UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF MICHIGAN

RICHARD P. TORRES and
POLLYANNA TORRES, his wife,

Plaintiffs,

v.

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

Defendants.

COMPLAINT AND JURY DEMAND

Richard P. Torres and Pollyanna Torres, his wife, by John A. Zick, state the following complaint against the defendants:

JURISDICTION

1. Richard P. Torres and Pollyanna Torres are citizens of the state of Michigan, residing in Wexford County, Michigan. Pollyanna Torres is the wife of Richard P. Torres.

2. Zimmer Biomet Holdings, Inc., formerly known as Zimmer Holdings, Inc., is a corporation organized under the laws of the state of Delaware, with its principal place of business in the state of Indiana. At all times relevant to this action, Zimmer Biomet Holdings, Inc. was the publicly traded holding company with wholly owned subsidiaries that it controlled which tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Zimmer Hip System in interstate commerce and throughout the State of

Michigan and generated substantial revenue as a result.

3. Zimmer Biomet, Inc. formerly known as Zimmer, Inc., is a corporation organized under the laws of the state of Delaware, with its principal place of business in the state of Indiana. At all times relevant to this action, Zimmer Biomet, Inc. was a wholly owned subsidiary of Zimmer Biomet Holdings, Inc. On April 24, 2014, Zimmer Holdings, Inc. entered into an agreement to merge with LVB Acquisition, Inc., the parent company of Biomet, Inc. After the merger, Zimmer Holdings, Inc. was renamed Zimmer Biomet Holdings, Inc. and Zimmer, Inc. was renamed Zimmer Biomet, Inc. At all times relevant to this action, Zimmer Biomet, Inc. tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Zimmer Hip System in interstate commerce and throughout the State of Michigan and generated substantial revenue as a result.

4. Zimmer Biomet U.S., Inc., formerly known as Zimmer U.S., Inc., is a corporation organized under the laws of the state of Delaware, with its principal place of business in the state of Indiana. At all times relevant to this action, Zimmer Biomet U.S., Inc. was a wholly owned subsidiary of Zimmer Biomet, Inc. At all times relevant to this action, Zimmer Biomet U.S., Inc. tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Zimmer Hip System in interstate commerce and throughout the State of Michigan and generated substantial revenue as a result.

5. The amount in controversy exceeds the sum of $75,000, exclusive of interest and costs.

6. This court has original diversity jurisdiction of this action pursuant to 28 U.S.C. § 1332(a).

GENERAL FACTUAL ALLEGATIONS

A. Background on the Zimmer Defendants

7. Founded in 1927, Zimmer is the third largest orthopedic device manufacturer in the United States.

8. Zimmer tests, studies, researches, designs, formulates, manufactures, inspects, labels, packages, promotes, advertises, markets, distributes, and sells reconstructive orthopedic implants, including joint, dental and spinal implants, trauma products and related orthopedic surgical products. Zimmer's related orthopedic surgical products include surgical supplies and instruments designed to aid in orthopedic surgical procedures. Zimmer also has a limited array of sports medicine products. Zimmer's primary customers include orthopedic surgeons, musculoskeletal surgeons, neurosurgeons, oral surgeons, dentists, hospitals, distributors, healthcare dealers and, in their capacity as agents, healthcare purchasing organizations or buying groups. These customers range from large multi-national enterprises to independent healthcare practitioners.

9. In 2008, the U.S. hip and knee replacement market was valued at $6.7 billion, with the hip replacement market contributing thirty-eight percent of the market at roughly $2.5 billion dollars.

10. According to Zimmer's 2008 Annual 10-K Report, Zimmer was number one in global market share for reconstructive hip components. In the period ending December 2008, Zimmer reported $1.2795 billion in hip component sales. Zimmer's

total 2008 sales exceeded $4 billion.

11. According to Zimmer's 2016 Annual 10-K Report, in the period ending December 2016, Zimmer reported $1.868 billion in hip component sales. Zimmer's total 2016 sales exceeded $7.684 billion.

B. Hip Replacement Surgery and Artificial Hip Devices

12. The hip joint, scientifically referred to as the acetabulofemoral joint, is the joint between the femur (the thigh bone) and the acetabulum (the hip socket) of the pelvis, and its primary function is to support the weight of the body in both static (i.e., standing) and dynamic (i.e., walking or running) postures.

13. Total hip replacement, also known as total hip arthroplasty, is a surgical procedure in which the patient's hip joint is resurfaced and replaced with an artificial implant which is designed to replicate the human anatomy – that is, the relatively simple ball and socket structure of the human hip joint.

14. Hip replacement surgery traditionally consists of several stages. First, the orthopedic surgeon removes the top of the femur, or thighbone. Next, the surgeon reams or hollows out a portion of the top of the femur and inserts a metal femoral stem into the remaining femur bone. The surgeon then uses a hammer to strike an artificial "ball" or femoral head typically made of a metal alloy, stainless steel or ceramic onto the top end of the femoral stem. Next, the surgeon reams out the patient's natural acetabulum and inserts an acetabular cup in the resulting space. In some hip implant systems, a metal, plastic or ceramic liner is then fitted inside the acetabular cup. Finally, the surgeon fits the ball-shaped femoral head into the liner of the acetabular cup where it should move easily, without friction or pain to the patient.

15. Total hip replacement is most commonly used to treat joint failure caused by osteoarthritis. Other indications for total hip replacement include rheumatoid arthritis, femoral head fracture, avascular necrosis, arthritis associated with Paget's disease of the bone, and ankylosing spondylitis. The aims of the procedure are pain relief and improvement in hip function. Hip replacement is usually considered only after other non-surgical options, such as pain medications and physical therapy, have failed.

16. Total hip replacement is a common medical procedure performed on more than 420,000 patients in the U.S. each year. In 2010, the prevalence of total hip and total knee replacement in the total U.S. population was 0.83% and 1.52%, respectively. Prevalence was higher among women than among men and increased with age, reaching 5.26% for total hip replacement and 10.38% for total knee replacement at eighty years of age. These estimates correspond to 2.5 million individuals (1.4 million women and 1.1 million men) with a total hip replacement and 4.7 million individuals (3.0 million women and 1.7 million men) with a total knee replacement in 2010.

C. Modularity in Hip Implant Design and Mechanically Assisted Crevice Corrosion

17. Traditional hip replacement devices consisted of a monobloc stem, which was a femoral stem with a single neck/head option, all constructed from a single piece of metal. Monobloc stems made restoring a patient's leg length and femoral offset challenging and increased the component inventory at healthcare facilities.

18. The concept of "modularity" was introduced into the design of hip prostheses and has become increasingly common in the last two decades. Modularity aimed to provide surgeons with additional versatility when attempting to restore normal

biomechanical function in patients.

19. Modularity can be exhibited at the juncture between the femoral head and the trunnion of the femoral stem. The trunnion is the tapered top end of the femoral stem upon which the femoral head is affixed. The trunnion has a taper angle that is wider at the proximal end than the distal end. The bore (or hollow portion of the inside of the ball) of the femoral head has a corresponding taper angle which is wider at the distal than proximal end. When the two components are affixed together, the corresponding taper angles allow for an interference fit between the femoral head and femoral stem. The contact area between the inside of the bore of the femoral head (the female taper surface) and the trunnion of the femoral stem (the male taper surface) is called the taper interface.

20. The taper interface is designed to prevent motion when assembled; however, studies have demonstrated that micromotion can develop over time at a malfunctioning taper interface, resulting in articulation of the bore of the femoral head against the trunnion of the femoral stem to the degree that the oxide layer existing between the components is gradually worn down, resulting in metal debris wearing off the component parts.

21. Fluid from the joint can also enter a malfunctioning taper interface, particularly with femoral stems which employ a trunnion with microgrooves.

22. Historically, manufacturers have produced femoral stems with a trunnion that has either a smooth or microgrooved surface finish. A femoral stem trunnion with microgrooves has a rough surface area which looks like microscopic screw threads or the ridges of a vinyl record. The microgrooves are designed to allow for a better inter-

ference fit with ceramic femoral heads. However, when fluid enters the taper interface, the microgrooves create a crevice-like environment which facilitates a crevice corrosion process whereby the underlying metal corrodes and releases metal ions, particularly cobalt and/or chromium, off the components.

23. Whether caused by fretting or corrosion, the release of metal debris and/or ions can result in elevated serum metal ion levels, adverse local tissue reactions, pseudotumor formation, tissue destruction, the need for revision surgery and, in some cases, systemic effects of metal ion toxicity, including neurologuical (fatigue, weakness, poor coordination, cognitive dysfunction, depression, vertigo, visual and hearing impairment, and peripheral neuropathy), hematological (polycythaemia), endocrine (hypothyroidism), and cardiac (arrhythmias and cardiomyopathy) complications.

24. Studies have further shown that metal debris produced from a corrosive process is more biologically toxic and therefore more harmful to humans than metal particulates produced from a fretting process alone.

25. The process by which metal ions and debris buildup in the soft tissues of the hip joint and blood is often generally referred to as metallosis.

26. A hip implant should not cause metallosis to a patient in whom it is implanted. Although it is hypothesized that a small amount of asymptomatic or non-toxic corrosion or metal debris may occur with a well-functioning device, a hip implant that causes an excessive amount of fretting debris or corrosion sufficient to result in metallosis creates an unreasonable risk of injury.

27. The concern that fretting and corrosion damage could occur at the head-neck taper interface of a modular hip prosthesis was first reported in the early 1980's.

Since that time, increasingly numerous studies and reports have demonstrated that a malfunctioning taper interface between a metal femoral head and metal femoral stem may be susceptible to fretting and corrosion damage resulting in elevated serum metal ion levels, adverse local tissue reactions, pseudotumor formation, tissue destruction, metallosis, and the need for revision surgery.

28. As total hip replacement surgery became 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.

29. The Zimmer Hip System implanted into Plaintiff Richard P. Torres consisted of four component parts: a) the M/L Taper® Hip Prosthesis Femoral Stem which was made of titanium alloy; b) the VerSys® Hip System Femoral Head which was made of cobalt/chromium alloy which was affixed to the trunnion of the femoral stem; c) the Trilogy Acetabular System Shell which was made of titanium alloy; and d) the Trilogy Acetabular System Liner which was made of highly cross-linked polyethylene. Plaintiff's Zimmer Hip System is referred to as a "metal-on-polyethylene" bearing system.

30. In designing the Zimmer Hip System, Zimmer knew that the use of dissimilar metal alloys as well as taper size and geometry, trunnion surface finish, and flexural rigidity contribute to causing fretting and corrosion at the femoral head-femoral stem taper interface.

31. Mechanically assisted crevice corrosion ("MACC") has been identified as a cause for symptomatic implant failure in metal-on-polyethylene hip devices. MACC

produces cobalt and chromium ions, fretting byproducts and corrosive debris that can lead to adverse local tissue reaction.

32. Adverse local tissue reaction, also referred to as aseptic lymphocyte dominated vasculitis-associated lesions ("ALVAL"), represents a distinctive periprosthetic inflammatory reaction accompanied by extensive necrosis in the soft tissue-envelope of the hip. Early detection of adverse local tissue reaction is important because as time from onset of MACC to revision surgery increases, tissue damage may worsen.

33. A recent epidemiological study determined that the M/L Taper® Hip Prosthesis Femoral Stem had a greater prevalence (4.9%) of mechanically assisted crevice corrosion than all other Zimmer femoral stem types employing a 12/14 trunnion combined. Additionally, the study found that patients undergoing total hip arthroplasty between 2009 and 2012 with metal-on-polyethylene hip devices manufactured by Zimmer also had a significantly higher prevalence of mechanically assisted crevice corrosion. Hussey, et al., *Ten-Year Cross-Sectional Study of Mechanically Assisted Crevice Corrosion in 1352 Consecutive Patients With Metal-on-Polyethylene Total Hip Arthroplasty,* The Journal of Arthroplasty (March 18, 2017).

D. The Design and Manufacture of the Zimmer Hip System

34. Upon information and belief, the VerSys® Hip System Femoral Head was cleared by the FDA via section 510(k) of the Medical Device Amendments of 1976 ("MDA") to the Food, Drug and Cosmetic Act ("FDCA") on or about January 22, 1996.

35. Upon information and belief, the M/L Taper® Hip Prosthesis Femoral Stem was cleared by the FDA via section 510(k) of the MDA to the FDCA on or about

May 12, 2006.

36. In their 510(k) clearance submissions to the FDA, Defendants down-played, misstated and failed to adequately disclose the amount of wear, metal debris and corrosion that is generated at the juncture between the VerSys® Hip System Femoral Head and the M/L Taper® Hip Prosthesis Femoral Stem when these two components are used in combination. As a result, the FDA was unable to adequately consider the incidence of fretting and corrosion at this taper juncture before clearing the devices for sale and marketing.

37. At all times relevant to this action, Defendants marketed, promoted, advertised and sold the VerSys® Hip System Femoral Head for use in combination with the M/L Taper® Hip Prosthesis Femoral Stem.

38. Upon information and belief, Zimmer has never conducted a clinical trial on the M/L Taper® Hip Prosthesis Femoral Stem.

39. Upon information and belief, Zimmer has never conducted a clinical trial on the VerSys® Hip System Femoral Head.

40. Had Defendants conducted clinical trials of the Zimmer Hip System before the device was first released on the market, they would have discovered at that time the propensity of the device to undergo significant fretting and/or mechanically assisted crevice corrosion at the femoral head-stem taper juncture, resulting in elevated serum metal ion levels, adverse local tissue reactions, pseudotumor formation, tissue destruction, metallosis, the need for revision surgery and, in some cases, systemic effects of metal ion toxicity, including neurological (fatigue, weakness, poor coordination, cognitive dysfunction, depression, vertigo, visual and hearing impairment,

and peripheral neuropathy), hematological (polycythaemia), endocrine (hypothyroidism), and cardiac (arrhythmias and cardiomyopathy) complications.

41. At all times relevant to this action, Defendants were aware of the problems with the Zimmer Hip System's design and its propensity to undergo fretting and/or mechanically assisted crevice corrosion at the femoral head-stem taper interface resulting in elevated serum metal ion levels, adverse local tissue reactions, pseudotumor formation, tissue destruction, metallosis, the need for revision surgery and, in some cases, systemic effects of metal ion toxicity, including neurological (fatigue, weakness, poor coordination, cognitive dysfunction, depression, vertigo, visual and hearing impairment, and peripheral neuropathy), hematological (polycythaemia), endocrine (hypothyroidism), and cardiac (arrhythmias and cardiomyopathy) complications. Nonetheless, Defendants still did not adequately warn patients, the medical community, or the public about these risks, and continued and continue to the present day to promote, market, sell and defend the Zimmer Hip System.

42. At all times relevant to this action, Defendants failed to recognize the defects in the Zimmer Hip System due to poor and inadequate quality assurance procedures, including the failure of Zimmer to implement appropriate physical, manual, x-ray, microscopic and other inspections of the Zimmer Hip System. Zimmer also failed to implement or utilize adequate safeguards, tests, inspections, validation, monitoring and quality assessments to ensure the safety of the Zimmer Hip System.

43. At the time the Zimmer Hip System was manufactured and sold to patients, including Plaintiff Richard P. Torres, the device was defectively manufactured and unreasonably dangerous, and did not conform to the federal regulations, subject-

ing patients to unreasonable risks of injury.

44. At all times relevant to this action, Zimmer's inadequate manufacturing processes led to material flaws in the quality systems at its manufacturing facilities, including but not limited to Zimmer's manufacturing facility located in Ponce, Puerto Rico.

45. During the course of manufacturing the Zimmer Hip System, Defendants failed in several ways, including, without limitation, by:

a. failing to conduct adequate mechanical testing, including corrosion fatigue or other wear testing, on components, subassemblies and/or the finished Zimmer Hip System;

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

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

d. failing to identify and/or note the significance of any testing that resulted in failure of the Zimmer Hip System;

e. failing to take corrective actions to eliminate or minimize further failures of the Zimmer Hip System;

f. failing to adequately explain performance specifications for the components, subassemblies, and finished Zimmer Hip System;

g. failing to adequately explain or justify all test conditions and acceptance criteria for the Zimmer Hip System;

h. failing to perform adequate testing in an environment that adequately simulated in vivo conditions; and

i. failing to perform adequate quality assurance testing before and after sterilization.

46. At all times relevant to this action, Zimmer failed to perform adequate testing of the Zimmer Hip System, including its components and subassemblies, to ensure that the Zimmer Hip System functioned properly during and after implantation.

47. Upon information and belief, Zimmer never conducted Spectrum Accelerated Corrosion Fatigue ("SACF") Testing on the femoral head-stem juncture of the Zimmer Hip System at any time before Plaintiff's initial surgery on February 11, 2014.

48. Upon information and belief, Zimmer never conducted Spectrum Accelerated Corrosion Fatigue ("SACF") Testing on the femoral head-stem juncture of the Zimmer Hip System at any time after Plaintiff's initial surgery on February 11, 2014.

49. As a result of these manufacturing and quality control problems associated with the manufacture of the Zimmer Hip System, the device was inadequately and defectively manufactured, making it adulterated, and outside of the specifications expressly approved by the FDA.

50. On or before the date of Plaintiff's initial hip surgery, Defendants knew or should have known that the Zimmer Hip System was failing and causing serious complications after implantation in many patients. Such complications included, but were not limited to, elevated serum metal ion levels, adverse local tissue reactions, pseudotumor formation, tissue destruction, metallosis, the need for revision surgery and, in some cases, systemic effects of metal ion toxicity, including neurological (fatigue, weakness, poor coordination, cognitive dysfunction, depression, vertigo, visual and hearing impairment, and peripheral neuropathy), hematological (polycythaemia), endocrine (hypothyroidism), and cardiac (arrhythmias and cardiomyopathy) complications. Defendants, however, actively concealed the true information and spread false

information through, among other things, marketing and promotional materials, advertisements, and communications and meetings with orthopedic surgeons and other healthcare providers.

51. Before the date of Plaintiff's initial hip replacement surgery, Defendants knew or should have known that the Zimmer Hip System was defective and unreasonably dangerous to patients, that the product had an unacceptable failure and complication rate, and that the product had a greater propensity to undergo significant fretting and/or mechanically assisted crevice corrosion at the femoral head-stem taper juncture resulting in elevated serum metal ion levels, adverse local tissue reactions, pseudotumor formation, tissue destruction, metallosis, and the need for revision surgery.

52. Defendants had legal obligations to stop promoting, marketing, selling and defending the Zimmer Hip System. Defendants should have taken steps to notify physicians who had implanted and continue to implant the Zimmer Hip System of the device's increased risk for fretting and corrosion at the femoral head-stem taper interface, and for some patients to develop extremely adverse reactions to the high level of metal debris generated by wear of the device. Defendants should have attempted to convey this same information to patients who had been implanted with the Zimmer Hip System. Nonetheless, Defendants did not notify doctors or patients of the risks the Zimmer Hip System presented. Instead, Defendants purposefully concealed this material information, while using their sales representatives to market, promote, distribute, sell, and defend the Zimmer Hip System.

53. The Zimmer Hip System is not the first hip device manufactured by Defendants that has experienced complications at a metal-on-metal juncture. On July

22, 2008, Zimmer initiated a voluntary suspension of the Durom Cup from marketing and distribution in the United States. The Durom Cup consisted of an acetabular cup made of titanium, a femoral head made of cobalt/chromium and a femoral stem made of titanium. Zimmer announced that the company was taking this "voluntary action to address its concerns regarding reports of cup loosening and revisions of the acetabular component used in total hip replacement procedures."

54. On February 20, 2014, Zimmer instituted a worldwide recall of the VerSys Head, including the femoral head implanted in Plaintiff Richard P. Torres. Zimmer's recall notice indicated that packaging operations conducted in the company's manufacturing facility in Ponce, Puerto Rico were not properly validated.

55. On or about September 23, 2016, Zimmer filed a new 510(k) notification with the FDA for the M/L Taper femoral stem (K161830). According to Zimmer's 510(k) Summary, several changes were made to how the M/L Taper femoral stem is manufactured, including:

a. using a forge blank instead of a wrought blank;

b. using mass disc finishing in addition to hand polishing; and

c. a change to the laser etch type and location.

56. Upon information and belief, some or all of these manufacturing changes were made in order to address and improve the fretting and corrosion properties of the M/L Taper femoral stem when mated with the VerSys femoral head.

57. Approximately one month later on October 26, 2016, the FDA cleared the device for marketing and sale in the United States.

E. The Federal Requirements

58. The Medical Device Amendments of 1976 to the Food, Drug and Cosmetic Act established the current regulatory framework for medical devices.

59. The MDA, in theory, requires medical devices like the Zimmer Hip System to undergo premarket approval by the FDA, a process which obligates the manufacturer to design and implement a clinical investigation and to submit the results of that investigation to the FDA.

60. Premarket approval is a rigorous process that requires a manufacturer to submit what is typically a multivolume application that includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a full statement of the device's components, ingredients, and properties and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and when relevant, packing and installation of, such device; samples or device components required by the FDA; and a specimen of the proposed labeling.

61. The FDA may grant premarket approval only if it finds that there is reasonable assurance that the medical device is safe and effective, and must weigh any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

62. A medical device on the market prior to the effective date of the MDA – a so-called "grandfathered" device – is not required to undergo premarket approval. In addition, a medical device marketed after the MDA's effective date may bypass the

rigorous premarket approval process if the device is "substantially equivalent" to a "grandfathered" pre-MDA device (i.e., a device approved prior to May 28, 1976).

63. This exception to premarket approval is known as "510(k) clearance" which only requires the manufacturer to notify the FDA under section 510(k) of the MDA of its intent to market a device at least 90 days prior to the device's introduction on the market, and to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then "clear" the new device for sale in the United States.

64. 510(k) clearance is distinct from the FDA's pre-market approval ("PMA") process in that clearance does not require clinical confirmation of safety and effectiveness and as such, the manufacturer retains all liability for the assertions of safety and effectiveness.

65. All the component parts comprising Plaintiff's Zimmer Hip System were cleared for marketing by the FDA pursuant to 510(k) of the MDA or were marketed without receiving either 510(k) clearance or PMA approval by the FDA.

66. In *Buckman v. Plaintiffs' Legal Comm.,* 531 U.S. 341, 346 (2001), the U.S. Supreme Court explained that demonstrating that a device qualifies for this, known as the "§ 510(k) process," means 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).

67. The FDCA requires cleared medical devices to be demonstrated to be safe and effective for each intended use.[1] Not only is the medical device itself part of the 510(k) process, but so is the labeling and packaging that comes with it

68. A manufacturer is required to give adequate directions for the use of a medical device such that a "layman can use a device safely and for the purposes for which it is intended[2]", and conform to section 801.15 requirements governing the appearance of the label.

69. The FDCA requires medical device manufacturers to disclose all material facts in advertising and labeling[3]. False and misleading labeling is considered mis-branding[4], which is prohibited[5].

70. The distribution of a "misbranded" medical device is prohibited pursuant to 21 U.S.C. §§ 331(a), (k) (2012) and 21 U.S.C. § 352(f) (2012).

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[1] 21 U.S.C. § 360e(c)(2)(A)(iv) (2012).

[2] 21 C.F.R. § 810.5 (2012).

[3] 21 U.S.C. § 321(n) (2012)

[4] 21 U.S.C. § 321(a), q(1) (2012).

[5] 21 U.S.C. § 331(b).

71. The FDCA provides that a medical device is misbranded if, among other things, the labeling did not contain adequate directions for use, which includes critical information about adverse events. Adequate directions for use cannot be written including adverse events when the manufacturer has failed to disclose those adverse events to the FDA. Therefore, the labeling becomes inadequate and the product is misbranded.

72. Federal law requires a manufacturer to ensure that any warranty statements it voluntary makes are truthful, accurate, not misleading, and consistent with applicable federal and state law[6].

73. Under the FDCA, medical device manufacturers are prohibited from introducing the adulteration or misbranding of any medical device into interstate commerce[7].

1. The FDA, By Its Regulations and 510(k) Clearance Process, Prohibits Misleading or False Promotional and Marketing Activities

74. The FDA regulates the manufacture, sale, and distribution of medical devices in the United States under the authority of the FDCA. This authority includes oversight of labeling and advertising for all medical devices[8].

75. Under the FDCA and FDA's implementing regulations, labeling, promotional advertisements, and making claims about medical devices are deemed mislead-

[6] 21 U.S.C. § 331(b) (effective 2013)

[7] 7 Id.

[8] See 21 U.S.C. § 352(a), (n), (q) & (4) (2012).

ing if they omit or ignore certain information about the product's risks.

76. A medical device shall be deemed to be misbranded if its labeling is false or misleading in any particular. Labeling or advertising may be considered misleading if it fails to reveal material facts about the product being promoted, including facts about the consequences that can result from use of the product as suggested in a promotional piece[9].

2. After a Medical Device is Cleared via the 510(k) Process, a Device Manufacturer Still Has Requirements, Including General Reporting Requirements, to the FDA Mandated by Federal Regulations

77. A manufacturer's obligations do not end with 510(k) clearance by the FDA. Even after clearance, manufacturers are required to report to the FDA "no later than 30 calendar days after the day: the manufacturer receive[s] or otherwise become[s] aware of information, from any source, that reasonably suggests that a device" marketed by the manufacturer:

> a. May have caused or contributed to death or serious injury; or
>
> b. Has malfunctioned and this device or a similar device [likewise marketed by the manufacturer] would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur[10].

78. These 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.

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[9] 21 U.S.C. § 321(n) (2012); 21 C.F.R. §§ 1.21, 202.1(e)(5)(iii) (2012).

[10] 21 C.F.R. § 803.50(a) (2012); 21 U.S.C. § 360i(a) (2012).

79. In addition, manufacturers are responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event[11].

80. Manufacturers are required to make periodic reports to the FDA regarding cleared devices, such reports to include summaries of:

> a. Unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant; and,
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> b. Reports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant[12].

81. The medical device manufacturer has a continuing duty to monitor the product after FDA clearance and to discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which it .

82. The manufacturer is obligated to inform the FDA of new clinical investigations or scientific studies concerning the device about which the manufacturer knows or reasonably should know[13].

83. The FDA can revoke its clearance based on these post-approval reports[14].

84. The manufacturer must establish internal procedures for reviewing complaints and adverse event reports[15]. Medical device manufacturers are required by

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[11] 21 C.F.R. § 803.50(b)(3).

[12] 21 C.F.R. § 814.84(b)(2) (2012).

[13] Id.

[14] 21 U.S.C. §§ 360(e)(1), 360(h)(e) (2012).

[15] 21 C.F.R. § 820.198(a) (2012).

federal regulation to "establish and maintain" an adverse event database[16]. 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[17].

85. Federal law also mandates that the FDA establish regulations requiring the 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[18].

86. Manufacturers must disclose any reportable 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[19].

87. Device manufacturers must report promptly to FDA any device corrections and removals, and maintain records of device corrections and removals.

88. FDA regulations require submission of a written report within ten (10) 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

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[16] 21 C.F.R. § 803.1(a) (2012).

[17] 21 C.F.R. § 803.52 (2012).

[18] 21 U.S.C. § 360(i).

[19] See 21 C.F.R. § 806 (2012).

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[20].

89. Pursuant to federal regulation, 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.

90. Manufacturers must also meet quality standards in manufacture and production of the devices.

91. Manufacturers must establish and maintain procedures for implementing corrective actions and preventive actions; investigate the cause of nonconforming products; and take corrective action to prevent recurrence.

92. Manufacturers are also required to review and evaluate all complaints and determine whether an investigation is necessary.

93. Manufacturers are also required to use statistical techniques, where necessary, to evaluate product performance.

94. Zimmer failed to comply with several of these requirements, which led to the devices being on the market for use by Plaintiff's doctor.

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[20] See 21 C.F.R. § 806 (2012).

95. Zimmer failed to comply with many of these above-mentioned FDA regulations and requirements.

96. Zimmer failed to report adverse events timely to the FDA.

97. Zimmer failed to investigate and correct problems with the Zimmer Hip System.

3. After Clearance of a Medical Device, The FDA, By Its Regulations and PMA Process, Requires A Manufacturer To Follow Good Manufacturing Practices

98. Under 21 C.F.R. § 820.1(a) (2012) of the Quality System (QS) Regulation for Medical Devices, current good manufacturing practice (CGMP) requirements are set forth in this quality system regulation. The requirements in this part govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. The requirements in this part are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (FDCA). This part establishes basic requirements applicable to manufacturers of finished medical devices.

99. 21 C.F.R. § 820.5 (2012) "Quality Systems," the FDA regulations state, "Each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of this part."

100. 21 C.F.R. § 820.3(z)(2) (2012) "Design validation," means the manufacturer must establish objective evidence that device specifications conform with user needs and intended use(s)."

101. 21 C.F.R. § 820.22 (2012): "Quality Audit" states: "Each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system."

102. 21 C.F.R. § 820.160(a) (2012): "Distribution" states: "Each manufacturer shall establish and maintain procedures for control and distribution of finished devices to ensure that only those devices approved for release are distributed and that purchase orders are reviewed to ensure that ambiguities and errors are resolved before devices are released for distribution."

103. 21 C.F.R. § 820.170(a) (2012): "Installation" states: "Each manufacturer of a device requiring installation shall establish and maintain adequate installation and inspection instructions, and where appropriate, test procedures. Instructions and procedures shall include directions for ensuring proper installation so that the device will perform as intended after installation. The manufacturer shall distribute the instructions and procedures with the device or otherwise make them available to the person(s) installing the device."

104. 21 C.F.R. § 803 (2012), states: "Manufacturers must include information that is reasonably known to the manufacturer, timely make Medical Device Reporting ("MDR") submissions, define the procedures for implementing corrective and preventative actions, and review sampling methods for adequacy of their intended use."

105. 21 C.F.R. § 820.100 (2012) "Corrective and Preventive Action" states: (a) [e]ach manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

a. Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;

b. Investigating the cause of nonconformities relating to product, processes, and the quality system;

c. Identifying the actions needed to correct and prevent recurrence of nonconforming product and other quality problems;

d. Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device; and

e. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems.

4. Zimmer's Conduct in Violation of the FDCA

106. Zimmer violated these FDCA statutes and accompanying regulations by:

a. falsely and misleadingly promoting the Zimmer Hip System;

b. failing to report adverse events to the FDA;

c. failing to timely conduct failure investigations and analysis;

d. failing to timely report any and all information concerning product failures and corrections;

e. failing to timely and fully inform the FDA of unanticipated adverse effects, including device corrosion, increases in the incidence of adverse effects, and device failures necessitating a labeling, manufacturing or device modification;

f. failing to conduct necessary design validation;

g. selling and distributing a misbranded and adulterated product through interstate commerce; and

h. failing to immediately disclose the metallosis risk from the fretting and corroding failure of the Zimmer Hip System after implantation in patients.

107. Zimmer's violation of these FDCA statutes and accompanying regulations, as discussed above, supports the state law tort causes of action alleged in this complaint, as set forth herein.

108. Zimmer's violation of the FDCA statutes and accompanying regulations, as discussed above, directly caused or significantly contributed to the use of the Zimmer Hip System in Plaintiff, and Zimmer's misconduct in this regard thus directly caused or contributed to Plaintiff's injuries and damages.

PLAINTIFF'S IMPLANT, SURGERIES AND DAMAGES

109. On February 11, 2014, Plaintiff Richard P. Torres underwent a right total hip replacement surgery at Cadillac Hospital in Cadillac, Michigan. The surgery was performed by Paul R. Bizzigotti, M.D.

110. During the procedure, a Zimmer Hip System was implanted utilizing the following components:

a. VerSys® Hip System Femoral Head, 12/14 Taper, 32 mm diameter, +0 mm neck length, Lot No. 62516821, Ref. No. 8018-32-02 ("VerSys Head");

b. M/L Taper Hip Prosthesis Femoral Stem, Press-Fit, Plasma Sprayed, 12/14 Neck Taper, Standard Neck Offset, Size 11, Lot

No. 62540656, Ref. No. 00-7711-011-10 ("M/L Taper Stem");

c. Trilogy Acetabular System Shell with Cluster Holes, Porous, 54mm, Lot No. 62517074, Ref. No. 6200-54-22 ("Acetabular Cup"); and

d. Trilogy Acetabular System Liner, Standard, Longevity Crosslinked Polyethylene, 32 mm I.D, Lot No. 6250-15-92, Ref. No. 6305-62-36.

111. The VerSys Head is made of cobalt and chromium alloy.

112. The M/L Taper Stem is made of titanium (Ti6Al4V) and is circumferentially porous-coated with titanium alloy plasma spray over the proximal body region. The M/L Taper Stem is a flat, collarless, modular femoral stem with a proximal to distal taper in the mediolateral plane. The M/L Taper is designed for cementless fixation.

113. After initial recovery and for a period of time after the implantation surgery, Plaintiff's Zimmer Hip System performed as expected.

114. In late 2017, Plaintiff Torres attended an orthopedic visit because he had increasing pain and instability in his replaced hip. The orthopedic surgeon, Paul R. Bizzigotti, M.D., prescribed pain medications and ordered blood testing to determine ion levels.

115. The blood tests revealed elevated levels of cobalt (3.4 ng/ml) and chromium (1.1 ng/ml). Because Mr. Torres remained in considerable pain, and his left hip and leg continued to buckle, Dr. Bizzigotti directed him to use crutches or a walker to ambulate.

116. On March 8, 2018, Mr. Torres came under the care of another orthopedist, Bryan J. Pack, M.D. of Grand Rapids, Michigan.

117. Dr. Pack determined that Mr. Torres was experiencing mechanically assisted crevice corrosion, and that revision surgery was indicated.

118. On May 1, 2018, Mr. Torres underwent right hip revision surgery at Mercy Health St. Mary's Hospital in Grand Rapids, Michigan. The surgery was performed by Bryan J. Pack, M.D.

119. During the May 1, 2018 procedure, "significant corrosion around the (femoral) head-neck junction of the taper was identified. This was both at the engagement point of the taper as well as around the base of the trunnion and the base of the cobalt chrome femoral head."

120. In the course of the May 1, 2018 procedure, it was necessary for Dr. Pack to remove and exchange the acetabular liner and the femoral head.

121. Dr. Pack's diagnosis, both pre-operative and post-operative, was "Right hip mechanically assisted crevice corrosion of the head-neck junction of the total hip arthroplasty."

122. During the course of the May 1, 2018 revision surgery, Mr. Torres developed a left side inguinal hernia.

123. On June 19, 2018, Mr. Torres underwent surgical repair of the left inguinal hernia by Joel A. Strehl, D.O. at Munson Medical Center in Traverse City, Michigan. Since that time, he has continued to experience significant pain and a reduction in his activities.

124. As a direct and proximate result of the defective nature of the Zimmer Hip System as described herein, Plaintiff Richard P. Torres has experienced pain and suffering, disability, emotional distress and inconvenience.

125. As a further result of the defective nature of the Zimmer Hip System as described herein, Plaintiff Richard P. Torres has incurred special damages, including the cost of necessary medical care.

126. Pollyanna Torres is the wife of Richard P. Torres. As a result of the defective Zimmer Hip System, and the injuries to her husband, Ms. Torres has suffered a loss of consortium, including a loss of society and companionship, reduction of social pleasures and reduction of domestic assistance and activities.

Count I - Negligent Design, Manufacture and Sale

127. Plaintiff incorporates by reference all previous paragraphs of this complaint as if fully set forth herein and further alleges as follows:

128. Prior to, on, and after the dates of Plaintiff's initial hip surgery, and at all times relevant to this action, Defendants had a duty to exercise reasonable care in testing, study, research, design, formulation, manufacture, inspection, labeling, packaging, promotion, advertisement, marketing, distribution and sale of the Zimmer Hip System for implantation into consumers, such as Plaintiff, by physicians and surgeons in the United States.

129. Prior to, on, and after the dates of Plaintiff's initial hip surgery, Defendants failed to exercise reasonable care and were negligent and careless in the testing, study, research, design, formulation, manufacture, inspection, labeling, packaging, promotion, advertisement, marketing, distribution and sale of the Zimmer Hip System.

130. Prior to, on, and after the dates of Plaintiff's initial hip surgery, Defendants failed to perform adequate evaluation and testing of the Zimmer Hip System, where such adequate evaluation and testing would have revealed the device's pro-

pensity to undergo fretting and mechanically assisted crevice corrosion at the femoral head-stem taper juncture causing serious complications in patients.

131. Prior to, on, and after the dates of Plaintiff's initial hip surgery, Defendants had received complaints from healthcare providers that the Zimmer Hip System caused serious complications including but not limited to fretting and mechanically assisted crevice corrosion at the femoral head-stem taper juncture, but Defendants nonetheless consciously decided not to perform any further testing on the Zimmer Hip System; investigate the root cause of these complications; suspend sales and distribution of the device; or warn physicians and patients of the propensity of the Zimmer Hip System to undergo fretting and/or mechanically assisted crevice corrosion at the femoral head-stem taper juncture causing serious complications in patients.

132. Defendants' failure to exercise reasonable care in the design, testing, distribution, manufacture, advertising, sales, and marketing prior to, on, and after the dates of Plaintiff's initial hip surgery was a substantial factor in causing Plaintiff's injuries, losses, and damages, as alleged herein.

133. As alleged herein, Defendants knew and had reason to know that the Zimmer Hip System caused increased risk of harm to Plaintiff and other consumers. Defendants consciously disregarded this increased risk of harm by failing to warn of such risks; unlawfully concealing the dangerous problems associated with implantation of the Zimmer Hip System; and continuing to market, promote, sell and defend the Zimmer Hip System.

134. As a direct and proximate result of the defective nature of the Zimmer Hip System as described herein, Plaintiff Richard P. Torres has experienced pain and

suffering, disability, emotional distress and inconvenience.

135. As a further result of the defective nature of the Zimmer Hip System as described herein, Plaintiff Richard P. Torres has incurred special damages, including the cost of necessary medical care.

136. Pollyanna Torres is the spouse of Richard P. Torres. As a result of the defective Zimmer Hip System, and the injuries to her husband, Ms. Torres has suffered a loss of consortium, including a loss of society and companionship, reduction of social pleasures and reduction of domestic assistance and activities.

Count II - Breach of Implied Warranties

137. Plaintiff incorporates by reference all previous paragraphs of this complaint as if fully set forth herein and further alleges as follows:

138. Defendants impliedly warranted under Michigan common law and statute that the Zimmer Hip System, which Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold to Plaintiff, was merchantable and fit and safe for ordinary use. *M.C.L.A. 440.2314.*

139. Defendants further impliedly warranted that the Zimmer Hip System, which Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold, was fit for the particular purposes for which it was intended and was sold. *M.C.L.A. 440.2315.*

140. Contrary to these implied warranties, the Zimmer Hip System was defective, unmerchantable, and unfit for its ordinary use when sold, and unfit for the

particular purpose for which it was sold.

141. As a direct and proximate result of Defendants' breach of warranty in connection with the Zimmer Hip System, Plaintiff Richard P. Torres has experienced pain and suffering, disability, emotional distress and inconvenience.

142. As a further result of Defendants' breach of warranty in connection with the Zimmer Hip System, Plaintiff Richard P. Torres has incurred special damages, including the cost of necessary medical care.

143. Pollyanna Torres is the spouse of Richard P. Torres. As a result of Defendants' breach of warranty in connection with the Zimmer Hip System, and the injuries to her husband, Ms. Torres has suffered a loss of consortium, including a loss of society and companionship, reduction of social pleasures and reduction of domestic assistance and activities.

PRAYER FOR RELIEF

WHEREFORE, Richard P. Torres and Pollyanna Torres demand judgment against the Defendants for that amount in excess of $75,00 which is justified by the evidence adduced at trial, together with costs, interest and attorney fees.

/s/ John A. Zick
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Attorney for Plaintiffs

Dated: July 24, 2018

JURY DEMAND

Richard P. Torres and Pollyanna Torres, by counsel, John A. Zick, demand a trial by jury of all claims asserted in this complaint.

/s/ John A. Zick
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Attorney for Plaintiffs

Dated: July 24, 2018