

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF INDIANA

BEVERLY FRANCIS,	)	
	)	
Plaintiff,	)	
v.	)	Civil Action No.: 3:17-cv-00515
	)	
JOHN CUCKLER, M.D.; ALABAMA MEDICAL	)	
CONSULTANTS, INC.; BIOMET, INC.;	)	
BIOMET ORTHOPEDICS, LLC; BIOMET U.S.	)	
RECONSTRUCTION, LLC; and BIOMET	)	
MANUFACTURING, LLC;	)	
	)	
Defendants.	)	
_____	/	

**AMENDED COMPLAINT**

Plaintiff, BEVERLY FRANCIS (“Plaintiff”), brings suit against Defendants JOHN CUCKLER, M.D. (hereafter “CUCKLER”) and ALABAMA MEDICAL CONSULTANTS, INC. (hereafter “AMC”) (CUCKLER and AMC collectively referred to as “Cuckler Defendants”), as designers, developers, and promoters of the Biomet M2a Metal-on-Metal Hip Replacement System, and also against BIOMET, INC., (hereafter “BMI”), BIOMET ORTHOPEDICS, LLC, (hereafter “BMO”), BIOMET U.S. RECONSTRUCTION, LLC (hereafter “BMR”), and BIOMET MANUFACTURING, LLC. (hereafter “BMM”) (hereafter BMI, BMO, BMR, and BMM collectively referred to as “Biomet” or “Biomet Defendants”) as designers, developers, manufacturers, and promoters of the Biomet M2a Metal-on-Metal Hip Replacement System, and states as follows:

**INTRODUCTION, PARTIES, VENUE AND JURISDICTION**

1. This is a lawsuit regarding a defective metal-on-metal hip replacement implanted in Plaintiff which was designed, developed, and promoted by Cuckler Defendants and designed, developed, manufactured, and promoted by Biomet Defendants.

2. The particular hip replacement at issue in this case is the “Biomet M2a Metal-on-Metal Hip Replacement System” (hereafter referred to as the “M2a” or “M2a system”).

3. Defendant CUCKLER is domiciled in Florida, residing at 12005 Collier’s Reserve Drive, Naples, Florida, 34110, and as such is a citizen of the State of Florida.

4. Defendant AMC is a Foreign Profit Corporation incorporated in Florida. Its principal place of business, registered agent, and all corporate officers are located at 12005 Collier’s Reserve Drive, Naples, Florida, 34110. As such, AMC is a citizen of the State of Florida.

5. Defendant CUCKLER, personally and through his company, AMC, received royalties and financially profited from his design, development, and promotion of the M2a.

6. CUCKLER and AMC consented to being sued in this MDL court for claims of injury related to the products at issue in this Complaint.

7. Defendant BMI is an Indiana corporation, with its principal place of business in Warsaw, Indiana. Defendants BMO, BMR, and BMM each are wholly owned subsidiaries of Defendant BMI. As such, BMI is a citizen of the State of Indiana.

8. Plaintiff BEVERLY FRANCIS was and is at all times relevant to this Complaint domiciled and residing in the State of Michigan and as such is a citizen of the State of Michigan.

9. Jurisdiction is proper in federal court because no defendants share the same state of citizenship with Plaintiff and because the amount in controversy is greater than \$75,000.

10. Venue is proper in the United States District Court, Western District of Michigan, Lansing Division, because a substantial part of the events or omissions giving rise to Plaintiff’s claim occurred in this District. However, for pretrial proceedings, this matter is direct-filed in the Northern District of Indiana for inclusion in MDL 2391.

### **TOTAL HIP ARTHROPLASTY**

11. Total Hip Arthroplasty (hereafter “THA”) is the term used to describe hip replacement surgery wherein a patient’s natural hip anatomy is replaced with a hip prosthesis system made of synthetic components.

12. If a hip prosthesis fails in a patient, the patient’s surgeon may recommend a “revision” THA procedure.

13. A revision hip surgery is one in which any previously implanted component of a hip prosthesis system is removed and replaced.

14. A revision THA can be extremely traumatic to a patient, especially if the previous prosthesis failed in a manner that caused damage to the hip joint or other body systems.

15. 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.

16. 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.

17. The Charnley hip design showed promise, but had weaknesses. The one-piece design of the femoral stem and head did not allow surgeons to adjust the implant for any leg-length discrepancies due to surgery. Also, the design of the acetabular cup required the surgeon to apply bone cement to the back of the cup in order to affix it to the natural hip socket. These design elements contributed to a difficult and inflexible surgical procedure for surgeons.

Further, the polyethylene plastic used for the cup could wear off as the stainless steel ball articulated inside and against it. As these plastic particles wore off, they damaged local tissue and bone in the patient and could serve to loosen the acetabular cup from the acetabular bone.

18. 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.

19. Briefly, in the 1960s, the orthopedic device industry experimented with various metal-on-metal (hereafter “MoM”) designs for hip implants. These designs call for a metal femoral head to articulate directly against the metal interior of an acetabular cup. The perceived benefit of MoM was the idea that metal was stronger than plastic, would last longer, and wear less. Further, the strength of the metal would theoretically 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.

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

- a. High rates of early revision;
- b. The early success of the Charnley prosthesis;
- c. Frictional torque between the components;
- d. Concerns over the unknown carcinogenic and toxic effects of metal wear;
- e. Concerns over metal sensitivity in patients;
- f. High rates of infection; and
- g. Increased bone strain and fatigue fractures of the bones surrounding the MoM implant.

21. 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.

22. Despite the MoM hiccup in the evolution of THA surgery, various other improvements have been made to the Charnley design in recent decades.

23. One such advancement is the use of Highly Cross-Linked Ultra High Molecular Weight (“HXUHMW”) Polyethylene instead of Charnley’s original Ultra High Molecular Weight Polyethylene. This improved polyethylene is stronger, harder, and reduces the amount of plastic wear produced during articulation of components.

24. Ceramic components, regarded as typically being harder than polyethylene components, have also been used with great success.

25. These modern designs, which may utilize a variety of articulation types including but not limited to metal on polyethylene, ceramic on ceramic, ceramic on polyethylene, ceramic on metal, and others, were available for use in Plaintiff at the time Plaintiff was originally implanted with the M2a.

26. These modern, non-MoM designs have resulted in highly successful implants intended to last and capable of lasting more than 20 years in a patient.

**DEFENDANTS FAST-TRACKED M2A FOR SALE  
TO AVOID SCRUTINY FOR SAFETY AND EFFICACY**

27. Defendants utilized the FDA’s “510(k)” procedures to gain “clearance” to sell M2a components in the United States.

28. The “510(k)” process does not provide “approval” for sale based on any analysis of clinical safety or efficacy, nor is the process designed to do so.

29. Instead, the “510(k)” process is a way to fast-track a product to the market based on an intended seller’s representation that a product is “substantially equivalent” to products that

were either previously “cleared” for sale through the same process or were grandfathered in before regulations were adopted in 1976.

30. This means that not only is the regulatory clearance for the sale of the M2a products not based on their clinical safety or efficacy, none of the predicate devices to which Defendants claimed the M2a products are “substantially equivalent” gained regulatory clearance based on their safety or efficacy, either.

31. Alternatively, the FDA provides “approval” for sale for medical products through a stringent and comprehensive “Pre Market Approval” process. This process *does* require extensive evidence of clinical safety and efficacy.

32. Despite the poor clinical history of MoM components, Defendants intentionally chose to introduce M2a components to the market through the lower bar of the FDA’s “510(k) clearance” process (which does not analyze a product’s clinical safety or efficacy) instead of the more appropriate “Pre Market Approval” process.

33. Defendants’ knew or should have known that their M2a system was not safe or effective enough to gain “approval” for sale through the FDA’s Pre Market Approval process.

34. Defendants knew or should have known that the “predicate devices” for the M2a system includes products which are not “substantially equivalent” and which are not even metal-on-metal.

35. Defendants knew or should have known that the safety and efficacy of the M2a systems’ predicate devices did not adequately support the safety or efficacy of the M2a.

36. Defendants willfully and knowingly utilized the “510(k) clearance process” in an effort to mislead the orthopedic community, the public, and Plaintiff regarding the safety and efficacy of their M2a products.

## M2A METAL-ON-METAL HIP REPLACEMENT

37. 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, Defendants designed, developed, promoted and manufactured<sup>1</sup> the M2a metal-on-metal hip replacement.

38. In 2001, as a result of Defendants' design, development, promotion, and manufacture<sup>2</sup>, the M2a 38 metal-on-metal hip replacement system was made available for sale in the United States through the FDA's 510(k) clearance process.

39. Thereafter, Defendants similarly introduced the M2a Magnum and M2a ReCap products, as well.

40. Unfortunately, Defendants' M2a metal-on-metal hip replacement systems are defective.

41. Despite Defendants' claims of the advantages of the M2a, the product is unreasonably dangerous with an unreasonably high rate of complaints and revisions.

42. The testing done on the M2a systems prior to launch was woefully inadequate and not representative of real-world, clinical situations.

43. Defendants knowingly altered post-market clinical testing protocols in order to provide the appearance of acceptable results.

44. Defendants' claims regarding the risks of the M2a systems were inadequate.

45. When implanted in a patient, the metal-on-metal articulation of the M2a systems generates dangerous levels of cobalt and chromium metal debris that are released into the body.

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<sup>1</sup> Biomet Defendants, only.

<sup>2</sup> Biomet Defendants, only.

46. Further, the connection between the acetabular ball, taper sleeve, and femoral stem is a source for fretting and corrosion. This also leads to the release of metal debris and also can cause cold-welding, a phenomenon where separate components fuse together and make revision surgery more difficult and traumatic.

47. Additionally, defects in the system cause a failure of the acetabular cup to adequately adhere to bone, as intended. When this happens, the cup becomes loose and changes the dynamics of how the implant articulates. This results in greater release of metal wear.

48. Metal wear from the M2a results in elevated levels of cobalt and chromium in the blood, pseudotumors, tissue necrosis, osteolysis, muscle wasting, and other severe injuries in the hip region as well as other systems of the body.

49. The degenerative effects on a patient's anatomy can greatly decrease the chances of success for any replacement implant necessitated by the removal of the failed M2a components.

50. Defendants knew or should have known that there was a much greater incidence of these problems occurring with the M2a system than shared with the public, the orthopedic community, or Plaintiff.

51. Defendants knew or should have known that claims regarding the advantages of the M2a system were false or, at best, unsubstantiated.

52. Defendants falsely claimed to the public and orthopedic community that the bearing surfaces of the M2a system would be adequately lubricated by synovial fluid.

53. Defendants purposefully misled the public and orthopedic community by claiming that the M2a system produces less wear than comparable systems utilizing different materials, such as plastic or ceramic. Defendants were fully aware that despite producing less



volume of wear, the number of wear particles are actually an order of magnitude greater and the size of the particles an order of magnitude smaller. As a result of the greater *number* of wear particles, the M2a system actually provides a more foreign-body surface area against which the body releases an immune response. Therefore, despite producing less volumetric wear, Defendants were fully aware that the wear produced by the M2a system was actually more reactive and dangerous than that produced by other available types of hip systems.

54. Defendants knowingly underreported complaints and revision surgeries about the M2a and its predicate devices, both in the USA and abroad, in an intentional scheme to mislead the public, the orthopedic community, and Plaintiff about the safety and efficacy of the M2a. Defendants further based their claims regarding the adverse event rate of the M2a based on the underreported adverse event rates of the M2a's predicate devices.

55. Defendants intimidated surgeons who raised concerns with the M2a system by misrepresenting the safety record of the M2a system and by falsely placing blame for any M2a failures on the surgeons.

56. Defendants undertook an international scheme to provide grants and funds to medical facilities and surgeons in order to garner more control over the outcome and publishing of post-market clinical tests.

#### **DR. CUCKLER CRITICAL TO DESIGN AND MARKETING OF M2A**

57. Defendant CUCKLER, through his company AMC, was a critical component of the design and marketing of the M2a products.

58. Upon information and belief, the contractual relationship between Cuckler Defendants and Biomet Defendants for designing and marketing M2a products dates back at least to 1996.

59. Cuckler Defendants contracted and received substantial income for designing the M2a products.

60. However, Cuckler Defendants did more than just design the products, as evidenced by Cuckler Defendants receiving relatively high-percentage rolling royalty payments for every single M2a component sold.

61. In fact, one of Cuckler Defendants' main responsibilities was to alter the public's well-earned negative perception of MoM as a hip replacement technology in order to make the technology a desired option moving forward. In essence, Cuckler Defendants' main role beyond designing the M2a components was to convince the orthopedic community that MoM hips' history is clinically sound despite the opposite being true.

62. With the funding under the direction of Biomet Defendants, Cuckler Defendants engaged in a nationwide campaign to mislead the public regarding the clinical and long-term history of metal on metal hip implants.

63. Cuckler Defendants became the key cheerleader for MoM hip replacements, generally, and Biomet's key opinion leader in the orthopedic community for the M2a products, specifically.

64. Cuckler Defendants claimed that there are no adverse effects attributable to metal articulations. 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 wear and metal ions.

- a. At the 19<sup>th</sup> Annual Current Concepts in Joint Replacement Winter 2002 Meeting, Defendant CUCKLER claimed: "[I]n spite of the metal ion release issue, there are no adverse effects that have ever been demonstrated."
- b. In his 2005 article published in *Clinical Orthopaedics and Related Research*, entitled, *The Rationale for Metal-on-Metal Total Hip Arthroplasty*, Defendant CUCKLER states: "No adverse physiologic effects have been identified in the

long-term followup of patients exposed to cobalt-chromium implants.”

- c. Biomet’s M2a Magnum Design Rationale Brochure cites Defendant CUCKLER’s Article, *The Rationale for Metal-on-Metal Total Hip Arthroplasty* to claim “No adverse physiologic effects.”

65. Cuckler Defendants claimed that the M2a was appropriate for patients who were younger, heavier, or more active. This, however, was clearly false as higher stress and activity levels upon the M2a increase the levels of metal wear and ions released into the body, thereby increasing the risk of adverse events.

- a. At the 19th Annual Current Concepts in Joint Replacement Winter 2002 Meeting, Defendant CUCKLER suggested that metal hips, such as the M2a, are more cost-effective because, even in younger and more active patients, they would last longer and not subject a patient to the medical cost of revision surgery: “The conventional poly-metal combination is admittedly cheaper, but for a younger, high-demand patient, the metal-metal is more cost effective.”
- b. As advertised on Biomet.com in the form of a patient testimonial under the website’s “Patient Stories” section, for an active, 51-year old male patient, Defendant CUCKLER indicated that the M2a-38 Metal on Metal implant was the optimal implant “because it was designed to last longer than other conventional implant materials such as polyethylene.”

66. Cuckler Defendants claimed that MoM implants have a long history of clinical success. This, however, is clearly false: MoM implants have a long history of clinical failure, as evidenced by the orthopedic implant industry’s abandonment of the technology after the MoM’s high failures decades ago.

- a. At the 19th Annual Current Concepts in Joint Replacement Winter 2002 Meeting, Defendant CUCKLER Stated: “What would I want in myself? I’d want metal-metal ... First, there is a long and successfully documented clinical history.”
- b. Biomet’s M2a Magnum Design Rationale Brochure cites Defendant CUCKLER’s Article, *The Rationale for Metal-on-Metal Total Hip Arthroplasty* to claim the “Long-term clinical results of MoM hips.”

67. Cuckler Defendants claimed that there is a lesser histological response to the smaller wear particles produced by MoM implants as compared with the larger particles produced by MoP hips. The exact opposite, however, is true. The smaller size of metal particles

triggers a greater histological response and increased failure rates of metal on metal articulations, including the M2a.

- a. In *The Rationale for Metal-on-Metal Total Hip Arthroplasty*, Defendant CUCKLER states: “It has been hypothesized that the small metal particulates may be below the critical size necessary to elicit a phagocytic response from tissue macrophages. Therefore, the histologic response to metallic wear debris does not show the intense histiocytic response common to metal-on-PE THAs.”
- b. In the same article, Defendant CUCKLER claimed that “larger-diameter metal-on-metal femoral heads have superior wear behavior in comparison with smaller diameter heads.”
- c. During the 72<sup>nd</sup> Annual Meeting of the American Academy of Orthopaedic Surgeons, Defendant CUCKLER was one of a number of surgeons who discussed MoM issues. Defendant CUCKLER stated: “Metal-metal particulates are much smaller than polyethylene particulates on the order of 1/10 of a micron or less.” He continued, “This probably results in them being below the radar screen from detection of a macrophage or histocyte.”

68. Cuckler Defendants claimed tissues surrounding MoM implants, like the M2a, rarely exhibit signs of metalosis. This, however, is untrue, given the large numbers of metalosis-related complaints reported regarding MoM implants, including the M2a.

- a. In *The Rationale for Metal-on-Metal Total Hip Arthroplasty*, Defendant CUCKLER stated: “Examination of the periprosthetic tissues surrounding metal-on-metal THAs rarely shows metallosis.”

69. Cuckler Defendants claimed that MoM hips, such as the M2a, are immune to third-body wear or subluxation because MoM hips are self-polishing, and further claimed that surfaces damaged as a result of these phenomena can “return to their pre-damage status.” In essence, Cuckler Defendants claim that the metal hip implant can heal itself if it is damaged. This is simply not the case. Further, if third body wear or subluxation caused damage to the articulating surfaces, and if the hip implant is able to “self-polish,” this necessarily means that the implant polishes material off of the implant surface and into the body, creating the very wear the implant was purportedly designed to avoid.

- a. During the 72<sup>nd</sup> Annual Meeting of the American Academy of Orthopaedic Surgeons, Defendant CUCKLER was one of a number of surgeons who discussed MoM issues. Defendant CUCKLER stated: “Metal-metal has a unique advantage relative to other wear couples in that it can self-polish in the event of damage caused by third-body wear or subluxation. The damaged surfaces can return to their pre-damage status.”

70. Cuckler Defendants also touted an artificially low .056% rate of “adverse events reported to the FDA” with respect to the M2a. Cuckler Defendants knew or should have known that a large number of adverse events were not being properly reported to the FDA and that the actual rate of adverse events were actually much higher.

71. Defendant CUCKLER was held out by Biomet as a resource for other surgeons to contact regarding M2a products and metal on metal research.

72. When complaints or concerns were raised to Biomet Defendants regarding the M2a, Biomet employed Cuckler Defendants to visit with the concerned orthopedic surgeons in order to assuage their worries and falsely confirm the clinical safety record of the M2a system.

73. To increase sales and profit, Biomet Defendants organized lavish retreats with small groups of orthopedic surgeons and Defendant CUCKLER. The purpose of these retreats was to allow Defendant CUCKLER to have focused personal time engaging key surgeons in relaxed and fun environments in order to falsely claim the purported advantages of the M2a system.

74. Additionally, with the funding of Biomet Defendants, Cuckler Defendants attended various conferences and events internationally in order to falsely market the M2a products as safe and effective.

75. Internally, Biomet Defendants employed Cuckler Defendants to falsely educate sales staff regarding the safety and efficacy of M2a products.

76. Biomet Defendants provided no other orthopedic surgeon in the country with the same high level of responsibility and financial rewards connected to the design and marketing of M2a products.

**BIOMET DEFENDANTS' MARKETING AND MISREPRESENTATIONS**

77. Supplementing Cuckler Defendants' promotion of the M2a, Biomet promoted the M2a itself, as well.

78. Biomet provided its distributors with marketing, product education, and medical education with which to support their distributors' efforts to sell the M2a.

79. Biomet undertook national and regional advertising and marketing campaigns, directed both to consumers and orthopedic surgeons.

80. Unfortunately, Defendants' marketing of the M2a contained a number of statements which have been revealed to be false. These false statements were material to Plaintiff and the orthopedic community's understanding of the known and unknown risks and benefits with the M2a.

81. These campaigns incorporated Mary Lou Retton, who received bilateral M2a Magnum implants, as a spokesperson for M2a metal on metal implants. Mrs. Retton was utilized in mass media campaigns as well as with trade shows in which she had direct personal contact with orthopedic surgeons. Biomet Defendants' website still utilizes Mary Lou Retton.

82. However, the same defects which caused the M2a here to fail also caused both of Mrs. Retton's implant systems to fail requiring revision surgery. In fact, Mrs. Retton herself has filed suit against Biomet Defendants for her injuries.

83. Biomet Defendants' continued to utilize Mrs. Retton as a spokesperson even after finding out that her implants were failing. Biomet Defendants' goal in doing so was to continue to mislead the public about their product.

84. Presently, Biomet Defendants publish an article on their website citing a January 2008 MHRA (U.K. equivalent of FDA) publication for the following proposition: "In January, 2008, an MHRA (Medicines and Healthcare products Regulatory Agency) Expert Advisory Group observed, 'There is no evidence that increased levels of cobalt and chromium ions are associated with any clinical effects.'"<sup>3</sup>

85. Biomet Defendants know or should know that the MHRA updated their 2008 observations in 2010. The 2010 update to the cited article directly and materially contradicts the quote cited by Biomet Defendants. The updated article now reads: "There is some evidence that increased levels of cobalt and chromium ions are associated with soft tissue changes."

86. Biomet Defendants knew or should have known that this statement was clearly false as of 2010.

87. BIOMET, in its sales presentations, sales training, printed marketing and communications to surgeons and the public regarding the Magnum, touted a purportedly low .056% rate of "adverse events reported to the FDA." BIOMET communicated this adverse event rate to the orthopedic community directly and through its sales representatives, including DISTRIBUTORS.

88. Unfortunately, BIOMET intentionally suppressed its rate of "adverse events reported to the FDA" with regards to the M2a Magnum.

89. BIOMET accomplished this, at least in part, by a pattern and practice of only

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<sup>3</sup> As appears on <http://www.biomet.com/campaign/trueAlternativeBearings/BOI04401ThePerformance.pdf> on 5/1/2017.

reporting revision surgeries as adverse events to regulatory bodies if patients who underwent a revision surgery *also* filed a lawsuit.

90. At all times relevant to this lawsuit, BIOMET was aware that its pattern and practice of reporting adverse events contingent upon whether the patient also filed a lawsuit relating to the adverse event would result in an underreporting of adverse events.

91. At all times relevant to this lawsuit, BIOMET was aware that if it was able to market a lower reported adverse event rate for its M2a Magnum product as compared with the actual adverse event rate, BIOMET could more easily convince the orthopedic community to purchase and implant the M2a Magnum device.

92. At all times relevant to this lawsuit, BIOMET was aware that the actual adverse event rate is material in the medical community's consideration of the safety and efficacy of a medical product.

93. At all times relevant to this lawsuit, BIOMET was aware that it was deceiving the orthopedic community by underreporting adverse events and by not sharing the actual adverse event rate.

94. 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.



95. 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.

96. 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.

97. Upon information and belief, further false statements by Biomet Defendants include, but are not limited to, the following:

- a. Biomet Defendants claimed that the M2a was a safe and effective hip replacement system.
- b. Biomet Defendants claimed that the M2a was clinically safe and effective based on laboratory tests.
- c. Biomet Defendants claimed that the M2a was clinically safe and effective based on clinical tests.
- d. Biomet Defendants attributed data regarding clinical failures of the M2a to improper patient selection by surgeons.
- e. Biomet Defendants attributed data regarding clinical failures of the M2a to improper surgical technique by surgeons.
- f. Biomet Defendants attributed data regarding clinical failures of the M2a to patient characteristics.
- g. Biomet Defendants claimed the clinical existence of a run-in period for the M2a.
- h. Biomet Defendants claimed that the metal wear clinically produced during the theoretical run-in period was within safe limits.
- i. Biomet Defendants claimed that metal wear clinically released from the M2a is reduced after a theoretical run-in period of three years.
- j. Biomet Defendants presented clinical research data from within the theoretical run-in period as being indicative of the long-term clinical safety and efficacy of the M2a.
- k. Biomet Defendants claimed knowledge of clinically safe limits for metal wear.
- l. Biomet Defendants attributed metal wear production to surgical technique and environmental contaminants to the exclusion of device related factors.
- m. Biomet Defendants attributed clinical reactions to metal wear to patient hypersensitivity.
- n. Biomet Defendants claimed the M2a was highly wear-resistant.
- o. Biomet Defendants claimed the M2a exhibits less metal wear than other competing types of hip implants.

- p. Biomet Defendants claimed they could not draw conclusions regarding the safety or efficacy of the M2a even after analyzing reports of revisions and explanted components.
- q. Biomet Defendants claimed that the design differences between the M2a and other MoM hips made the M2a more safe and effective than other MoM hips.
- r. Biomet Defendants claimed that the design differences between the M2a and other MoM hips made the M2a a clinically safe and effective hip replacement system.

98. Biomet Defendants omitted a great deal of material information regarding the safety and efficacy of the M2a to Plaintiff, Plaintiff's surgeon, and the orthopedic community including, but not limited to:

- a. The lack of evidence to support the clinical existence of fluid film lubrication during a large percentage of normal, everyday use of the M2a;
- b. The clinical existence of greater histological reaction to the comparatively smaller wear particles produced by the M2a as compared to the larger particles produced by MoP hips that were available at the same time.
- c. The likelihood of a smaller volume of metal particles from the M2a producing greater negative clinical effects than a larger volume of plastic particles from other MoP hips available at the same time;
- d. A large number of M2a failures were assumed to not be device-related despite a lack of adequate investigation;
- e. M2a design characteristics were a known potential cause of the complaints and revisions being reported;
- f. Long-term clinical studies of the M2a were purposefully avoided or omitted when promoting the long-term outcome of the M2a;
- g. "Hypersensitivity" to the M2a is defined solely by the occurrence of a negative outcome and not by a pre-disposition for a negative outcome;
- h. Citations to data regarding the purported long-term success of past generations of MoM hips focused solely on the percentage of those devices not revised after a certain period of time, omitting data regarding those that failed and required revision;
- i. Though metal ions can be excreted through the urine, the excretion can not be enough to offset the amount of metal ions and wear being released into the body;
- j. The FDA's "clearance" for the M2a to be sold did not involve any extensive scrutiny for clinical safety and efficacy before sale and instead only required a showing of substantial equivalence to previously cleared devices (which also were not scrutinized for clinical safety before "clearance" for sale).

99. Biomet Defendants continued efforts to silence valid concern in the orthopedic community about the products at issue in this Complaint results in a public hazard. So long as

Biomet Defendants continue to keep orthopedic surgeons in the dark about the actual incidence of adverse events and falsely claim that the M2a system does not exhibit similar modes and rates of failure as other metal on metal systems, orthopedic surgeons will not know to follow their M2a patients with the requisite level of care. By choosing their bottom line, Biomet Defendants are directly placing the public in greater danger.

100. The products at issue in this Complaint were 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.

#### **PLAINTIFF BEVERLY FRANCIS' M2A EXPERIENCE**

101. Plaintiff experienced a history of pain in Plaintiff's right hip that caused Plaintiff to be treated by orthopedic surgeon Kelly P. Coffey, D.O. ("Dr. Coffey")

102. Dr. Coffey determined Plaintiff needed surgery to replace Plaintiff's right hip with an artificial hip with the goal of providing Plaintiff a well-functioning hip.

103. The surgery was conducted on January 12, 2010, with a M2a metal-on-metal hip replacement being implanted in Plaintiff's right hip.

104. The M2a was utilized as the orthopedic surgeon was convinced that the M2a, of all hip replacements, would best serve to replace Plaintiff's natural hip.

105. Unfortunately, that was far from the case.

106. The M2a metal-on-metal hip initially appeared to work well. Thereafter, Plaintiff began to experience pain, discomfort, and lack of mobility from the affected hip. These issues began to increase in severity until they eventually became debilitating and limited Plaintiff's lifestyle and activities of daily living.

107. On October 21, 2014, Plaintiff was seen at the Michigan Orthopedic Center by orthopedic surgeon James M. Cochran, D.O. (“Dr. Cochran”). Dr. Cochran examined Plaintiff’s affected hip and scheduled Plaintiff for surgery to remove the M2a metal-on-metal hip replacement.

108. The revision surgery to remove components of the M2a metal-on-metal hip was performed on December 8, 2014. Following the surgery to remove the M2a metal-on-metal, Plaintiff was forced to go through an extensive period of rehabilitation and recovery.

### **DAMAGES**

109. As a direct and proximate result of the defective M2a metal-on-metal hip replacement, Plaintiff suffered injuries, including but not limited to significant debilitating pain, tissue destruction, bone destruction, metal wear, metal poisoning, loss of enjoyment of life, and limitation of daily activities.

110. Plaintiff expects to continue suffering such injuries in the future as a result of the M2a System and component parts.

111. As a direct and proximate result of the defective M2a, Plaintiff was caused to incur medical expenses, and expects to incur additional medical expenses in the future.

112. As a direct and proximate result of the defective M2a, Plaintiff experienced emotional trauma and distress, and is likely to experience emotional trauma and distress in the future.

### **COUNT ONE – ALL DEFENDANTS – INFORMATION NEGLIGENTLY SUPPLIED FOR THE GUIDANCE OF OTHERS**

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

114. Plaintiff’s purchase of the products at issue in this Complaint was a business

transaction.

115. All Defendants had a pecuniary interest in the sale of the products at issue in this Complaint.

116. The sale of the products at issue in this Complaint was in the course of each Defendants' business, profession, or employment.

117. All Defendants supplied false information for the guidance of others regarding the selection of the M2a as a safe and effective hip replacement option, as alleged in paragraphs 57 to 98.

118. Biomet Defendants perpetuated their false messages directly to the orthopedic community, through Cuckler Defendants, and through local distributors.

119. 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.

120. 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.

121. Defendants intended for their information to influence either the transaction in which Plaintiff, through Plaintiff's orthopedic surgeon agent, purchased the products at issue in this Complaint or a substantially similar transaction.

122. 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 products at issue in this Complaint or a substantially similar transaction.

123. Plaintiff, through Plaintiff's orthopedic surgeon agent, justifiably relied upon the

false adverse event rate provided by Defendants.

124. As a direct and proximate result of Defendants' false information, Plaintiff suffered pecuniary loss, as described in paragraph 111, above.

**COUNT TWO – ALL DEFENDANTS –  
MISREPRESENTATION**

125. Plaintiff re-alleges and incorporate by reference paragraphs 1-112 above as if fully stated herein.

126. Defendants made statements concerning material facts which Defendants may have believed to be true but which in fact were false, or otherwise omitted material facts.

127. Defendants were negligent in making such statements because they should have known the statements were false or omitted material information.

128. In making these statements, Defendants intended or expected that another would rely on the statements.

129. Plaintiff, through her surgeon agent, justifiably relied on the false statements.

130. As a direct and proximate result of the misrepresentations regarding the M2a, Plaintiff suffered injuries as described in paragraphs 109-112, above.

**COUNT THREE – ALL DEFENDANTS –  
NEGLIGENCE**

131. Plaintiff re-alleges and incorporates by reference paragraphs 1-112 above as if fully stated herein.

132. Defendants, as the designers, manufacturers, promoters, marketers, sellers, suppliers, distributors, and/or servicers of the M2a system components, owed a duty to use reasonable care in the design, manufacture, promotion, marketing, selling, supplying, distribution, and/or service of Plaintiff's M2a system.

133. Defendants, in breach of the duties described above, negligently and carelessly designed, manufactured, promoted, marketed, sold, supplied, distributed and/or serviced the products at issue in this Complaint.

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

135. Defendants breached this duty by failing to adequately warn Plaintiff, Plaintiff's orthopedic surgeon, and the orthopedic community regarding the products at issue in this Complaint.

136. As a direct and proximate result of Biomet Defendants' breaches of duty, Plaintiff needlessly suffered injuries as described specifically in paragraphs 109-112.

**COUNT FOUR – ALL DEFENDANTS –  
STRICT LIABILITY FAILURE TO WARN**

137. Plaintiff re-alleges and incorporates by reference paragraphs 1-112 above as if fully stated herein.

138. At the time Defendants designed, manufactured, promoted, marketed, sold, supplied, distributed and/or 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.

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

140. 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.

141. 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.

142. Defendants failed to provide adequate instructions or warnings regarding the defects in the products at issue in this Complaint which were known by Defendants or should have been known by Defendants.

143. As a direct and proximate results 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 109-112.

**COUNT FIVE – ALL DEFENDANTS –  
STRICT LIABILITY DESIGN AND MANUFACTURING DEFECT**

144. Plaintiff re-alleges and incorporates by reference paragraphs 1-112 above as if fully stated herein.

145. At the time that defendants designed, manufactured, promoted, marketed, sold, supplied, distributed and/or serviced the products at issue in this Complaint, such components contained defects that made them unreasonably dangerous beyond the expectations of the ordinary consumer, and were unfit for their intended use.

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

147. 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.

148. The products at issue in this Complaint, for the reasons stated herein, were defective and unreasonably dangerous in design and manufacture.



149. As a direct and proximate result of the defects in the products at issue in this Complaint, Plaintiff suffered injuries described in paragraphs 109-112.

**COUNT SIX – BIOMET DEFENDANTS –  
BREACH OF IMPLIED WARRANTY**

150. Plaintiff re-alleges and incorporates by reference paragraphs 1-112 above as if fully stated herein.

151. Biomet Defendants impliedly warranted that the products at issue in this Complaint and its component parts were merchantable and fit for the ordinary and intended purposes for which hip systems are used.

152. Plaintiff was a foreseeable user of the products at issue in this Complaint.

153. Plaintiff's surgeon, as a purchasing agent, purchased the products at issue in this Complaint for Plaintiff from Biomet Defendants.

154. At all times relevant to this Complaint, Plaintiff was in privity with Biomet Defendants.

155. Plaintiff used the products at issue in this Complaint for its ordinary and intended purpose.

156. The products at issue in this Complaint failed while being used for their ordinary and intended purpose.

157. As a direct and proximate result of Biomet Defendant's breach of implied warranty, Plaintiff suffered injuries as described specifically in paragraphs 109-112.

**COUNT SEVEN – BIOMET DEFENDANTS –  
BREACH OF EXPRESS WARRANTY**

158. Plaintiff re-alleges and incorporates by reference paragraphs 1-112 above as if fully stated herein.

159. Biomet Defendants sold and Plaintiff purchased, through Plaintiff's purchasing agent surgeon, the products at issue in this Complaint.

160. At all times relevant to this Complaint, Plaintiff was in privity with Biomet Defendants.

161. Biomet Defendants expressly warranted by affirmation, promise, description, and sample to Plaintiff and Plaintiff's physicians that the products at issue in this Complaint were of a quality and character suitable for implantation and extended safe use in Plaintiff.

162. Such representations by Biomet Defendants were meant to induce Plaintiff, through Plaintiff's physicians, to purchase the products at issue in this Complaint.

163. The products at issue in this Complaint did not conform to the representations made by Biomet Defendants.

164. Biomet Defendants breached the express warranty it provided with the products at issue in this Complaint.

165. As a direct and proximate result of Biomet Defendant's breach of express warranty, Plaintiff suffered injuries as described specifically in paragraphs 109-112.

#### **DEMAND FOR JURY TRIAL**

166. 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, Plaintiff respectfully demands judgment against Defendants for compensatory damages and any other relief the Court deems just and proper.

Dated July 17, 2017.

*/s/ Ilyas Sayeg*

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**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that a true and correct copy of the foregoing has been furnished to counsel of record via notification through the CM/ECF system for the Northern District of Indiana on July 17, 2017 to:

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