IN THE CIRCUIT COURT OF THE SEVENTEENTH JUDICIAL CIRCUIT
IN AND FOR BROWARD COUNTY, FLORIDA

ROBERT VAGI and GLORIA VAGI, His wife, Plaintiffs, *v.* ORTHOPEDICS, INC.; JAMES H. BARR ORTHODYNAMICS, INC; PAUL HABER BIOMET, INC.; BIOMET ORTHOPEDICS, LLC; BIOMET U.S. RECONSTRUCTION, LLC; and BIOMET MANUFACTURING, LLC; Defendants.	)	CASE NO: JUDGE:

COMPLAINT

The Plaintiffs, **ROBERT VAGI and GLORIA VAGI**, by and through undersigned counsel and sues the Defendants, **ORTHOPEDICS, INC. (hereafter "ORTHOPEDICS"), JAMES H. BARR (hereafter "BARR"), ORTHODYNAMICS, INC. (hereafter "ORTHODYNAMICS"), PAUL HABER (hereafter "HABER"), BIOMET, INC., (hereafter "BMI"), BIOMET ORTHOPEDICS, LLC, (hereafter "BMO"), BIOMET U.S. RECONSTRUCTION, LLC (hereafter "BMR"), and BIOMET MANUFACTURING, LLC. (hereafter "BMM")**[1], alleges and as grounds therefore states as follows:

INTRODUCTION, PARTIES, VENUE AND JURISDICTION

1. This is a lawsuit over defective hip implant components designed and manufactured by Defendants BMI, BMO, BMR and BMM (hereafter collectively "BIOMET") and distributed within the State of Florida by Defendants ORTHOPEDICS, BARR, ORTHODYNAMICS, and

[1] Formerly known as Biomet Manufacturing Corporation.

HABER (hereafter collectively "DISTRIBUTORS"; BIOMET and DISTRIBUTORS hereafter collectively referred to as "Defendants").

2. The particular components at issue in this case were marketed by Defendants as the "M2a Magnum Metal-on-Metal" hip system (hereafter "M2a Magnum", "Magnum System" or "Magnum").

3. Defendants marketed, promoted, and sold the Magnum System that is the subject of this lawsuit. In addition, BIOMET designed and manufactured the Magnum System that is the subject of this lawsuit.

4. At all times relevant to this Complaint, ROBERT VAGI, ("Plaintiff") was and is a resident of the State of Florida.

5. At all times relevant to this Complaint, GLORIA VAGI, ("Plaintiff") was and is a resident of the State of Florida

6. At all times relevant to this Complaint, Defendant, ORTHOPEDICS, was and is a Florida Corporation with its principal place of business in Fort Lauderdale, Florida and as such is a citizen of the State of Florida.

7. Defendant BARR is the owner of ORTHOPEDICS.

8. At all times relevant to this Complaint, Defendant, BARR, was and is a citizen of the State of Florida.

9. At all times relevant to this Complaint, Defendant, ORTHODYNAMICS, was and is a Florida Corporation with its principal place of business in Tampa, Florida and as such is a citizen of the State of Florida.

10. Defendant HABER is the owner of ORTHODYNAMICS.

11. At all times relevant to this Complaint, Defendant, BMI, was and is an Indiana corporation, with its principal place of business in Warsaw, Indiana. Further, at all times relevant to this Complaint, Defendants, BMO, BMR, and BMM, each are and have been wholly owned subsidiaries of Defendant BMI.

12. Upon information and belief, at all times relevant to this Complaint, DISTRIBUTORS, individually working as independent contractor sales agents and distributors for BIOMET, marketed, sold, supplied and distributed BIOMET's products in Florida.

13. Upon information and belief, ORTHOPEDICS' and BARR's relationship with BIOMET is defined in a confidential distributorship agreement between BARR and/or ORTHOPEDICS and BIOMET.

14. Upon information and belief, ORTHODYNAMICS' and HABER's relationship with BIOMET is defined in a confidential distributorship agreement between HABER and/or ORTHODYNAMICS and BIOMET.

15. DISTRIBUTORS are and/or employ independent contractors who complete sales calls on surgeons wishing to acquire hip replacement components manufactured by BIOMET for implantation in patients.

16. Upon information and belief, at all times relevant to this Complaint, DISTRIBUTORS received commissions and intended to financially profit from marketing, selling, supplying and distributing the products at issue in this lawsuit.

17. Upon information and belief, DISTRIBUTORS did, in fact, receive payment from BIOMET in relation to the sale of the hip replacement components sold to and implanted in Plaintiff.

18. Jurisdiction is proper in Florida State Courts because Plaintiff and Defendants lack completely diversity.

19. Venue is proper in Broward County in that at present and at all times relevant to this action, the actions underlying this suit took place in Broward County:

a) Defendants do business in this county;
b) the product at issue was marketed, distributed, sold, and supplied in this county;
c) the surgery to implant the product took place in this county;
d) Defendants' defective product injured Plaintiff in this county; and
e) Plaintiff was treated for his injuries in this county.

TOTAL HIP ARTHROPLASTY

20. Total Hip Arthroplasty (hereafter "THA") is the term used to describe surgery wherein a patient's natural hip anatomy is replaced with synthetic components. THA is also commonly referred to as "hip replacement surgery." A patient may need a THA for a variety of medical reasons including degenerative bone disease and avascular necrosis. THA involves invasive and traumatic surgery in which a surgeon saws and removes a considerable portion of bone from the top of the femur. In place of the removed bone, the surgeon places a metal shaft, called a "stem," down into what remains of the femoral bone. A component called a "taper," which can be roughly described as similar to a metal sleeve, fits on top of, and around, the exposed neck of the stem. A synthetic ball, whether made of metal, plastic, or ceramic, is then attached on top of, and around, the taper. The surgeon also replaces the anatomical hip socket, the acetabulum, with an artificial "cup" against which the new, synthetic ball articulates. This cup is sometimes referred to as an "acetabular cup." To implant an acetabular cup, the surgeon removes bone from the natural acetabulum in an effort to create a new hip socket large enough to house the synthetic cup. The surgeon then places the synthetic cup into the newly formed hip socket. The cup affixes

to the bone either through the use of screws, bone cement, a porous metal coating on the back of the synthetic cup into which the natural bone will grow, or by a combination of the three.

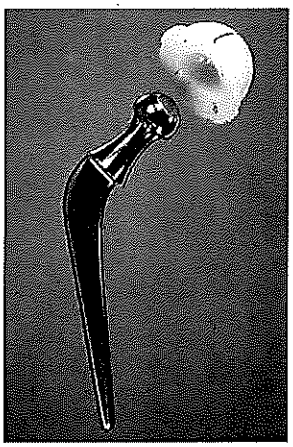
21. A successful THA results in a hip prosthesis that should last 20+ years in a patient.

22. If a hip prosthesis fails in a patient, the patient's surgeon may recommend a "revision" THA procedure in order to replace the failed hip components.

23. A revision THA is extremely traumatic to a patient, multitudes more so than a primary THA. The surgery is typically much longer, with greater blood loss, greater surgeon difficulty, and greater mortality rate. The rehabilitation period for a revision THA can be much longer. In most revision THA procedures, the synthetic components that must be replaced are either the acetabular cup or the femoral ball or both. Further, depending on the mode of failure for a hip prosthesis, the patient's natural anatomy may be so damaged that subsequent revision hip implants will be more likely to fail prematurely.

HIP IMPLANT DESIGN

24. Modern techniques for performing THA and for designing and manufacturing hip replacement components are based on a design introduced by Sir John Charnley in 1962. The design he created and used to perform THA consisted of three components: a one-piece stainless-steel femoral stem and head; an acetabular cup made of Ultra High Molecular Weight Polyethylene (a very hard type of plastic); and acrylic bone cement. A picture is found below for reference:

 [2]

25. Over time, varying designs and various compounds of plastic, ceramic, and metal have been implemented for the stem, femoral head (or ball) and the acetabular cup in an effort to improve upon the Charnley design.

26. Typically, modern acetabular cups are "modular." This means the cups have multiple components. The components of a modular acetabular cup include the cup, which is implanted into the hip socket, and a "liner" which is placed on the inside of the cup and forms the surface against which the femoral head (or ball) articulates. Further, most modern acetabular cups now implement some form of porous coating on the backside where the cup affixes to the hip socket. This allows for bone to naturally grow into the pores so that the surgeon does not need to use screws or bone cement to seat the cup in the bone.

27. Another improvement was the use of Highly Cross-Linked Ultra High Molecular Weight ("HXUHMW") Polyethylene instead of Charnley's original Ultra High Molecular Weight ("UHMW") Polyethylene. This improved polyethylene is stronger, harder, and reduces the amount of plastic wear produced during articulation of components. HXUHMW Polyethylene Hip Implants were introduced years prior to Defendants' MoM implant.

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[2] Charnley Hip Implant. Available at http://whichorthopaedicimplant.com/wp-content/uploads/2011/06/classic-charnley.jpg. (last visited Feb. 25, 2014.)

28. Femoral heads of modern implants may be made of HXUHMW Polyethylene or various forms of metal or ceramic.

29. These modern designs have resulted in highly successful implants intended to last and capable of lasting 20+ years in a patient.

30. Briefly, in the 1960s, the orthopedic device industry experimented with various metal-on-metal (hereafter "MoM") designs for hip implants. This design calls for a metal femoral head to articulate directly against the metal interior of an acetabular cup. The perceived benefit of this design was the idea that metal was stronger than plastic and would hopefully last longer and wear less. Further, the strength of the metal would allow for designs that increased range of motion. However, by the mid-1970s, MoM hip implants were completely abandoned in favor of utilizing polyethylene components.

31. Factors that led to the complete abandonment of the MoM designs for hip implants related to:

1. High rates of early revision;
2. The early success of the Charnley prosthesis;
3. Frictional torque between the components;
4. Concerns over the unknown carcinogenic and toxic effects of metal wear;
5. Concerns over metal sensitivity in patients;
6. High rates of infection; and
7. Increased bone strain and fatigue fractures of the bones surrounding the implant.

32. Due to the limited use and subsequent complete abandonment of MoM technology by the mid-1970s, there had been almost no medical or scientific advancement in decades relating to understanding the *actual, clinical* risks associated with using MoM technology for hip implants.

BIOMET M2a MAGNUM HIP SYSTEM

33. BIOMET designs and manufactures various medical devices and implants.

34. BIOMET marketed itself as "a leader in the design and manufacture of total joint replacement products."[3]

35. Despite the early failure of metal-on-metal technology, and despite the near complete lack of a *clinical* safety record due to the previous abandonment of the technology, BIOMET decided to begin marketing metal-on-metal hips again in 1996.

36. According to BIOMET's marketing, "During the past decade, Biomet has emerged as a recognized leader in metal-on-metal articulations."

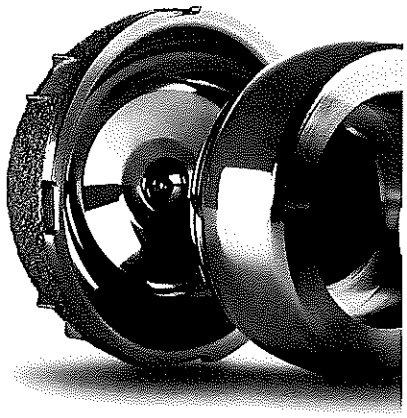
37. In 2001, BIOMET began marketing a "monoblock" metal on metal acetabular cup called the M2a-38.

38. A monoblock cup is different from a modular cup in that a monoblock cup does not utilize a liner. Instead, the portion of the cup with porous coating on the outside (which is intended to fuse with the natural bone) and the inside surface of the cup (which articulates against the femoral ball) are part of one, continuous metal component. Utilizing a monoblock design allows for the design of a larger articulating surface inside the cup and a larger femoral ball. The intended end benefit of this design is greater range of motion and stability. However, this design also increases the surface area of metal-on-metal articulation. The increased surface area risks increasing friction between the metal components and increasing wear.

39. In 2004, BIOMET released the Magnum System, a monoblock metal-on-metal hip replacement system which BIOMET claimed was substantially equivalent to the M2a-38. The Magnum hip system utilizes a monoblock metal cup made of a Cobalt Chromium alloy. The back of the Magnum cup utilizes a porous coating intended to promote bone fixation. The Magnum hip system also utilizes a metallic femoral ball made of a Cobalt Chromium alloy. The femoral ball

[3] According to www.biomet.com/orthopedics/index.cfm. (as archived from March 7, 2009.)

of the Magnum attaches to the neck of whatever stem is mated with it via a taper made of Titanium. Below is a picture of the Magnum acetabular cup and femoral ball, as found in BIOMET's marketing brochures:



40. Like its predecessor, the M2a 38, the M2a Magnum was "cleared" for sale by the FDA through the 510(k) process instead of being "approved" for sale through the FDA's more stringent Pre-Market Approval process.

41. In 2012, at the request of the FDA, the National Institute of Health (hereafter "NIH") conducted a thorough review of the 510(k) process, coming to the following major conclusions:

> **The 510(k) clearance process is not intended to evaluate the safety and effectiveness of medical devices with some exceptions. The 510(k) process cannot be transformed into a pre-market evaluation of safety and effectiveness so long as the standard for clearance is substantial equivalence to any previously cleared device.**

The NIH explained, "The assessment of substantial equivalence does not require an independent demonstration that the new device provides a 'reasonable assurance of safety and effectiveness.'" Further, the NIH even pointed out that the classification of predicate devices approved for sale prior to the 1976 MDA "did not include any evaluation of the safety and effectiveness of individual medical devices . . . Thus is common for devices to be cleared through the 510(k) program by

being found substantially equivalent to devices that were never individually evaluated for safety and effectiveness, either through the original device classification program or through the 510(k) process."

DISTRIBUTORS

42. BIOMET utilized sales representatives, including DISTRIBUTORS, who were responsible for educating Plaintiff's orthopedic surgeon regarding the claimed advantages of the products at issue in this Complaint, answering any questions Plaintiff's orthopedic surgeon asked regarding the products, assisting Plaintiff's orthopedic surgeon at surgery regarding the products, and selling the products to Plaintiff through his orthopedic surgeon agent.

43. DISTRIBUTORS or their sales representatives were regularly present within the operating room during the implantation of the devices sold by DISTRIBUTORS.

44. DISTRIBUTORS received education and training on the surgical techniques, scientific studies, and purported benefits related to the products they sold in their sales territory.

45. DISTRIBUTORS trained and educated their sales representatives regarding the products at issue, including orthopedic and surgical training, product design rationale, surgical technique tips, training in the use of implanting tools, training in selecting the hip replacement components to mate with the products at issue, and training on how to sell to orthopedic surgeons, including training on the advantages of the product at issue over its competitors.

46. BIOMET provided instructional materials to DISTRIBUTORS, including videos of surgeries and exemplar surgical instruments, in an effort to train DISTRIBUTORS (and sales representatives of DISTRIBUTORS) on proper surgical techniques regarding the products at issue in this Complaint.

47. BIOMET insisted that DISTRIBUTORS and their sales representatives take time to review surgical instructions and practice with provided surgical instruments before attending surgeries.

48. DISTRIBUTORS, assisted by BIOMET, organized events where surgeons in their sales territory could attend group viewings of live surgeries via-webcast to promote the products at issue and to educate surgeons on surgical techniques for the products at issue.

49. DISTRIBUTORS, assisted by BIOMET, organized events where surgeons in their sales territory could participate in or attend cadaver surgeries in order to promote the products at issue and to educate surgeons on surgical techniques for the products at issue.

50. DISTRIBUTORS, assisted by BIOMET, organized educational courses where a select surgeon would be paid by either DISTRIBUTORS or by BIOMET to promote the products at issue and discuss surgical techniques with surgeons in DISTRIBUTORS' territory

51. DISTRIBUTORS, assisted by BIOMET, took part in conferences, either in person or by telephone or web-cast, with BIOMET in order to receive updates on metal-on-metal concerns.

52. Prior to Plaintiff's THA surgery, DISTRIBUTORS provided information to Plaintiff's orthopedic surgeon, including but not limited to: the advantages of the products at issue compared to competitors' products; information regarding the design rationale for the products at issue; surgical techniques and use of instrumentation during the implanting of the products at issue.

53. The above information was provided to Plaintiff's orthopedic surgeon with the intended purpose of convincing and inducing Plaintiff's orthopedic surgeon to use the products at issue instead of other hip implants available for implantation in Plaintiff.

54. At all times relevant to this Complaint, Plaintiff's orthopedic surgeon, nurses and hospital staff relied on the information and assistance from DISTRIBUTORS and their sales representative agents.

55. DISTRIBUTORS held themselves out as BIOMET representatives and were the first line of communication for orthopedic surgeons, such as Plaintiff's surgeon, who wished to communicate concerns or complaints about BIOMET products, such as the Magnum.

PROBLEMS WITH THE BIOMET M2a MAGNUM HIP SYSTEM

56. BIOMET did not test the M2a Magnum for safety prior to its release. The only testing conducted was "mechanical testing" to determine "substantial equivalence" to the predicate devices listed on the 510(k) report. No clinical testing was performed whatsoever.

57. The testing done on the product prior to launch was woefully inadequate and not representative of real-world, clinical situations.

58. Despite Defendants' claims of the advantages of the BIOMET Magnum System, the product is and always was deeply flawed and defective.

59. The various metal components within the Magnum System cause metal "wear" to be released into the patient's body. Metal wear is of a particularly small, "microparticle" or "ion" size relative to wear due to plastic components. These microparticles and ions pose a greater danger to local, regional, and systemic body parts because of their smaller size and composition. These microparticles can cause bone death, tissue death, excessive fluid build-up, and pseudotumors, among other things. The destructive effect may also serve to loosen the acetabular cup. A loose acetabular cup, in turn, causes greater amounts of metal wear. Further, research suggests that metal wear can cause neurological problems and carcinogenic cell activity regionally and systemically.

The degenerative effects on the patient's anatomy may be so great as to decrease the chances of success for any replacement implant necessitated by the failure of the Magnum System.

60. Defendants marketed their Magnum System as safe merely based on a lack of conclusive connection to hazards, as opposed to an affirmative clinical determination of safety. Indeed, Defendants knew that there was no *clinical* evidence to support the contention that the product was safe or effective.

61. Upon information and belief, both prior and subsequent to Plaintiff's implant surgery, Defendants were aware of defects and unreasonably high rates of problems with the Magnum, including, but not limited to high incidences of metal wear causing local and/or systemic damage in patients' bodies. Specifically, Defendants were aware of unreasonably high rates of loosening of the acetabular component, metallosis, pseudotumors, pain, elevated metal levels, and other maladies requiring revision of the hip implant. As a result, Defendants knew or should have known that the Magnum was not a clinically safe prosthesis.

62. Defendants were made aware of Magnum failures through interactions and communications with customer surgeons. Defendants did not take proper action in response to these interactions and communications.

63. Despite knowing, or being in a position where they should have known, of the unreasonable risks associated with the Magnum System, Defendants continued to market and sell the Magnum System. Defendants failed to provide adequate warning to the public or the medical community regarding the risks associated with the Magnum System.

64. The Magnum System was more dangerous than an ordinary consumer would reasonably expect, and the risks associated with it were more dangerous than the risks associated with other hip replacement devices that were available to treat Plaintiff's condition.

DEFENDANTS' FALSE GUIDANCE TO THE MEDICAL COMMUNITY

65. Defendants provided statements in support of the Magnum to the orthopedic community.

66. Unfortunately, Defendants' statements in support of the Magnum contained a number of facts which have been revealed to be false.

67. In various marketing materials disseminated to patients and the orthopedic community, Defendants market their Magnum as having three-year survivorship rates of "over 98%" and "99.2%." These survivorship rates are inaccurate and misleading. First, Defendants manipulated the raw data in a manner that artificially inflated the survivorship statistics. Second, Defendants are aware that three-year survivorship rates are not representative of long-term success.

68. Defendants' marketing claims that the Magnum hip system "delivers a clinically proven" design. For example, Defendants claim that a "significant number of long-term clinical studies" show "remarkably low wear rates of metal-on-metal bearings implanted over the past 40 years."[4] This is false. The clinical results of metal-metal-bearings in the past decades were so poor that the industry as a whole abandoned the technology. Further, no long-term clinical studies exist that are representative of the M2a Magnum or the M2a 38 implant upon which the Magnum's design is claimed to have been based.

69. Defendants claimed that "ultra-low wear exhibited in numerous clinical and simulator studies" contribute to metal-on-metal being a "particularly attractive" total hip replacement option.[5] This is false. Metal-on-metal hips have a dangerous propensity to exhibit high wear. Further, even where the wear exhibited from metal-on-metal hips is lower than other

[4] See "white paper" titled "Metal Ions – A Scientific Review," authored and published by Biomet and disseminated to the public and the orthopedic community by Defendants.
[5] Id.

types of implants, the nature of the type of wear exhibited makes the metal wear more dangerous, even if volumetrically less than other types of wear.

70. Defendants claimed in their marketing to the orthopedic community that the "metal ion debate" is "inconsequential" [6] and that "ion release remains a non-issue among most European orthopedic surgeons."[7] These are dangerously false statements purposefully designed to marginalize and silence valid voices of concern. Defendants knew that metal ion release was an issue with their metal-on-metal products and knew that metal ion release had a propensity to cause damage in patients' bodies. Defendants further knew that metal ion release was an issue in Europe just as it was in the USA and globally. Despite this knowledge, Defendants misused their brand equity to suggest to patients and the orthopedic community to suggest that metal ions are not concerning and that they should pay no mind to debates about metal ions. Metal ions released from metal-on-metal implants, even if volumetrically less than wear released from competing types of implants, are more dangerous due to their smaller size and the greater immune reaction triggered by the body.

71. Defendants claimed that "[c]ase reports and studies of cobalt and chromium in other industries support the use of metal-on-metal bearings in orthopedics." [8] This is not true. While studies of cobalt and chromium in other industries exist, most notably, among others, studies of Canadian beer drinkers exposed to cobalt used as a beer foaming agent, these studies generally indicate negative effects of such exposure. For those that state "no systemic toxicity" as Defendants claim, those studies do nothing to link the studied exposure with the type of exposure a hip patient would experience. Thus, case reports and studies of cobalt and chromium in other

[6] Id.
[7] Id. at *2.
[8] Id. at *5

industries do not to support the contention that cobalt and chrome are safe in hip implants.

72. Defendants claim that "Cobalt and Chromium may be beneficial to the body" and suggest that the chromium in their implants may "burn fat and regulate metabolism," as well as "regulate diabetes" and "control sugar cravings."[9] Further, they claim that "Cobalt is an essential element necessary for the formation of Vitamin B12 and the metabolism of proteins."[10] Defendants are aware that exposure to Cobalt and Chromium through metal wear from a hip implant is different than the exposure cited to for these propositions, such as ingestion as part of vitamins. Cobalt and Chromium, in the context of hip implants, is not beneficial to the body. Released as metal wear, Cobalt and Chromium trigger a great variety of negative clinical reactions.

73. Defendants claim that reports of osteolysis caused by metallic particles "are lacking, and occurrence is rare."[11] Reports are not lacking. In fact, concerns over metal particle induced osteolysis has been consistently reported to Defendants. Metallic particles are known to cause osteolysis. The occurrence is unreasonably often.

74. Defendants claim that "[m]etal-on-metal is the most clinically proven alternate bearing available today, with over 40 years of clinical use."[12] This is wholly untrue. Defendants are fully aware that HXUHMW polyethylene hip implants as well as ceramic implants are both more clinically proven bearings available today and were available on the date Plaintiff was implanted.

75. Defendants, in their sales presentations, sales training, printed marketing and communications to surgeons and the public regarding the Magnum, touted a purported ".056% adverse event rate" for the M2a Magnum. This, however, is a gross underreporting of adverse

[9] Id. at *8.
[10] Id. at *9.
[11] Id. at 10.
[12] Id. at 11.

event rates with their M2a and Magnum products. A *much* higher incidence of adverse events exists, but was not shared with the orthopedic community by Defendants or reported to regulators. Upon information and belief, BIOMET purposefully did not report a large number of adverse events such as revision surgeries in an effort to artificially inflate their safety statistics and hide negative outcomes.

76. Defendants claimed, in their M2a Design Rationale brochure, that there are "no adverse physiologic effects" attributable to metal articulations in the M2a. This is clearly false. M2a MoM hips, and MoM hips in general, have a long history of adverse events, such as bone and tissue death, implant failure, and early revisions, due directly to metal articulations.

77. Defendants claimed, in nearly all of their sales presentations and in their marketing, including their M2a Design Rationale brochure, that the Magnum head and cup have "optimal clearance" which "allows for proper fluid lubrication." BIOMET further claimed that the "radial clearance level is maintained at 75-150 microns to capture the ideal amount of fluid lubrication ...." Only laboratory testing which was not representative of clinical use supported such statements. In clinical use, the components are not adequately lubricated as Defendants claim they would be. Because of the lack of clinical lubrication, the components rub against each other during articulation and cause excessive metal wear.

78. BIOMET continues to tout their spokesperson for the Magnum, Mary Lou Retton, as a "Patient Success Story" on their website. She was a bilateral recipient of Magnum implants and presented a great opportunity for Defendants to market to their target of young and active patients. In fact, however, Mary Lou Retton is anything but a "success story." Her implants have failed and she, too, has sued BIOMET for injuries related to the defects in the Magnum.

79. BIOMET's sales staff, including DISTRIBUTORS, were trained by BIOMET to describe and did describe the longevity of the Magnum to orthopedic surgeons as capable of lasting longer than the remainder of their patients' lives. Unfortunately, the dangerous propensities of the Magnum cause the Magnum to fail within just a few short years, coming well short of the expected longevity of comparable types of implants and even previous generations of implants.

80. DEFENDANTS claimed in their product marketing that the Magnum would "withstand the higher demands of more active lifestyles." However, active lifestyles generate higher amounts of metal wear and accelerate the dangerous propensities of the Magnum. Thus, the Magnum does not withstand the higher demands of active lifestyles, instead it becomes more dangerous as a result.

PLAINTIFF'S IMPLANT AND REVISION

81. Plaintiff experienced a history of pain and disease in his hip that caused his to be treated by William V. Burke, M.D. ("Dr. Burke").

82. Dr. Burke determined Plaintiff needed a THA of his right hip.

83. On October 13, 2008, Dr. Burke performed a THA on Plaintiff's right hip at Broward General Medical Center in Broward, Florida.

84. During this THA (also referred to as "implant surgery"), Dr. Burke implanted Plaintiff with a number of Defendants' products:

1. Biomet Orthopedics Magnum MDA PF cuff 64 mm in diameter
2. Biomet Modular porous lateralized reduced distal Taperloc Femoral component size 15.
3. Forty-eight mm Magnum head -3 neck length.

85. In preparation for this implant surgery, Dr. Burke - or someone at his direction - contacted DISTRIBUTORS, or an agent and/or employee of DISTRIBUTORS, to notify them of the need for the Magnum hip system components.

86. DISTRIBUTORS selected and provided the specific Magnum System components manufactured by BIOMET for use in Plaintiff and delivered them to Plaintiff's implant surgery operating room.

87. Upon information and belief, an agent or employee of DISTRIBUTORS was present in the operating room during Plaintiff's implant surgery.

88. After being implanted with the Magnum System components, Plaintiff developed severe pain emanating from his hip, high levels of cobalt and chromium in his blood, a large fluid collection in his right hip, failed conservative treatment, and concern for suspected metal-on-metal reaction.

89. Thereafter, Plaintiff and his orthopedic surgeon decided to have his right hip revised and replaced with non-metal components.

90. On September 19, 2016, Plaintiff underwent a revision surgery on his right hip performed by Dr. William V. Burke to replace Plaintiff's failed Magnum Systems at Broward General Medical Center in Broward, Florida.

91. Dr. Burke's pre-operative diagnosis was, "Metal on metal reaction. Right hip." Dr. Burke's post-operative diagnosis was, "Metal on metal reaction, right hip and abductor deficiency, right hip."

DAMAGES

92. As a direct and proximate result of the defective design, manufacture, marketing and distribution of the Magnum System and component parts, Plaintiff suffered injuries, including but not limited to significant pain, pseudotumors, elevated metal levels, metal wear, metal poisoning, loss of enjoyment of life, and limitation of daily activities. Plaintiff expects to continue suffering such injuries in the future as a result of the Magnum System and component parts.

93. As a direct and proximate result of the failed Magnum System, Plaintiff was caused to incur medical expenses, and expects to incur additional medical expenses in the future.

94. As a direct and proximate result of his failed Magnum System, Plaintiff experienced emotional trauma and distress, and is likely to experience emotional trauma and distress in the future.

95. After undergoing the recommended revision of his Magnum hip system, Plaintiff underwent lengthy and protracted rehabilitation preventing his from performing activities of daily living, suffered scar tissue in his hip, and has a right hip implant with decreased longevity.

COUNT ONE – NEGLIGENCE – ALL DEFENDANTS

96. Plaintiff re-alleges and incorporates by reference paragraphs 1-94 above as if fully stated herein.

97. Defendants, as the designers (BIOMET only), manufacturers (BIOMET only), promoters, marketers, sellers, suppliers, distributors, and servicers of the Magnum System components, owed a duty to use reasonable care in the design (BIOMET only), manufacture (BIOMET only), promotion, marketing, selling, supplying, distribution, and service of Plaintiff's Magnum System.

98. Defendants, in breach of the duties described above, negligently and carelessly designed (BIOMET only), manufactured (BIOMET only), promoted, marketed, sold, supplied, distributed and serviced the products at issue in this Complaint.

99. Further, Defendants owed Plaintiff a duty to provide reasonable complete and accurate information to Plaintiff, his orthopedic surgeon, and the orthopedic community regarding the products at issue in this Complaint.

100. Defendants, in breach of the duties described above, negligently and carelessly failed to provide reasonable complete and accurate information to Plaintiff, his orthopedic surgeon, and the orthopedic community regarding the products at issue in this complaint.

101. As a direct and proximate result of Defendants' breaches of duty, Plaintiff needlessly suffered injuries as described specifically in paragraphs 91-94.

COUNT TWO – NEGLIGENT FAILURE TO WARN – ALL DEFENDANTS

102. Plaintiff re-alleges and incorporates by reference paragraphs 1-94 above as if fully stated herein.

103. Defendants had a duty to give adequate and appropriate warnings to Plaintiff regarding particular risks about the products at issue in this Complaint.

104. Plaintiff's use of the products at issue in this Complaint was reasonably foreseeable by Defendants.

105. Defendants knew or should have known of particular risks involved in Plaintiff's reasonably foreseeable use of the products at issue in this Complaint.

106. Breaching their duty, Defendants failed to provide adequate or appropriate warnings to Plaintiff.

107. As a direct and proximate result of the Defendants' conduct, Plaintiff needlessly suffered injuries as described specifically in paragraphs 91-94.

COUNT THREE – STRICT LIABILITY FAILURE TO WARN – ALL DEFENDANTS

108. Plaintiff re-alleges and incorporates by reference paragraphs 1-94 above as if fully stated herein.

109. At the time that Defendants designed (BIOMET only), manufactured (BIOMET only), promoted, marketed, sold, supplied, distributed and serviced the products at issue in this

Complaint, such products contained defects that made them unreasonably dangerous beyond the expectations of the ordinary consumer, and were unfit for their intended use.

110. The products reached Plaintiff without substantial change in the condition in which they were sold.

111. At the time and on the occasions in question, the products at issue in this Complaint were being properly used for the purpose for which they were intended, and such products were in fact defective, unsafe and unreasonably dangerous.

112. The foreseeable risk of harm from the defects in the products at issue in this Complaint could have been reduced or avoided by providing adequate instructions or warnings.

113. Defendants failed to provide adequate instructions or warnings regarding the defects which were known by Defendants or should have been known by Defendants.

114. As a direct and proximate result of the lack of reasonable and adequate instructions or warnings regarding the defects in the products at issue in this Complaint, Plaintiff suffered injuries as described specifically in paragraphs 91-94.

COUNT FOUR – STRICT LIABILITY DESIGN AND MANUFACTURING DEFECT– ALL DEFENDANTS

115. Plaintiff re-alleges and incorporates by reference paragraphs 1-94 above as if fully stated herein.

116. At the time that Defendants designed (BIOMET only), manufactured (BIOMET only), promoted, marketed, sold, supplied, distributed and serviced the products at issue in this Complaint, such products contained defects that made them unreasonably dangerous beyond the expectations of the ordinary consumer, and were unfit for their intended use.

117. The products at issue in this Complaint reached Plaintiff without substantial change in the condition in which they were sold.

118. At the time and on the occasions in question, the products at issue in this Complaint were being properly used for the purpose for which they were intended, and such components were in fact defective, unsafe and unreasonably dangerous.

119. The hip replacement components, for the reasons stated herein, were defective and unreasonably dangerous in design and manufacture.

120. As a direct and proximate result of the defects in the products at issue in this Complaint, Plaintiff suffered injuries as described specifically in paragraphs 91-94.

COUNT FIVE – BREACH OF IMPLIED WARRANTY – BIOMET DEFENDANTS

121. Plaintiff re-alleges and incorporates by reference paragraphs 1-94 above as if fully stated herein.

122. BIOMET impliedly warranted that the Magnum System and its component parts were merchantable and fit for the ordinary and intended purposes for which hip systems are used.

123. Plaintiff was a foreseeable user of the Magnum System.

124. Plaintiff's surgeon, as purchasing agent, purchased the Magnum System for Plaintiff from BIOMET.

125. At all times relevant to this Complaint, Plaintiff was and is in privity with BIOMET.

126. Plaintiff used the product for its ordinary and intended purpose.

127. The Magnum System failed while being used for its ordinary and intended purpose.

128. As a direct and proximate result of BIOMET's breach of implied warranty, Plaintiff suffered injuries as described specifically in paragraphs 91-94.

COUNT SIX – BREACH OF EXPRESS WARRANTY – BIOMET DEFENDANTS

129. Plaintiff re-alleges and incorporates by reference paragraphs 1-94 above as if fully stated herein.

130. BIOMET sold and Plaintiff purchased, through his purchasing agent surgeon, the Magnum System.

131. BIOMET expressly warranted by affirmation, promise, description, and sample to Plaintiff and his physician that the Magnum System components were of a quality and character suitable for implantation and extended safe use in Plaintiff.

132. Such representations by BIOMET were meant to induce Plaintiff, through his physician, to purchase the Magnum System components.

133. The Magnum System components did not conform to the representations made by BIOMET.

134. Within a reasonable time after Plaintiff knew or should have known of the failure of his Magnum hip system components, Plaintiff gave notice to BIOMET of such failure.

135. BIOMET breached the express warranty it provided with the device in violation of § 672.313, Fla. Stat. (2011) as aforesaid.

136. As a direct and proximate result of BIOMET's breach of its express warranty, Plaintiff suffered injuries as described specifically in paragraphs 91-94.

COUNT SEVEN – ALL DEFENDANTS
INFORMATION NEGLIGENTLY SUPPLIED FOR THE GUIDANCE OF OTHERS

137. Plaintiff re-alleges and incorporates by reference paragraphs 1-90 above as if fully stated herein.

138. Plaintiff's purchase of the Magnum was a business transaction.

139. Defendants had a pecuniary interest in the sale of Plaintiff's Magnum.

140. The sale of Plaintiff's Magnum was in the course of Defendants' business, profession, or employment.

141. Defendants supplied false information for the guidance of others regarding the

selection of the Magnum as a safe and effective hip replacement option, as alleged in Paragraphs 64 through 79.

142. Defendants failed to exercise reasonable care or competence in obtaining and communicating the information supplied for the guidance of others regarding the Magnum.

143. Plaintiff, through Plaintiff's orthopedic surgeon agent, is within the limited group of persons for whose benefit and guidance Defendants intended to supply the information.

144. Alternatively, Defendants knew that Plaintiff, through Plaintiff's orthopedic surgeon agent, is within the limited group of persons for whose benefit and guidance the recipient of Defendants' information intended to supply Defendants' information.

145. Defendants intended for their information to influence either the transaction in which Plaintiff, through Plaintiff's orthopedic surgeon agent, purchased the Magnum or a substantially similar transaction.

146. Alternatively, Defendants knew the recipient of their information intended for the information to influence either the transaction in which Plaintiff, through Plaintiff's orthopedic surgeon agent, purchased the Magnum or a substantially similar transaction.

147. Plaintiff, through Plaintiff's orthopedic surgeon agent, justifiably relied upon the information provided by Defendants.

148. As a direct and proximate result of Defendants' false information, Plaintiff suffered pecuniary loss, as described in Paragraph 92, above.

COUNT EIGHT – ALL DEFENDANTS – MISREPRESENTATION

149. Plaintiff re-alleges and incorporates by reference paragraphs 1-94 above as if fully stated herein.

150. Defendants made statements concerning material facts which Defendants may have

believed to be true but which in fact were false.

151. Defendants made statements concerning material facts which in fact omitted material facts.

152. Defendants were negligent in making such statements because he or she should have known the statements were false or omitted material information.

153. In making these statements, Defendants intended or expected that another would rely on the statements. Plaintiff justifiably relied on the false statements and omissions.

154. As a direct and proximate result of Defendants' false statements and omissions, Plaintiff suffered damages as described in Paragraphs 91-94.

COUNT NINE – ALL DEFENDANTS - DERIVATIVE CLAIM OF GLORIA VAGI

155. Plaintiffs, ROBERT VAGI and GLORIA VAGI, re-allege each and every allegation contained in paragraphs 1 through 4 as if fully set forth herein, and further allege:

156. At all material times hereto, Plaintiff, GLORIA VAGI, was and is the lawful wife of the Plaintiff, ROBERT VAGI.

157. As a direct and proximate result of the negligence of Defendants, ORTHOPEDICS, INC., JAMES H. BARR, ORTHODYNAMICS, INC., PAUL HABER, BIOMET, INC., BIOMET ORTHOPEDICS, LLC, BIOMET U.S. RECONSTRUCTION, LLC, and BIOMET MANUFACTURING, LLC, Plaintiff, GLORIA VAGI, has been deprived of the comfort, attention, services, society and consortium of her husband, ROBERT VAGI.

DEMAND FOR JURY TRIAL

158. Plaintiff respectfully requests that a jury be impaneled to hear this cause of action and to award such damages as the jury finds to be fair and reasonable under the circumstances.

WHEREFORE, Plaintiffs respectfully demand judgment against Defendants for

compensatory damages and any other relief the Court deems just and proper.

Dated June 2, 2017.

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