. had the legal obligation, discussed above, to demonstrate the Products were safe and effective for their intended use, adequately warn of the risks associated with the Products, and conduct post-market surveillance and report adverse events.

127. The facts concealed or not disclosed by Defendants to Plaintiff and Plaintiff's surgeon were material facts that a reasonable person, including Mr. Brosnan and his implanting surgeon, would have considered to be important in deciding whether or not to undergo a procedure or surgery using the Zimmer hip joint implant products.

128. Plaintiff and his physician were ignorant of Zimmer's misrepresentations and concealments at all material times. In fact, it would have been impossible for them to have known of these misrepresentations and concealments because Zimmer, Inc. and Zimmer US, Inc. were in exclusive possession of this information.

129. Plaintiffs and his surgeon were induced to rely on Zimmer, Inc. and Zimmer US, Inc.'s misrepresentations and omissions. But for this reliance Plaintiff would not have permitted his surgeon to proceed as usual, using the Zimmer Products; Plaintiff's surgeon would not have selected the Products for Mr. Brosnan's initial hip replacement; and Plaintiff and his surgeon would have closely monitored the metal ion levels in Mr. Brosnan's blood for early detection of corrosion and fretting of the Products (via regular metal ion lab testing and MRI imaging), which caused severe necrosis of the tissue and muscle surrounding the hip prosthetics, worsening Mr. Brosnan's outcome.

130. Plaintiffs and his surgeon were justified in relying on Zimmer because, as explained above, Zimmer was in a superior position to know the true facts and to be the experts of the Products. The reliance was also justified because Zimmer, Inc. and Zimmer US, Inc. were in

[7] *Available at* https://www.accessdata.fda.gov/cdrh_docs/pdf3/K032726.pdf, incorporated by reference herein.

a special or fiduciary relationship with Plaintiff's surgeon, and Plaintiff and Plaintiff's surgeon reasonably relied upon Zimmer, Inc. and Zimmer US, Inc.'s representations and omissions concerning the Products, having no independent knowledge that the information provided by Zimmer, Inc. and Zimmer US, Inc. was anything other than what Zimmer, Inc. and Zimmer US, Inc. stated.

131. By failing to disclose this information, Zimmer, Inc. and Zimmer US, Inc. gained a competitive advantage in the prosthetic hip industry. Indeed, the purpose of Zimmer, Inc. and Zimmer US, Inc. marketing scheme to withhold this information was for orthopedic surgeons to rely on this information and select Zimmer products over competitor products.

132. As a proximate result of Zimmer, Inc. and Zimmer US, Inc.'s false representations and concealment, Plaintiff was caused to sustain the injuries and damages described in this Complaint.

133. As a direct and proximate result of Zimmer's conduct, Plaintiff Daniel Brosnan has been severely and permanently damaged; has sustained economic losses; and will be required to incur additional medical expenses in the future to care for himself as a result of the injury and damages he has suffered; and Plaintiff Roberta Brosnan has lost the society, comfort and consortium of her beloved husband. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

134. Defendants' conduct as alleged above was malicious, intentional and outrageous and constitutes a willful and conscious disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiffs and as such, warrants an imposition of punitive damages.

CLAIM SIX

BREACH OF IMPLIED WARRANTIES

135. Plaintiffs re-allege and incorporates by reference the allegations set forth above as if set forth herein.

136. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Products for the purpose of total hip replacement surgery.

137. At all relevant times, Defendants intended that the Products be used in the manner that Plaintiff herein in fact used the Products, and Defendants impliedly warranted each of the Products to be of merchantable quality; safe and fit for such use; and warranted that each of the Products was adequately tested.

138. Defendants were aware that consumers, including Plaintiff, would use the Products as hip implants; which is to say that Plaintiff was a foreseeable user.

139. The Products were expected to reach and did in fact reach consumers, including Plaintiff herein, without substantial changes in the condition in which the Products were manufactured and sold by Defendants.

140. Defendants breached various implied warranties with respect to the Products in the following manner:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Products were safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using the Products;

b. Defendants represented that the Products were safe, and/or safer than other alternative hip implants and fraudulently concealed information which demonstrated that the Products were not safer than alternatives available on the market; and

c. Defendants represented that the Products were more efficacious than other alternative devices and fraudulently concealed information, regarding the true efficacy of the Products.

141. In reliance upon Defendants' implied warranties, Plaintiff herein used the Products as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

142. Defendants breached their implied warranty to Plaintiff in that the Products were not of merchantable quality, safe and fit for their intended use, or adequately tested.

143. As a direct and proximate result of Zimmer's conduct, Plaintiff Daniel Brosnan has been severely and permanently damaged; has sustained economic losses; and will be required

to incur additional medical expenses in the future to care for himself as a result of the injury and damages he has suffered; and Plaintiff Roberta Brosnan has lost the society, comfort and consortium of her beloved husband. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

144. Defendants' conduct as alleged above was malicious, intentional and outrageous and constitutes a willful and conscious disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiffs and as such, warrants an imposition of punitive damages.

CLAIM SEVEN

VIOLATION OF CALIFORNIA UNFAIR COMPETITION LAW

(Cal. Bus. & Prof. Code § 17200, et seq.)

145. Plaintiffs adopt and re-alleges the allegations contained in the above paragraphs as if set forth fully herein.

146. Plaintiffs are informed and believes, and thereon alleges, that Defendants, by the acts and misconduct alleged, violated the California Unfair Competition Law, Cal. Bus. & Prof. Code § 17200, *et seq.* ("UCL").

147. The UCL applies to Defendants' actions and conduct described herein because it extends to transactions which are intended to result, of which have resulted, in the sale of goods to consumers.

148. Plaintiff purchased (directly, or through his surgeon, and/or the heath care facility at which his surgery was performed) primarily for personal use the Products implanted into his body during surgery and, thereby, suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

149. Upon information and belief, said purchase occurred in the State of California.

150. Defendants have violated the UCL in representing that goods have characteristics and benefits which they do not have.

151. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for the Products (directly, or through his surgeon, and/or

the heath care facility at which his surgery was performed), and would not have incurred related medical costs and injury.

152. Defendants engaged in knowingly wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiffs for the Products, that would not have been paid for had Defendants not engaged in such unfair and deceptive conduct.

153. Defendants engaged in unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

a. making untrue, misleading, and/or deceptive assertions, representations, or statements of fact that goods or services have characteristics, components, uses benefits, or quantities that they do not have;

b. advertising goods or services with the intent not to sell them as advertised; and

c. engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

154. The untrue, misleading, and/or deceptive assertions, representations, or statements of fact regarding the Products were made by Zimmer, Inc. and Zimmer US, Inc. to the public in promotional materials, Defendants-sponsored medical literature, videos, Defendants-sponsored presentations, and/or face-to-face sales calls with Defendants sales representatives and/or agents, with the intent to induce an obligation.

155. Plaintiff and his surgeon justifiably relied on the untrue, misleading, and/or deceptive assertions, representations or statement of fact made by Defendants to the public in promotional materials, Defendants-sponsored medical literature, videos, Defendants-sponsored presentations, and/or face-to-face sales calls regarding the Products, in selecting the Products for Mr. Brosnan.

156. Under the UCL, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under this statute for unfair, deceptive, fraudulent, and unconscionable consumer sales practices.

157. Defendants violated the statutes that were enacted to protect consumers against unfair, deceptive, and misleading business practices and false advertising by knowingly and falsely representing that their Products were fit to be used for the purpose for which they were intended, when in fact the devices were defective and dangerous, and by other acts alleged herein.

158. Plaintiff was injured by the nature of Defendants' conduct. The effect of Defendants' conduct directed at patients, physicians, and consumers was to create demand for and sell their Products. Each aspect of Defendants' conduct combined to artificially create sales of said Products.

159. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

160. The acts of untrue and misleading statements by Defendants described above presented a threat to members of the public and individual consumers, and the public and individual consumers suffered harm.

161. Defendants had actual knowledge of the defective and dangerous conditions of the Products and failed to take immediate action to cure the defective and dangerous conditions.

162. Plaintiffs and the medical community relied upon Defendants' misrepresentations and omissions in determining which treatment to prescribe.

163. Reasonable consumers, including Plaintiffs, were injured by Defendants' unfair and deceptive acts.

164. As a direct and proximate result of the false representations described herein, Plaintiff was injured, as described above.

165. As a direct and proximate result of Zimmer's conduct, Plaintiff Daniel Brosnan has been severely and permanently damaged; has sustained economic losses; and will be required to incur additional medical expenses in the future to care for himself as a result of the injury and damages he has suffered; and Plaintiff Roberta Brosnan has lost the society, comfort and consortium of her beloved husband. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

166. Defendants' conduct as alleged above was malicious, intentional and outrageous and constitutes a willful and conscious disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiffs and as such, warrants an imposition of punitive damages.

CLAIM EIGHT

PUNITIVE DAMAGES

167. Plaintiffs adopt and re-alleges the allegations contained in the above paragraphs as if set forth fully herein.

168. At all times herein referenced, officers, directors, and managing agents of Zimmer knew, and were aware, and concealed, hid, and/or otherwise downplayed the true risks of Zimmer hip joint implant products.

169. At all times herein referenced, officers, directors, and managing agents of Zimmer knew, and were aware, that the Zimmer hip joint implant products was associated with metallosis, trunnionosis, high cobalt and/or chromium levels, corrosion, pseudotumors, adverse tissue reaction and/or necrotic tissue, need for revision and/or explanation, and other adverse medical conditions as described herein

170. Zimmer designed, engineered, developed, manufactured, fabricated, assembled, equipped, tested or failed to test, inspected or failed to inspect, labeled, advertised, promoted, marketed, supplied, distributed, wholesaled, and sold the Zimmer hip joint implant products, products which Defendants knew to be dangerous and unsafe for the purpose for which it was intended to be used.

171. At all times herein mentioned, prior to and at the time that Defendants designed, engineered, developed, manufactured, fabricated, assembled, tested or failed to test, promoted, marketed, supplied, distributed, and/or sold the Zimmer hip joint implant products to Plaintiff and Plaintiff's physicians, and prior to the time that the product was used, Zimmer knew, or should have known, that the Zimmer hip joint implant products were defectively designed and manufactured, that it had extremely dangerous properties and defects, and that it had defects which would cause serious injuries and damage to users of said product, thereby threatening the

life and health of the users. Further, at all times, all Defendants knew that the Zimmer hip joint implant products had caused serious injuries and damage to other members of the public.

172. At all times herein mentioned, Zimmer, despite actual knowledge described herein, intentionally suppressed the complaints and adverse events, actively concealed and downplayed the risks associated with the Zimmer hip joint implant products, actively promoted the Zimmer hip joint implant products, failed to warn Plaintiffs and the medical community of the true risks associated with the Zimmer hip joint implant products, saturated the scientific and medical literature with biased, industry-funded studies to conceal the true risks of the Zimmer hip joint implant products, and otherwise failed to warn Plaintiffs, the medical community, of the true risks of the Zimmer hip joint implant products.

173. At all times herein mentioned, Zimmer had actual knowledge of the facts hereinabove alleged demonstrating that serious injuries occur to patients in whom the Zimmer hip joint implant products were implanted. Nevertheless, Zimmer deliberately suppressed, concealed, downplayed, and/or otherwise hid any information demonstrating the true risks associated with the Zimmer hip joint implant products from Plaintiffs, the medical community, and/or the general public Zimmer continued, and continues, to actively promote the Zimmer hip joint implant products to orthopedic surgeons in an effort to maintain and increase the Zimmer hip joint implant products enormous profitability.

174. As a legal and proximate result of Zimmer's misconduct, callous, disregard, and omissions as alleged, Plaintiffs sustained the injuries, damages and losses described.

175. Zimmer's conduct and omissions in allowing such an extremely dangerous product to be used by members of the general public, including Plaintiffs, constitutes fraud, malice and oppression toward Plaintiffs and others, and demonstrates a callous and intentional disregard of the rights of Plaintiffs and others.

176. Plaintiffs are therefore entitled to exemplary or punitive damages, which would serve to punish Zimmer and to deter wrongful conduct in the future.

CLAIM NINE

LOSS OF CONSORTIUM

177. Plaintiffs adopt and re-allege the allegations contained in the above paragraphs as if set forth fully herein.

178. Daniel Brosnan was and still is the lawful husband of Plaintiff Roberta Brosnan.

179. As a result of Zimmer's actions, Plaintiff Roberta Brosnan has been deprived of the consortium of her husband, including, but not limited to, his services, love, companionship, affection, society, loss of physical relations and solace.

180. The damages sustained by Plaintiff Roberta Brosnan are a direct and consequential result of the action or inaction of negligence and palpable negligence of Zimmer.

181. As a result of Zimmer's negligent and outrageous conduct, by its agents, servants and/or employees, described herein, Zimmer acted with gross reckless disregard for the probability of causing Plaintiff Roberta Brosnan, to suffer severe emotional distress and loss of the consortium of her husband.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against the Defendants, and each of them, in an amount which exceeds the jurisdictional limits of all lower courts, together with interests, costs, and disbursements of this action, including damages including, but not limited to:

a. Compensatory damages in excess of the jurisdictional amount of this Court, in an amount to be proven at trial;

b. Exemplary damages to be proven at trial;

c. Incidental, hospital, and medical expenses according to proof;

d. Punitive damages for the conscious, willful, fraudulent, reckless acts of Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiffs in an amount sufficient to punish Defendants and to deter future similar conduct;

e. Loss of consortium damages on behalf of Plaintiff's spouse;

f. For reasonable attorneys' fees and costs;

g. For pre-judgment interest; and

h. For such further and other relief the Court deems just, equitable, and proper.

Dated: September 27, 2018

Respectfully submitted,

By: /s/Frabice N. Vincent

Fabrice N. Vincent (State Bar No. 160780)
LIEFF CABRASER HEIMANN & BERNSTEIN, LLP
275 Battery Street, 29th Floor
San Francisco, CA 94111-3339
Telephone: 415.956.1000
Facsimile: 415.956.1008

Wendy R. Fleishman (*pro hac vice forthcoming*)
Kelly McNabb (*pro hac vice forthcoming*)
LIEFF CABRASER HEIMANN & BERNSTEIN, LLP
250 Hudson Street, 8th Floor
New York, New York 10013-1413
Telephone: 212.355.9500
Facsimile: 212.355.9592

Attorneys for Plaintiff

JURY DEMAND

Plaintiff hereby demands a trial by jury on all issues so triable.

Dated: September 27, 2018

Respectfully submitted,

By: /s/Fabrice N. Vincent

Fabrice N. Vincent (State Bar No. 160780)
LIEFF CABRASER HEIMANN & BERNSTEIN, LLP
275 Battery Street, 29th Floor
San Francisco, CA 94111-3339
Telephone: 415.956.1000
Facsimile: 415.956.1008

Wendy R. Fleishman (*pro hac vice forthcoming*)
Kelly McNabb (*pro hac vice forthcoming*)
LIEFF CABRASER HEIMANN & BERNSTEIN, LLP
250 Hudson Street, 8th Floor
New York, New York 10013-1413
Telephone: 212.355.9500
Facsimile: 212.355.9592

Attorneys for Plaintiff

CERTIFICATION OF OTHER ACTIONS

The undersigned hereby certifies that the matter in controversy is not the subject of any other action pending in any court, arbitration, or administrative proceeding other than the following matters:

1. GLEN DAVIS and DARCY DAVIS v. ZIMMER, INC., et al., Case No. 4:18-CV-04412-JSW; and

2. JENNIFER ROBERTS v. ZIMMER, INC., et al., Case No. 4:18-CV-03564-JSW.

Dated: September 27, 2018

Respectfully submitted,

By: /s/Fabrice N. Vincent

Fabrice N. Vincent (State Bar No. 160780)
LIEFF CABRASER HEIMANN & BERNSTEIN, LLP
275 Battery Street, 29th Floor
San Francisco, CA 94111-3339
Telephone: 415.956.1000
Facsimile: 415.956.1008

Wendy R. Fleishman (*pro hac vice forthcoming*)
Kelly McNabb (*pro hac vice forthcoming*)
LIEFF CABRASER HEIMANN & BERNSTEIN, LLP
250 Hudson Street, 8th Floor
New York, New York 10013-1413
Telephone: 212.355.9500
Facsimile: 212.355.9592

Attorneys for Plaintiff

JS 44 (Rev. 06/17)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

DANIEL BROSNAN and ROBERTA BROSNAN

(b) County of Residence of First Listed Plaintiff Lake County
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Fabrice N. Vincent, LIEFF CABRASER HEIMANN & BERNSTEIN, LLP
275 Battery Street, 29th Floor, San Francisco, CA 94111-3339
Telephone: 415.956.1000; fvincent@lchb.com

DEFENDANTS

ZIMMER BIOMET, INC., f/k/a ZIMMER, INC.; ZIMMER BIOMET US, INC., f/k/a ZIMMER US, INC.; and ZIMMER BIOMET HOLDINGS, INC., f/k/a ZIMMER HOLDINGS

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ❒ 1 U.S. Government Plaintiff
- ❒ 3 Federal Question *(U.S. Government Not a Party)*
- ❒ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	❒ 4
Citizen of Another State	❒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	☒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
❒ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	❒ 625 Drug Related Seizure of Property 21 USC 881	❒ 422 Appeal 28 USC 158	❒ 375 False Claims Act
❒ 120 Marine	❒ 310 Airplane	☒ 365 Personal Injury - Product Liability	❒ 690 Other	❒ 423 Withdrawal 28 USC 157	❒ 376 Qui Tam (31 USC 3729(a))
❒ 130 Miller Act	❒ 315 Airplane Product Liability	❒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability		PROPERTY RIGHTS	❒ 400 State Reapportionment
❒ 140 Negotiable Instrument	❒ 320 Assault, Libel & Slander	❒ 368 Asbestos Personal Injury Product Liability		❒ 820 Copyrights	❒ 410 Antitrust
❒ 150 Recovery of Overpayment & Enforcement of Judgment	❒ 330 Federal Employers' Liability	PERSONAL PROPERTY		❒ 830 Patent	❒ 430 Banks and Banking
❒ 151 Medicare Act	❒ 340 Marine	❒ 370 Other Fraud	LABOR	❒ 835 Patent - Abbreviated New Drug Application	❒ 450 Commerce
❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)	❒ 345 Marine Product Liability	❒ 371 Truth in Lending	❒ 710 Fair Labor Standards Act	❒ 840 Trademark	❒ 460 Deportation
❒ 153 Recovery of Overpayment of Veteran's Benefits	❒ 350 Motor Vehicle	❒ 380 Other Personal Property Damage	❒ 720 Labor/Management Relations	SOCIAL SECURITY	❒ 470 Racketeer Influenced and Corrupt Organizations
❒ 160 Stockholders' Suits	❒ 355 Motor Vehicle Product Liability	❒ 385 Property Damage Product Liability	❒ 740 Railway Labor Act	❒ 861 HIA (1395ff)	❒ 480 Consumer Credit
❒ 190 Other Contract	❒ 360 Other Personal Injury		❒ 751 Family and Medical Leave Act	❒ 862 Black Lung (923)	❒ 490 Cable/Sat TV
❒ 195 Contract Product Liability	❒ 362 Personal Injury - Medical Malpractice		❒ 790 Other Labor Litigation	❒ 863 DIWC/DIWW (405(g))	❒ 850 Securities/Commodities/ Exchange
❒ 196 Franchise			❒ 791 Employee Retirement Income Security Act	❒ 864 SSID Title XVI	❒ 890 Other Statutory Actions
				❒ 865 RSI (405(g))	❒ 891 Agricultural Acts
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS			❒ 893 Environmental Matters
❒ 210 Land Condemnation	❒ 440 Other Civil Rights	Habeas Corpus:	IMMIGRATION	FEDERAL TAX SUITS	❒ 895 Freedom of Information Act
❒ 220 Foreclosure	❒ 441 Voting	❒ 463 Alien Detainee	❒ 462 Naturalization Application	❒ 870 Taxes (U.S. Plaintiff or Defendant)	❒ 896 Arbitration
❒ 230 Rent Lease & Ejectment	❒ 442 Employment	❒ 510 Motions to Vacate Sentence	❒ 465 Other Immigration Actions	❒ 871 IRS—Third Party 26 USC 7609	❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
❒ 240 Torts to Land	❒ 443 Housing/ Accommodations	❒ 530 General			❒ 950 Constitutionality of State Statutes
❒ 245 Tort Product Liability	❒ 445 Amer. w/Disabilities - Employment	❒ 535 Death Penalty			
❒ 290 All Other Real Property	❒ 446 Amer. w/Disabilities - Other	Other:			
	❒ 448 Education	❒ 540 Mandamus & Other			
		❒ 550 Civil Rights			
		❒ 555 Prison Condition			
		❒ 560 Civil Detainee - Conditions of Confinement			

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from Another District *(specify)* ❒ 6 Multidistrict Litigation - Transfer ❒ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. § 1332

Brief description of cause:
Product liability and negligence for injuries caused by defective medical device.

VII. REQUESTED IN COMPLAINT:

❒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $ in excess of $75,000

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Jeffrey S. White DOCKET NUMBER 4:18-CV-04412; 4:18-CV-03564

DATE 09/27/2018

SIGNATURE OF ATTORNEY OF RECORD Fabrice N. Vincent

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.