IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

IN RE: SMITH & NEPHEW BIRMINGHAM HIP RESURFACING (BHR) HIP IMPLANT PRODUCTS LIABILITY LITIGATION	MDL-17-md-2775 Master Docket No. 1:17-md-2775 JUDGE CATHERINE C. BLAKE

THIS DOCUMENT APPLIES TO ALL BHR-THA CASES

MASTER AMENDED CONSOLIDATED COMPLAINT FOR PLAINTIFFS WITH BHR CUPS, MODULAR FEMORAL HEADS AND STEMS

This is a product liability action involving a metal-on-metal hip implant system that Smith & Nephew tried, and failed, multiple times, to get approved by the FDA for use in the United States, but nonetheless marketed and promoted to the medical community and the public for almost a decade, causing serious and permanent injuries to thousands of men and women in almost every state. This Master Amended Consolidated Complaint (MACC) is filed on behalf of Plaintiffs with Smith & Nephew cobalt-chrome modular femoral heads ("MFH") implanted in a total hip arthroplasty ("THA") with a Birmingham Hip Resurfacing (BHR) cup, as described in more detail below, with claims pending in MDL 2775, *In re: Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Products Liability Litigation*.[1]

[1] This THA-MACC does not apply to cases involving the recalled R3 metal liner and/or R3 acetabular device, which are also pending before this Court.

PARTIES, VENUE AND JURISDICTION

1. Defendant Smith & Nephew, Inc. ("Inc.") is, and at all times relevant to this action was, a corporation organized and existing under the laws of the State of Tennessee, with its principal place of business in Memphis, Tennessee.

2. Smith & Nephew, plc ("PLC") is the parent company of S&N and is a foreign company incorporated in the United Kingdom and regularly doing business in the United States, by and through its employees and its subsidiary S&N. PLC may be served, pursuant to The Hague Convention, at 15 Adam Street London, WC2N 6LA United Kingdom.

3. Smith & Nephew, Limited ("LTD") is a foreign company incorporated in the United Kingdom and regularly doing business in the United States. LTD may be served, pursuant to The Hague Convention, at 101 Hessle Road, Hull, HU3 2BN, United Kingdom.

4. PLC's Board of Directors runs, manages or otherwise controls Inc., PLC and LTD, and the companies together manufacture the various components of the BHR and THA systems in Birmingham, England. S&N's website also lists its "corporate headquarters" at PLC's address in London. Smith & Nephew holds itself out to the public as Smith & Nephew plc, on its website, on its Twitter page https://twitter.com/smithnephewplc, and through its Annual Report and other documents presented to shareholders (available at: http://www.smith-nephew.com/investor-centre/ and http://www.smith-nephew.com/global/assets/pdf/corporate/2017%20ar%20-%20interactive%20final.pdf, all of which are incorporated by reference herein). PLC is also listed on the New York Stock Exchange under the symbol SNN.

5. LTD is a subsidiary of PLC, and its employees, including but not limited to Andrew Weymann, Lindsay D'Alessandro, Amelie Chollet, and the entire Board of Directors, played key roles in post-approval surveillance, adverse event reporting, Health Hazard Evaluation process, and

decisions related to the continued sale of the BHR and THA-MFH and other devices that are the subject of Plaintiffs' claims.

6. Inc., LTD and PLC were each and all specifically involved in the designing, developing, testing, manufacturing, assembling, promoting, labeling, packaging, marketing, distribution, and market withdrawal of the Modular Femoral Head component and/or the BHR System in the United States and its actions directly affected United States patients.

7. PLC, LTD, Inc., and their executive officers are actively involved in running Smith & Nephew and are engaged in direct contact with various U.S. states by selling the Modular Femoral Head ("MFH"), modular neck sleeve and femoral stems involved in Plaintiffs' surgeries, and which caused injury to Plaintiffs. The devices were combined as part of a total hip arthroplasty ("THA") system.

8. As part of its Initial Disclosures pursuant to Federal Rule of Civil Procedure 26 in this MDL, Smith & Nephew produced insurance policies that demonstrate that "an insurance business may be liable to satisfy all or part of the judgment in the action or to indemnify or reimburse for payments made to satisfy the judgment." *See* FRCP 26(A)(iv). PLC is the named insured for these policies.

9. Throughout this Master Complaint, Inc., PLC and LTD are collectively referred to as "S&N", "Smith & Nephew" or "Defendants" except where allegations specific to that entity are made.

10. Complete diversity of citizenship exists between Plaintiffs and Defendants pursuant to 28 U.S.C. § 1332. At all times relevant to this cause of action, Defendants had the requisite minimum contacts with Plaintiffs' states of residence, and the amount in controversy in this action exceeds Seventy Five Thousand Dollars ($75,000.00) exclusive of interest and costs.

11. Plaintiffs adopting this THA Master Consolidated Complaint ("THA-MACC") hereby adopt and incorporate by reference all of the allegations and facts contained in the previously filed

BHR-MACC on behalf of resurfacing plaintiffs on August 8, 2017 (Dkt. 124) in this MDL, to the extent those allegations are applicable for the BHR device that is one of the components in the THA system.

12. But for the creation of this MDL, Plaintiffs adopting this THA-MACC would have filed their claims in the jurisdiction where they reside and/or where their injuries took place.

FACTUAL BACKGROUND

13. S&N, LTD and their shared parent company PLC are a global medical technology company, with PLC's headquarters in England, and S&N's domestic headquarters in Memphis, Tenn. Defendants reported more than $4.6 billion in revenue in their most recent fiscal year, or approximately $13 million in revenue every day. Defendants employ more than 15,000 people globally and have a presence in more than 100 countries.

14. Defendants are a global enterprise with more than 160 years of experience in their industry. Despite having extensive knowledge of both foreign and domestic regulation of medical devices, Defendants jointly designed, manufactured, marketed, and sold a dangerous and illegal THA system in the United States without permission to do so, and despite being warned by the FDA not to do so. Some of this work was performed only by employees of PLC, while other work was performed only by employees of S&N. The three entities are all liable for Plaintiffs' injuries.

15. This action arises out of Defendants' violations of various sections of the Code of Federal Regulations, the common and statutory law of Plaintiffs' home states, and the damages suffered by Plaintiffs as a result thereof.

A. The Modular Femoral Head THA System is Unsafe

16. Most total hip replacement systems consist of a cup that fits into the acetabulum, a femoral head that is fitted into the cup, and a femoral stem that is driven into the femur. They are

usually categorized as either monoblock or modular systems. In a monoblock system, each piece is a single component that can only be matched with another component of the same size. In a modular system, components of different sizes can be mixed and matched based on the surgeon's preference and the patient's body size.

17. Modularity is most common at the femoral head-stem junction and within the acetabular cup. Modular heads allow adjustment of head diameter and neck length (offset and height). However there are also multi-modular femoral stems where the upper body or neck portion of the femoral stem is separated from the distal stem. When large femoral heads are used, a modular neck sleeve is often used to connect the stem and femoral head to allow for greater flexibility in fit with different stem tapers. Thus, the head-stem connection itself can be multi-modular.

18. The most common configuration of the acetabular cup for hard-on-hard bearings is monoblock. The most common configuration of the cup for hard-on-soft bearings such as polyethylene is modular.

19. The modular components can be used independently or in combination with other pieces. A modular neck sleeve is often used to connect the stem and femoral head to allow for greater flexibility in length.

20. The first widely marketed metal-on-metal total hip systems were introduced in the 1950s and 1960s, including the McKee-Farrar device. These devices suffered from unacceptable premature failure rates, and by the 1970s were replaced by low friction, ultra-high-weight polyethylene systems. These metal-on-polyethylene systems were further refined over the following decades, and by the late 1990s had become the gold standard for hip replacement, and they remain so today.

21. Defendants' unapproved, illegally promoted metal-on-metal BHR-THA system suffers from the same defects that have plagued other systems, to different degrees, such as the Zimmer Durom, the DePuy ASR, the DePuy Pinnacle, the Biomet M2a, and the Wright Conserve.

22. Defendants listed the Biomet M2a Magnum and the Wright Conserve metal-on-metal hip systems as "predicate" devices when they sought FDA approval for their own cobalt-chrome Modular Femoral Head, but they continued to sell the MFH system even after Biomet and Wright had removed their metal hip systems from the U.S. market due to unreasonably high failure rates.

23. All of these metal-on-metal devices fail prematurely due to the generation of metal wear debris, which has a toxic effect on patients' bodies. Although the metal particles generated by metal-on-metal hip replacements are smaller than polyethylene particles, they are far more dangerous to humans because polyethylene particles are chemically stable and inert. In this context, smaller does not mean safer. For example, if two equal-sized piles of metal and polyethylene particles were compared side by side, the pile of metal would have thousands of times more particles, which are biologically reactive and cytotoxic in the human body. Thus, while the size of the pile with metal particles might be smaller, it is far more dangerous to patients. Smith & Nephew understood this difference.

24. Defendants knew that metal particles were dangerous and cytotoxic, meaning they kill living cells in the same way that chemotherapy treatment attacks living cells in cancer patients. However, in their rush to market and promote the metal-on-metal MFH system, Defendants joined their competitors in deciding to ignore the need for long-term studies on safety and efficacy, opting to sell first and worry about the consequences later.

25. As explained in the BHR-MACC, which Plaintiffs adopt and incorporate here, the Committee on Safety of Devices (now, the Devices Expert Advisory Committee, DEAC) is

responsible for providing independent expert input and advice on medical devices to the United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA) to aid the MHRA in its role in ensuring the safety introduction and management of medical devices to the population. In October 2006, the minutes from the first Expert Advisory Group (EAG) established by the Committee on Safety of Devices, note that wear debris can be generated from articulating surfaces, specifically metal-on-metal couples, and that as of 2006, there has been a growing concern about the biological effects of metal wear debris generated from hip replacement implants.

26. Similarly, in 2007, analysis by the Australian Register of Therapeutic Goods (ARTG) of data reported by the Australian National Joint Replacement Registry suggested that the DePuy ASR resurfacing hip implant was associated with a higher than average replacement rate.

27. On January 2, 2008, the EAG issued a report containing advice on the biological effects of metal wear debris generated from hip implants. The report required all adverse incidents associated with metal-on-metal hip implants, including early revisions, and soft tissue reactions, be reported to the MHRA. The report further recommended research to determine the distribution of cobalt and chromium ions, and to characterize the potential adverse health effects that may result from increased exposure to chromium and cobalt ions. Despite early advertising and communications to surgeons relying on the MHRA to show the safety of the MFH system components, Smith & Nephew did not communicate this MHRA action, information, or guidance to surgeons.

28. Because Defendants' modular BHR-THA system is not approved by the FDA, its safety and efficacy are difficult to study. Furthermore, Defendants have failed to produce much of their research, correspondence, and marketing materials for the system in the cases pending before this Court, despite years of litigation and numerous discovery requests. Even from the limited amount of information available at this time, nearly all of which predates 2008, it is clear that Defendants'

modular THA system, when combined with the BHR cup, suffers from the same problems that doomed all metal-on-metal hips, including the BHR resurfacing system without a traditional stem. For example, a February 2012 article in the Journal of Bone and Joint Surgery revealed the BHR has a 26 percent failure rate in women after ten years, and the authors of the article warned that "results in women have been poor and we do not recommend metal-on-metal resurfacing in women."[2] Smith & Nephew knew this, or should have known it with the exercise of reasonable care, but chose not to inform patients and the medical community. Indeed, the recall was not issued until well over three years after the JBJS authors made that recommendation.

29. Another example of the dangerous nature of Defendants' modular BHR-THA system is a 2011 article in the same journal showing that cobalt and chromium metal ion levels are "significantly higher" in THA patients than in resurfacing patients, and that patients with both systems show similar wear rates on their metal devices.[3]

30. Another example of the dangerous nature of the BHR-THA system is a notice from the New Zealand Medicines and Medical Devices Safety Authority on Oct. 3, 2012, in which the agency alerted all surgeons implanting the BHMH that the system is "no longer recommended for total hip replacement surgery" due to higher than expected revision rates.[4] A similar alert was issued in Australia several weeks later on Oct. 30, 2012.[5]

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[2] D.W. Murray, et. al., *The Ten-Year Survival of the Birmingham Hip Resurfacing*, J. BONE & JOINT SURG., 2012;94-B.
[3] A. Matthies, et. al., *Retrieval Analysis of 240 Metal-on-Metal Hip Components, Comparing Modular Total Hip Replacement with Hip Resurfacing*, J. BONE & JOINT SURG., 2011;93-B:307-14.
[4] The alert stated that the higher revision rate was reflected in New Zealand's national joint registry data, and noted that similar joint registries in the UK and in Australia had previously reported similarly high revision rates for the same BHMH device. The alert is available at http://www.medsafe.govt.nz/hot/media/2012/RecalSmithAndNephewBirminghamHipModularHead.asp (last visited Aug. 1, 2018).
[5] Australia Therapeutic Goods Administration, *High Revision Rates Alert*, available at https://www.tga.gov.au/alert/birmingham-hip-modular-head-used-hip-replacements (last visited Aug. 1, 2018).

31. U.S. surgeons don't generally read journals from other countries, but Smith & Nephew and similar manufacturers often use data from these countries to make safety decisions because, due to the nature of their government-funded health care system, patient data is much more robust, open and available. Therefore, trends in revisions and patient safety are often first spotted in these countries, and Smith & Nephew is aware of this and should have used this data to protect Plaintiffs in the United States from its dangerous products.

32. Plaintiffs' THA fails in part because metal ions created by the metal components articulating against each other inside the hip joint entered Plaintiffs' bloodstream, destroyed tissue, created an adverse reaction and caused the THA to fail and require a painful revision surgery. The metal ions produced by the THA include metal ions from the BHR cup and from the modular femoral head placed inside that cup, in addition to fretting and corrosion caused by micromotion at the modular neck-stem junction.

33. The metal ions produced by the modular femoral head and/or at the modular neck-stem junction are sufficient on their own to cause the tissue damage, negative reaction and injury to the Plaintiffs that requires revision.

34. The THA and MFH produce metal ions because the design leads to edge loading, which is a risk of larger metal head devices. Edge loading occurs when too much pressure is exerted on the contact area between the cup and the head, and produces too much wear and metal ions. The edge loading of the MFH in THA means that it is not necessarily just the BHR cup but the specific use of the MFH that is a substantial factor in causing metal ions and failure of the device.

35. Because the THA is not an approved device in the United States, it was impossible for Smith & Nephew to properly investigate, monitor failures, perform studies or otherwise understand the true revision rate and whether it was acceptable or not.

36. These are the same or similar problems that plague other metal-on-metal hip implant systems including those identified above. However, unlike those other metal hip systems, which were removed or recalled from the U.S. market, Defendants continued to sell their MFH system without approval, at least as recently as 2015. By comparison, the Zimmer Durom was recalled in 2008, the DePuy ASR was recalled in August 2010, and similar metal-on-metal systems made by Biomet and Wright Medical were withdrawn from the market in the 2012 to 2013 time frame. *See also* BHR-MACC at 39-41. It is unclear exactly when Defendants finally stopped selling their BHR-THA system, because Defendants have only produced limited documents from 2008 and previous years in this MDL. The only documents available to Plaintiffs are those that are publicly available, or the Smith & Nephew documents produced voluntarily that predate 2008.

37. Smith & Nephew issued an announcement on March 19, 2015, stating that the MFH had been phased out of the U.S. market in mid-2014 due to a "decline in sales," but never referenced the safety of the device. It is unclear how long it took to complete this phase-out process.

38. This notice states that Smith & Nephew became aware of problems with the MFH after reviewing clinical data from a study in the United Kingdom published in Nov. 2014 related to the MFH used in a THA procedure with a Synergy stem. The study showed elevated metal ion levels in patients, which Smith & Nephew believed to be linked to taper corrosion at the modular neck sleeve. Smith & Nephew did not issue a recall for the MFH device, did not offer any guidance to patients, and stated that surgeons should follow the same precautions that they normally would for any hip implant recipient, without any special instructions or warnings for metal-on-metal device recipients.

39. This shows that the PLC and/or LTD were monitoring patient safety and making the decision about the THA for the United States and its patients, including Plaintiffs. The failure to make this decision before March 19, 2015 or "mid-2014" constitutes affirmative action by the PLC and/or

LTD that reached into, involved, or otherwise affected the United States, and patients here, including, but not limited to, the Plaintiffs.

40. Despite Smith & Nephew claiming to have only learned about the dangers of its product in late 2014, the dangers posed by metal ions in the body have been known since at least the late 1960s. Additional evidence is reported in medical literature from the 1970s and 1980s, noting the effects of cobalt-chrome alloy particles on macrophages — large stationary cells in body tissue — and their biological reactivity.

41. Smith & Nephew began monitoring metal-on-metal device failures as early as 2008, yet failed to act to remove them from the market or prevent their sale in the United States until 2015.

42. Defendants knew that their modular metal-on-metal THA system was dangerous for patients, and that it suffered from some of the same defects that caused the BHR resurfacing system to fail. The BHR's unreasonably high risk of premature failure for certain patient populations became known at least by early 2007, when the Australian Orthopaedic Registry published data from September 1999 to December 2006 showing that female resurfacing patients had a two-fold increase of revision at three years compared to men, and a nearly three-fold increased risk of revision at five years.

43. The following year, in 2008, the Australian registry gave additional warnings, stating in its annual report that women with a femoral head size of less than 50 mm faced a more than three-fold increased risk of revision (Hazard Rate "HR" = 3.22, at 95 percent confidence interval) compared to female patients with a larger head size. Similarly, men with a femoral head size of less than 50 mm faced a far higher risk of revision compared to other male patients with a larger head size (HR = 2.69, at 95 percent confidence interval).

44. Additional data from Australia and other foreign joint registries show that metal-on-metal total hip systems are far more prone to premature failure compared to systems with ceramic or polyethylene components. For example, the 2010 annual report of the Australian registry, which included data from 1999 to 2009, showed the cumulative revision rate for all metal-on-metal bearing systems was 1.14 per 100 observed component years, or almost twice as high as the rate of 0.68 for all metal-on-polyethylene systems.[6]

45. As described in the BHR-MACC, in February 2011 the FDA launched a metal-on-metal hip implant webpage, providing updated safety information and recommendations for patients and healthcare providers, including responding to localized symptoms, recommendations for metal ion testing, and information concerning joint revision.

46. On May 6, 2011, the FDA ordered all manufacturers of metal-on-metal devices to perform post-market surveillance studies, requiring manufacturers to examine adverse events as well as patients' pre- and post-implantation levels of cobalt and chromium. The alert required manufacturers to study the effects of metal ion concentrations in the bloodstream.

47. On February 28, 2012, the MHRA issued a medical device alert recommending annual patient follow-up for not less than five years, MARS MRI testing, as well as initial and follow-up blood metal ion testing. MDA 2012/008. Despite early advertising and communications to surgeons relying on the MHRA to show the safety of the components in the BHR-THA system, Smith & Nephew did not communicate this new MHRA action, information or guidance to surgeons.

[6] Australian Orthopedic Association National Joint Replacement Registry, 2010 Annual Report at 57-65, available at https://aoanjrr.sahmri.com/documents/10180/42844/Annual%20Report%202010?version=1.1&t=1349406187793 (last visited August 3, 2018)

48. On May 9, 2012, Health Canada issued a public health communication to all orthopedic surgeons and patients concerning management and follow-up for patients implanted with a metal-on-metal hip device.

49. On June 25, 2012, MHRA updated its previous medical device alert, including updated advice on follow-up recommendations for metal-on-metal hip resurfacing patients. The alert recommended patient follow-up annually for the life of the implant in patients that received a resurfacing product, as well as MARS MRI or ultrasound imaging, and at least one blood metal ion test. Despite early advertising and communications to surgeons relying on the MHRA to show the safety of the BHR-THA components, Smith & Nephew did not communicate this new MHRA action, information or guidance to surgeons.

50. In June 2012, the FDA convened the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee seeking scientific and clinical expert opinions on the risks of metal-on-metal hip systems.

51. The next month, July 2012, Stryker issued a Class 2 recall of its ABG II and Rejuvenate hip systems due to revisions associated with fretting and corrosion of the dual-modular femoral stem.

52. On October 3, 2012, cases against Biomet, Inc. and various co-defendants concerning its defective metal-on-metal hip implants were consolidated for multidistrict litigation in Indiana. This litigation included the Biomet M2a Magnum, which was one of Smith & Nephew's two predicate devices for the MFH in the U.S.

53. In 2012, Smith & Nephew commissioned an internal dossier to determine the state of the evidence around metal-on-metal. This document was presented by Smith & Nephew Chief Medical Officer Andy Weymann, who is an employee of PLC and/or LTD, to the Board of Directors

of PLC.[7] After this presentation, the Board of Directors of PLC, on behalf of itself, LTD and/or Smith & Nephew determined to continue selling the BHR and the THA in the United States. This represents another PLC and/or LTD decision, affirmative action and decisions that affected the United States and plaintiffs.

54. After this presentation, the Board of Directors determined that Smith & Nephew would still sell the MFH to patients who had BHR devices for their revisions. However, Smith & Nephew continued to sell the MFH and THA as an initial implant surgery device. Thus, at least as far back as 2012, if not earlier, actions of PLC and/or LTD directly impacted Plaintiffs in the United States and in this litigation. PLC and/or LTD, by and through its agents, employees, and Board of Directors, knew that their decisions would affect patients in the United States including Plaintiffs, and specifically intended to make decisions that affected sales and patients in the United States.

55. Smith & Nephew did not determine or even attempt to determine a safe level of metal ions that could be released by a THA device. The standard of care for metal-on-metal device manufacturers includes determining a safe level of metal ion for human beings, determining whether their device produced less or more than this safe level, and not selling the device and/or recalling and/or removing the device from the market if it did not meet that safety level. Smith & Nephew failed to do each and every one of these things.

56. Smith & Nephew's Medical Director, an employee of LTD and/or PLC, is ultimately responsible for performing a Health Hazard Evaluation on devices, and specifically was responsible for the HHE on the THA device here. The Health Hazard Evaluation is part of the process to determine

[7] (https://ch.linkedin.com/in/andy-weymann-36b182a (last visited August 2, 2018); *see also* http://www.smith-nephew.com/careers/working-at-smith-and-nephew/meet-our-people/working-in-research-development/andy-clinical-affairs/) (last visited August 2, 2018)

if a device should be taken off the market and/or recalled. Therefore, the decisions, acts and omissions of LTD and/or PLC employees directly affected patients, including Plaintiffs, in the United States.

57. Specifically, according to deposition testimony of Smith & Nephew employee John Kenneth Blair Fraser, LTD and/or PLC employees Amelie Chollet and Andrew Weymann were both involved in this HHE process.

58. As part of this process, Smith & Nephew used worldwide data, including data held by, gathered by or otherwise in the custody and control of LTD and/or PLC, to analyze the safety of the MFH and its use with the BHR specifically.

59. Despite the unquestionable danger of metal-on-metal hips by 2012, Smith & Nephew's Senior Vice President continued to publicly state, a press release dated February 9, 2012, entitled "New clinical results further distance the BIRMINGHAM HIP Resurfacing System from failed metal-on-metal hip implants," that the BHR was "unlike any other metal-on-metal hip implant" in an effort to distinguish the BHR from its failing competitors. This representation was not true, and in fact, the BHR had similar or even higher failure rates than other metal-on-metal devices. Although a lack of discovery from Smith & Nephew makes it difficult to determine the extent of the company's marketing efforts for the BHR-THA system, Smith & Nephew was clearly aware the components were being used in an off-label manner given hundreds of adverse event reports, correspondence with surgeons, and widespread efforts to market and promote the BHR-THA system in other countries including New Zealand, the United Kingdom and Australia.

60. Smith & Nephew admitted that the MFH could be used in a total hip arthroplasty, and that it designed the MFH for that purpose, as illustrated in the following deposition testimony from Jason Sells, Senior Director of Regulatory Affairs:

Q: "And can you explain to me what the intended use for this product is?"

A: "… The modular heads can be used as part of a total hip replacement system when articulating against the BH Modular System Acetabular cups or as part of a hemi-hip replacement system when articulating against the natural acetabulum."[8]

61. In his deposition, Mr. Sells testified that there is a difference between the intended use for the MFH by Smith & Nephew, and the indicated use approved by the FDA. He also acknowledged that the indications for use that Defendants circulated to surgeons in the U.S. for the MFH system do not disclose that the MFH is only indicated for use in a hemi-arthroplasty. *Id.* at 100; *see also Id.* at 103(acknowledging that "[t]here is no mention of metal-on-metal" in the labeling for the MFH component).

62. Smith & Nephew was aware that the MFH was being used as part of THA procedures with the BHR cup and as a full metal-on-metal hip replacement product in an initial surgery.

63. While Smith & Nephew may allege that surgeons have the power to determine whether to use components off-label, Smith & Nephew withheld material information from surgeons that would affect their decision, including, but not limited to, the fact that the FDA had multiple times declined to approve the MFH as part of a MOM THA, the fact that the MFH had not been properly tested with the BHR so that safety and efficacy data could be studied, the fact that not only was the BHR no different than other metal-on-metal products, the use of the MFH with the BHR in a THA surgery was even more dangerous and even more like standard metal-on-metal hips, and the fact that the Smith & Nephew metal-on-metal THA product was unreasonably dangerous.

64. Had surgeons been told the complete truth about Smith & Nephew's THA product, the MFH used with the BHR, Plaintiffs' surgeons would not have used Smith & Nephew's THA products in Plaintiffs' initial revision surgery, and would have instead used a safer alternative. Had Plaintiffs

[8] Deposition of Jason Sells at 56, Jan. 30, 2018 (Edward McAnneny v. Smith & Nephew, Inc., 3:17-cv-12, D. Conn.).

known the truth about the safety of the BHR being used with a MFH in a THA procedure, Plaintiffs would not have agreed to have a metal-on-metal Smith & Nephew product implanted in their bodies.

65. Surgeons' willingness to use a MFH in a THA procedure despite no clinical evidence of safety, relative safety, or benefits of the Smith & Nephew products over safer alternatives confirms that Smith & Nephew withheld material information from Plaintiffs' surgeons.

66. Even if Plaintiffs' surgeons had informed them that the MFH was being used as part of the THA procedure in a way that was not approved by the FDA, there was no knowing waiver or informed consent because material information about the safety of the THA was withheld from surgeons and Plaintiffs, including true revision/failure rates, revision rates of predicate devices, the risk of increased metal ions from additional metal components, the risks of the BHR components themselves when used with the MFH, and other material information regarding the safety of the MFH.

67. The Instructions for Use and labeling for the BHR and MFH components failed to properly warn of the risks and proper use of the BHR and MFH components and/or did not properly limit use of the device to its intended and approved used, and Smith & Nephew's sales representatives would provide contradictory information to Plaintiffs' surgeons about the safety of the MFH and THA procedure.

68. Smith & Nephew is aware that there is medical literature, such as that by Paul Pynsent, suggesting that metal ions from the taper junctions of the MFH and that arise from THA usage looks different than patients with a BHR-only, in terms of the quantity and/or specific type of metal ions. Thus, Smith & Nephew is or should have been aware that non-PMA components are, on their own, sufficiently dangerous to cause revisions due to metallosis and tissue damage from metal ions.

69. Smith & Nephew, through its agents, employees, sales representatives, and corporate parent and subsidiary companies, intentionally and affirmatively promoted the MFH components for

sale and use as part of a THA procedure, and/or failed to take steps to prevent its use as part of a THA procedure.

70. Smith & Nephew tried, and failed, multiple times, to receive FDA approval for use of the MFH as part of a THA procedure with the BHR.

71. The FDA did not approve the MFH as part of a THA procedure with the BHR because Smith & Nephew could not provide sufficient evidence that it was safe to do so.

72. Had Smith & Nephew performed sufficient studies, analysis, and pre-market testing of the MFH, it would have learned that the MFH was unreasonably dangerous and not fit for sale in the United States as a hip revision device.

73. It was foreseeable - and in fact, Smith & Nephew had actual knowledge, as testified to by John Kenneth Blair Fraser - that surgeons would use the MFH as part of a THA off-label, and that the use of the MFH would lead to failures in those patients at unreasonably high levels.

74. While the marketing and sales team at Smith & Nephew continued to sell the unapproved BHR-THA system, with the full knowledge, support and agreement of PLC and/or LTD, red flags about the dangers of metal-on-metal hips continued to surface. On January 17, 2013, the FDA issued a safety communication to orthopedic surgeons, healthcare providers, and patients, stating there are unique risks associated with metal-on-metal implants in addition to the general risks of all hip implants. The safety communication further explained that metal release from the articulation of the components can cause damage to bone and tissue causing pain, implant loosening, device failure and the need for revision surgery.

75. The following day, January 18, 2013, the FDA published proposed rules requiring all manufacturers of metal-on-metal hips establish the safety of their devices, even those already marketed.

76. On November 19, 2013, the first settlement in the DePuy ASR metal-on-metal hip MDL was announced. To date more than 25,000 lawsuits involving metal-on-metal hip implants have been filed in federal courts.

77. A 2013 study looked at 143 BHR hips and found pseudotumors in 28 percent of all patients, regardless of gender, less than four years after implantation.[9]

78. Another 2013 study sought to determine whether elevated blood cobalt concentrations were associated with early failure of metal-on-metal hip resurfacings secondary to adverse reaction to metal debris (ARMD) by comparing the DePuy ASR and Smith & Nephew's BHR.[10] The results revealed blood cobalt concentration was a positive and significant risk factor for joint failure.

79. Despite the well-documented, public failure of metal-on-metal hip prosthesis, Smith & Nephew continued to not only sell its metal-on-metal hips like the BHR and the THA, but to attempt to distinguish it from the failed products of DePuy, Zimmer, and Biomet. It was not until September 2015 that Smith & Nephew recalled the BHR. By this time, the MFH device had been withdrawn from the U.S. market but not recalled.

80. On February 18, 2016, the FDA issued a final order requiring manufacturers to submit premarket approval (PMA) on or before May 18, 2016 for two types of metal-on-metal hip systems.

81. Smith & Nephew knew that MOM devices were unsafe, and the explicit and implicit message of its slogan "BHR is not your average 'metal on metal.'" was that metal on metal hips were unsafe, but the BHR was somehow different. In fact, BHR *was* the average metal on metal hip — a higher failure rate than some, a lower failure rate than other metal hips. The same was true of the BHR

[9] R. Bisschop, et al., *High Prevalence of Pseudotumors in Patients with a Birmingham Hip Resurfacing Prosthesis,* J. BONE JOINT SURG. AM. (2013) 4;95(17).
[10] Langton DJ, Sidaginamale RP, Joyce TJ, et al. *The clinical implications of elevated blood metal ion concentrations in symptomatic patients with MoM hip resurfacings: a cohort study*. BMJ OPEN 2013; 3:e001541.

when combined with a MFH, modular neck sleeve and traditional femoral stem. Advertising for the BHR implicitly advertised for the THA because it involved the same cup component.

82. Once Smith & Nephew communicated the actions of the MHRA to surgeons to represent that the BHR and MFH were safe, Smith and Nephew had a duty to update or to continue to communicate MHRA actions that implicated the safety of the BHR and MFH system products. Smith & Nephew failed to do so, causing or contributing to Plaintiffs' injuries.

83. Because Smith & Nephew expressly distinguished the safety of its BHR-THA products from other MOM devices through communications outside their labeling, Plaintiffs' surgeons and the medical community had a misimpression of the true safety of the MFH-BHR system, and continued to implant it into Plaintiffs. Had Smith & Nephew complied with its duties of care and state statutory duties as defined below, Plaintiffs would not have been injured.

84. The failure mechanism of the metal-on-metal THA system therefore can be traced to multiple points of articulation and movement, including between the BHR cup and MFH, but also at the junction of the modular neck sleeve and stem. This second failure mechanism involves only the 510(k) approved components, and involves fretting and crevice corrosion due to micromotion, and a metallurgical reaction of dissimilar metals used in the stem, neck, and head.

B. The Modular Femoral Head THA System Was Never Approved For Sale in the U.S.

85. Defendants designed and sold the cobalt-chrome Modular Femoral Head, or MFH, in both Europe and Asia for use in total hip arthroplasty surgeries. However, because this total hip system relied on the BHR cup from the company's resurfacing portfolio, S&N was not able to gain quick 510(k) approval in the U.S.

86. At the time Smith & Nephew filed the Pre-Market Approval for the Birmingham Resurfacing System (BHR)[11], the application did not include a Modular Femoral Head to be used in the event the femoral resurfacing head of the BHR System failed. At the time, the MFH was available for use with the BHR System in the United Kingdom, Europe, and elsewhere. The ability to substitute the Modular Femoral Head in the event the resurfacing cup failed would avoid the need to remove and replace the BHR Acetabular Cup which would add cost, risk, and patient recovery time.

87. The BHR System was approved by the FDA on May 6, 2006 subject to a number of conditions including post-approval clinical studies, adverse event reporting, surgeon training, and other obligations. *See, e.g.,* Plaintiffs' BHR Master Amended Consolidated Complaint at 56-57, Dkt. 124 (Aug. 11, 2017).

88. The failure of the BHR cup and/or BHR head was a known risk with the system. The lack of a Modular Femoral Head to be used in such an event reduced the appeal of the BHR System for surgeons opting to use the product.

89. To fill this need, Defendants, in October of 2005, filed a traditional 510k Application (K052808) with the FDA to have a Modular Femoral Head cleared for use with the Metal Acetabular Cup of the BHR System. Defendants did not amend their PMA Application to add the Modular Femoral Head to the PMA Application at the time it was still pending. In response to this 510k Application, the FDA requested, in part, the following information and advised:

(a) Clinical data to assess the safety and effectiveness of the total metal-on-metal device for its intended use in order to support its substantial equivalence to predicate devices;

(b) Wear analysis with the wear testing;

[11] Smith & Nephew filed for pre-market approval of the BHR System (July 16, 2004). None of the amendments in the application included the Modular Femoral Head. BHR PMA (P-04033).

(c) A table in which each Modular Femoral Head size with the corresponding acetabular cup style that may be used as a total metal-on-metal hip couple. This information was to be included in a revised device package insert;

(d) It advises that the packing insert does not provide adequate instructions for the use of the subject device; and

(e) The notice also advises that "you may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(i) ..."

90. Defendants failed to submit this requested information, and the 510(k) Application, K052808, was subsequently withdrawn by Smith & Nephew on March 23, 2006.

91. During this time, and until the FDA granted clearance, Defendants were prohibited from marketing or distributing the Modular Femoral Head in the U.S.

92. On May 1, 2006, Defendants filed an abbreviated 510k Application (K061243) to have the MFH cleared. The application's indications for use were limited to the following: "The Modular Femoral Heads are for single use only and are intended to be used as part of a hemi-hip replacement system when articulating against the natural acetabular".

93. On July 17, 2006, the FDA determined the device is substantially equivalent "for the indications for use stated in the enclosure". The enclosure was the Indications for Use approved and signed off on by the FDA Division of General Restorative and Neurological Devices. The indications for use cleared and ordered by the FDA specifically provided "the Modular Femoral Heads are for single use only and are intended to be used as part of a hemi-hip replacement system when articulating against the natural acetabular". The FDA further advised that the issuance of a substantially equivalent determination does not mean the FDA made a determination that the device complies with other requirements of the Act, including the labeling requirements of 21 CFR Part 801. The FDA's notice

further offers assistance with the labeling regulations. However, Smith & Nephew did not accept the offer of assistance with the labeling.

94. Thereafter, on July 28, 2006, Smith & Nephew filed a second traditional 510k application (K062189) to have the Modular Femoral Head cleared with an intended use of articulating against the BHR Modular System's Acetabular Cup as part of a total hip replacement system. Again, the FDA requested significant supporting documentation to clear the application. In addition, Smith & Nephew was advised by the FDA that the "intended use and all supporting data should be submitted as a PMA supplemental to the Birmingham Hip Resurfacing (BHR) System PMA (P-04-0033)". Smith & Nephew did not submit the requested information nor did it amend or supplement the BHR PMA Application. During the pending and until such time as the FDA granted clearance, the Defendant was prohibited from marketing or distributing the Modular Femoral Head to articulate or be combined with the BHR Acetabular Cup. On March 21, 2007, Smith & Nephew withdrew the application. No supplement was filed.

95. On August 15, 2006, Smith & Nephew filed a special 510k application (K062408). The indications for use in this application again were limited as follows: "the Modular Femoral Heads are for single use only and are intended to be used as part of a hemi-hip replacement system when articulating against the natural acetabular." This application added the modular neck sleeve.

96. Design verification testing of this device noted an increased risk in corrosion between the Modular Femoral Head, Tapered Sleeve, and Femoral Stem. These components and the risk of corrosion have nothing to do with the BHR device for which Defendants were granted Pre-Market Approval.

97. On September 12, 2006, the FDA determined the device was substantially equivalent "for the indicated use stated in the enclosure" and cleared the device. The Indication For Use ("IFU")

order approved and signed off on by the FDA Division of General Restorative and Neurological Devices was approved as part of the labeling and packaging. The IFU cleared and ordered by the FDA specifically provided *"the Modular Femoral heads are for single use only and are intended to be used as part of a hemi-hip replacement system when articulating against the natural acetabular"* (i.e., not a metal cup like the BHR). The FDA further advised Smith & Nephew that this finding did not mean that the FDA made a determination that the device complied with other requirements of the Act, including the labeling requirements under 21 CFR 801. The FDA further offered assistance with the labeling regulations. Smith & Nephew did not accept this assistance.

98. On September 30, 2009, Smith & Nephew filed yet another traditional 510k (K093095) seeking to have the Modular Femoral Head cleared for use with the BHR Acetabular Cup. Again, the FDA requested additional information about the safety of the device, which Smith & Nephew did not provide, and Smith & Nephew withdrew the application in February 2010.

99. Smith & Nephew required surgeons in the United States to undergo training before performing BHR Resurfacing surgery, but Defendants failed to inform surgeons that they could only safely implant the BHR after they had performed at least 1,000 surgeries — a fact that was only publicized later by the BHR's inventor, Derek McMinn.[12] During the BHR training process, surgeons were advised that the BHR Resurfacing Head (femoral neck) was subject to failure. However, in the event of such a failure, Defendants informed surgeons that the MFH was available to convert the resurfacing system to an off-label and unapproved total hip arthroscopy.

100. Off-label use in the context of a medical device means the device is used in a way that is not included as an indication approved by the FDA. There are several reasons a physician might use a medical device in an off-label manner. For example, a surgeon might make an error or might not be

[12] https://www.youtube.com/watch?v=o-gco9zNlnA

aware of the approval indications. David Y, et. al., *Issues Associated with Off-Label Use of Medical Devices*, ENG. MED. BIOL. SOC. (2007). Alternatively, a physician might believe an existing device could be modified or used in a unique way to save a patient's life. *Id.*

101. But here, Smith & Nephew failed to obtain the necessary approval from the FDA despite multiple attempts, but decided to market and promote the device anyway to maximize profits.[13]

102. The lack of adequate data about off-label applications of medical devices is, in many cases, a serious challenge to physicians' ability to make sound treatment choices. F. Nahai, *Off-label Drug and Device Applications: Meeting the Challenge,* AESTHETIC SURG. J. (2010).

103. Defendants aggressively promoted the off-label use of the MFH in a THA procedure, and their clandestine marketing campaign was devoid of any steps to inform patients about their MFH devices being used off-label. Smith & Nephew had a duty to inform surgeons and end-users of their products, including Plaintiffs, that the MFH was being used off-label.[14] Defendants failed to take steps to make Plaintiffs aware of this off-label status, and they therefore breached their duty.

104. Smith & Nephew represented that through new design and manufacturing techniques, Smith & Nephew had addressed the issue of metal wear debris and the risks associated with this known phenomenon.

105. Defendants recruited surgeons from the United States for this training and knew they would be applying what they learned in operating rooms in the United States.

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[13] Although the profit motive for Smith & Nephew was clear in this instance, the financial temptations that prompt companies to market off-label is widely known. See, e.g., Richard Ausness, *There's Danger Here, Cherie!: Liability for the Promotion and Marketing of Drugs and Medical Devices for Off-Label Uses*, 73 BROOK. L. REV. 1253 (2007-2008). Defendants' brazen strategy is no surprise given the medical device industry's relentless drive for profits, its $300 billion in annual revenue from the U.S. market, and its chief lobbyist's claim that it boasts more power than the regulatory agencies that govern it. *See* The Bleeding Edge (Netflix 2018) ("Sure, we'll pay attention to Washington, that's my job, that's what I do — but we have more power in this room than most governments around the world," Scott Whitaker, President & CEO of Advanced Medical Technology Association.).

[14] N. Lennard, et. al., *The Surgeon and Medical Devices: Adverse Incident Reporting and Off-Label Use*, ANN. R. COLL. SURG. ENG. (July 2013).

106. The FDA's approval of the "hemi head" was limited to Defendants' intended use of the MFH in a hemiarthroplasty, usually as part of a revision surgery of a BHR or to repair a fracture. Defendants did not inform the FDA that they intended to market the MFH for use in a total hip arthroplasty, and they did not tell the FDA that they intended to promote the device for use with the BHR acetabular cup.

107. However, the number of patients implanted with an MFH in a hemiarthroplasty was very small, and Defendants knew that the far greater demand was for the MFH being paired with the cobalt-chrome BHR cup in a total hip arthroplasty, along with the modular neck sleeve and a traditional femoral stem.[15]

108. As just one example of Smith & Nephew's awareness of the off-label and unapproved use of the MFH, a search for adverse events related to the MFH reveals 152 such reports, with numerous events and injuries taking place in 2006, the same year that the BHR device was approved for use in the U.S.[16] However, even though Smith & Nephew had an obligation to report these MFH failures to the FDA in a timely manner, many of the adverse events were in fact not sent to the FDA until 2012 or later.[17] Furthermore, the number of overall adverse events for the MFH that were reported to the FDA is much smaller than the number of lawsuits that Smith & Nephew have settled in recent years, suggesting that numerous adverse events were and still are not being reported at all.[18]

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[15] Hemiarthroplasty procedures, usually indicated for a fractured hip, make up only about 10 percent of all hip replacements in the U.S. annually, compared to about 80 percent for total hip replacements, and another 10 percent for revision surgeries. Hip resurfacing procedures, such as those that include the BHR, make up less than 1 percent of all hip procedures. American Joint Replacement Registry, 2016 Annual Report at 14-15, available at http://www.ajrr.net/images/annual_reports/AJRR_2016_Annual_Report_final.pdf

[16] FDA MAUDE Database, available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm (last visited July 30, 2018).

[17] The results of the database search, performed by the undersigned counsel, reveal numerous references to "off-label" use of the MFH in a metal-on-metal total hip arthroplasty. Many of the events were reported by patients or attorneys, and not by S&N or PLC. Some patients described a "nightmare" due to metallosis. Others described elevated cobalt and chromium levels, pseudotumors, and similar signs of premature failure.

[18] Smith & Nephew Annual Report 2017, citing legal costs of $225 million in 2016 and $190 million in 2017 for metal-on-metal hip legal costs respectively, available at http://www.smith-nephew.com/global/assets/pdf/corporate/2017%20ar%20-%20interactive%20final.pdf

109. Notwithstanding these limited indications of approval, the combination of modular components gave Smith & Nephew an entry into the lucrative and growing market for metal-on-metal total hip arthroplasty systems in the U.S. These all-metal systems typically a more expensive than similar components made of ceramic or polyethylene, and are marketed to younger and more active patients. Even better for Defendants, the unapproved MFH could be used in either an initial, or primary THA, or as a replacement device for a patient with a failed BHR system who required conversion to a THA system with a well-fixed acetabular cup.[19] Smith & Nephew thus had two powerful incentives for marketing the MFH system, neither of which was approved by the FDA in its labeling.

110. Smith & Nephew's executives also knew that substantial unanswered safety questions existed with regard to metal-on-metal hip systems, but they instructed the S&N subsidiary in Memphis to sell the metal-on-metal devices anyway so as to maximize profit and to provide an additional revenue stream for the company when patients' BHR systems failed and required a revision surgery.

111. The BHR resurfacing system offers just two components — an acetabular cup and a femoral head affixed to the femur with a metal pin. When the resurfacing system fails, Smith & Nephew promoted the MFH — without approval from the FDA — as a replacement device along with a traditional femoral stem such as the Anthology or Synergy. Alternatively, they promoted the MFH and traditional femoral stem as part of an initial, or primary, total hip arthroplasty. Regardless of the manner in which the MFH is used, ***it is not approved for sale or use in the United States*** in combination with the BHR cup, and Defendants have been told repeatedly by U.S. regulatory authorities not to promote or allow this illegal use.

112. Despite this lack of approval, Defendants sold and marketed the MFH in the U.S. as part of a THA system for years beginning in 2006 and collected massive profits, despite early reports

[19] B. Bolland, et. al., *High Failure Rates with a Large-Diameter Hybrid Metal-on-Metal Total Hip Replacement*, J. BONE AND JOINT SURG. (Br.), 2011;93-B:608-15.

about unacceptably high failure rates for the unapproved system. Smith & Nephew typically refers to the device as the Birmingham Hip Modular Head, or BHMH, in the United Kingdom. It calls the device the MFH in the U.S. market.

113. Smith & Nephew issued a Class II recall for the BHR system on September 10, 2015, due to high failure rates, especially for women. However, Smith & Nephew never issued a formal recall for the THA "mix and match" system in the U.S. because it was ***never approved*** for a THA in the first place. Instead, Defendants engaged in a silent market withdrawal without informing patients and/or the medical community whatsoever.

114. One of the only signs of the market withdrawal for the MFH was an "Urgent Field Safety Notice" issued in late 2014 in the United Kingdom for the MFH, stating that the device's IFU was being revised due to a higher than expected revision rate. The urgent notice was signed by Andy Weymann, Chief Medical Officer, but it is undated, and it is unclear whether the notice was ever sent to the FDA or to surgeons in the United States. Importantly, the 2014 notice does not mention the MFH being used in a hemiarthroplasty whatsoever. Instead, it states that the MFH is only to be used in combination with a BHR cup, which is not legal or approved in the United States. Defendants directed surgeons to call them in Europe, and directed them to a website, http://BHMH.smith-nephew.com, that no longer exists.

115. Separately, Defendants issued an "advisory notice" to the FDA in November 2015 alerting the agency that the MFH was being used off-label with the BHR and that 16 of the devices had been sold with surgical instructions for a total hip arthroplasty as opposed to a hemiarthroplasty.

116. All of Plaintiffs' claims involve surgical implantation of the BHR cup in combination with the MFH, the modular neck sleeve, and a traditional femoral stem such as the Anthology, Synergy, or Echelon.

117. Just as the 510(k) for the MFH did not allow its use in a THA procedure, the approval order for the acetabular BHR cup was likewise limited to it being used in a resurfacing procedure, and was part of a Premarket Approval application ("PMA") submitted by Smith & Nephew to the FDA.

118. Plaintiffs' hip implant surgeries included a PMA-approved BHR acetabular cup, in combination with an MFH and femoral stem that were never approved for use with the BHR cup as part of the above-referenced FDA letter, and all of these components together comprise the unapproved metal-on-metal THA. Plaintiffs' THA was not approved by the FDA, is an off-label use, and does not enjoy any of the protections or recommendations related to the FDA approval for the resurfacing system.

119. The practical impact of the widespread off-label use of the MFH is that patients were not informed about the dangers of this off-label system, in part because there was no approved labeling for U.S. surgeons and patients. Likewise, surgeons were not given instructions about how to adequately implant and use the MFH system, because there were no approved surgical instructions.

120. Smith & Nephew knew or should have known that its lack of instructions and lack of FDA approval made it difficult to track the safety of the THA device, and therefore made Plaintiffs unsafe because Smith & Nephew lacked the incentive — or even the ability — to issue a recall for a device that was never approved in the first place.

121. Even though the modular THA total hip system was not approved by the FDA, the decision to implant Defendants' BHR acetabular component with the MFH, modular neck sleeve and traditional femoral stem, was based on specific express and implied representations made by Defendant Smith & Nephew to Plaintiffs' surgeons and others, including:

a. Marketing materials such as the Smith & Nephew Birmingham Hip Resurfacing System "Metal-on-Metal: Questions & Answers" that expressly states, "If the acetabular component is well positioned, well fixed and undamaged it is totally acceptable to leave the cup in-situ;"

b. Smith & Nephew training provided to Plaintiffs' surgeons and their dealings with Smith & Nephew's sales representatives that led them to understand it was permissible to use Defendants' femoral stem, modular head sleeve and MFH with Defendant's BHR acetabular component;

c. Smith & Nephew training courses attended by Plaintiffs' surgeons that included written materials and instructional videos that did not advise the surgeons that it was not permissible to use the femoral stem, modular head sleeve and MFH head **with** the BHR acetabular component;

d. Defendant Smith & Nephew's sales representatives' conduct of bringing Defendant's femoral stem, Modular Head Sleeve and MFH to total hip arthroplasty and revision procedures on other patients of Plaintiffs' surgeons to be available for use leading the surgeons to believe that they were safe to use together;

e. Defendant Smith & Nephew's sales representatives' conduct of bringing Defendant's femoral stem, Modular Head Sleeve and MFH to Plaintiffs' initial total hip arthroplasty surgery, without telling the surgeons that said Class II components could not be safely used with the BHR acetabular component; and/or

f. The fact that if Defendants' sales representatives had told Plaintiffs' surgeons that the BHR cup could not be used with the femoral stem, MFH and Modular Head Sleeve and that the BHR cup could only be used with the BHR femoral head and that such use was in violation of the PreMarket Approval granted by the FDA, and in violation of the 510(k) for the MFH, the surgeons would have never used the BHR cup in Plaintiffs' total hip arthroplasty.

122. Defendants' marketing, distribution, training and/or permitted use of its femoral stem, modular head sleeve and MFH with its BHR acetabular cup violate the Federal Food, Drug and Cosmetic Act ("Act"), the regulations promulgated to it and the PMA and 510(k) orders granted to Smith & Nephew by the FDA. Specifically, the conduct of Smith & Nephew's sales representatives, including the training it provided to surgeons, and its marketing materials resulted in Plaintiffs' surgeons using an unreasonably dangerous device in Plaintiff and a combination of devices which were not approved by the FDA to be used in conjunction with one another.

123. Defendants' marketing, distribution, training and/or permitted use of its MFH with its BHR acetabular cup violates, among other things, the 510(k) approval by the FDA for the MFH because the modular femoral heads were only approved for articulation against the natural acetabulum as the intended use, not in a "mix and match" combination with a prosthetic acetabular cup like the BHR. The 510(k) approval method does not require that the manufacturer prove the safety and efficacy of the device under submission. Rather, this notification is based on the proposed device being "substantially equivalent" to another medical device already on the market pursuant to CFR 807.92(a)(3).[20]

124. The FDA did not approve the combination of these components, which creates a metal-on-metal articulation, leading to toxic metal ions of cobalt and chromium being released into the patient's body, eventually causing metallosis and other damage to the hip joint. Plaintiffs' unapproved total hip systems failed because of the metallurgical and biomechanical interaction between all of its metal-on-metal components, due to tens of thousands of natural articulations of the total hip system components over the course of Plaintiff's normal daily activity. The failure of the unapproved total hip system is therefore due to the metal debris generated by the articulation of the 510(k) approved components with the PMA-approved acetabular cup when used together.

125. The failure of the THA system is also due in part to micromotion and fretting at the stem-neck junction of the THA system, which is caused entirely by the interaction of the 510(k) approved components of the THA system, without regard to the BHR cup whatsoever. This failure is a well-documented for modular hip systems, and can lead to corrosion at the neck-stem junction,

[20] The 510(k) Premarket Notification process is described in more detail on the FDA's website. https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm (last visited February 21, 2018).

trunnionosis, and/or cold welding of the neck and stem junction due to the metallurgical reaction between dissimilar metals in these components.

126. In February 2015, Defendants conducted a Clinical Health Hazard Evaluation on the MFH and Modular Taper Sleeve, and determined that the taper junction at the Modular Taper Sleeve interface with the stem and the MFH presented an increased risk of fretting, corrosion, and accelerated release of metal debris and ions.

127. As part of this HHE, Smith & Nephew acknowledged that they had been aware that the MFH was being used by surgeons with the BHR Acetabular Cup in a metal-on-metal THA, contrary to the refusal of the FDA to approve such a use.

128. It was the duty of Defendants, Smith & Nephew, to comply with federal regulations for medical devices, including the PMA and 510(k) orders from the FDA. Notwithstanding this duty, Defendants violated the regulations and the PMA and the 510(k) in one or more of the following ways, as evidenced by the conduct described above, among other conduct:

a. Failed to submit a PMA supplement for review and approval by the FDA. 21 C.F.R.§814.39;

b. Defendants sold, distributed and permitted use of their devices in violation of the regulations prescribed under 21 U.S.C. §360j(e). 21 U.S.C. § 352(q);

c. Failed to restrict the use of the MFH to only hemiarthroplasty surgeries, as opposed to THA surgeries. 21 U.S.C. §352(r);

d. Failed to comply with the requirements of 21 U.S.C. §§§ 360h, 360i, and 360l;

e. Failed to implement a proper training course for surgeons using the MFH and BHR devices as required by the PMA Order, the 510(k) orders, and in violation of the Act;

f. Failed to properly train surgeons using Defendant's MFH and BHR devices on the permitted use of the devices and their respective component parts and failed to properly train and/or instruct surgeons on

what products/devices surgeons could and/or could not use in a total hip arthroplasty; and/or

g. Failed to, among other things, properly train and instruct surgeons on the proper and intended use of the modular femoral head and otherwise comply with the FDA's 510(k).

COUNT I
STRICT PRODUCTS LIABILITY - DESIGN DEFECT AND FAILURE TO WARN

129. Plaintiffs herein incorporate, reassert and reallege the allegations set forth above as if fully set forth herein below.

130. Defendants designed and/or manufactured the THA system implanted in Plaintiffs' hip joints in violation of federal regulations and various state laws, as well as the duties created by virtue of the agreements in both the 510(k) and PMA orders related to the various components used in this system.

131. At the time the THA systems left the control of Defendants, they were unreasonably dangerous due to Defendant's non-compliance with the Act, in one or more of the following ways.

a. Failed to accurately establish the in vivo life expectancy, in violation of 21 C.F.R. 820.30(f);

b. Failed to validate the anticipated wear of the acetabular cup prior to its release into commercial distribution, in violation of 21 C.F.R. 820.30(g);

c. Failed to establish and maintain appropriate reliability assurance testing to validate the BHR-THA system design both before and after its entry into the marketplace, in violation of 21 C.F.R. 820.30 (g);

d. Failed to conduct adequate bio-compatibility studies to determine the THA's latent propensity to effuse metallic contaminants into the human blood and tissue;

e. Failed to identify the component discrepancy, in violation of 21 C.F.R. 820.80(c);

f. Failed to capture the component discrepancy or defect during their Final Acceptance Activities, in violation of 21 C.F.R. 820.80(d);

g. Failed to establish and maintain procedures for implementing corrective and preventative action in response to, *inter alia*, complaints regarding the THA system, returned THAs, and other quality problems associated with the THA, in violation of 21 C.F.R. 820.100;

h. Failed to appropriately respond to adverse incident reports and complaints that strongly indicated the acetabular component was Malfunctioning [as defined in 21 C.F.R. 803.3], or otherwise not responding to its Design Objective Intent, in violation of 21 C.F.R. 820.198;

i. Failed to conduct complete device investigations on returned BHR and components, including the acetabular component, in violation of 21 C.F.R. 820.198; and/or

j. Continued to place the THA into the stream of interstate commerce when it knew, or should have known, that the acetabular component was malfunctioning [as defined in 21 C.F.R. 803.3] or otherwise not responding to its Design Objective Intent.

k. Failed to investigate reports of User Error so as to determine why User Error was occurring and to try to eliminate User Error in the future through improved physician training.

132. Smith & Nephew's failure to comply with the above-stated requirements is evident through the following non-exhaustive list of malfeasance, misfeasance, and/or nonfeasance on the part of Defendant:

a. Smith & Nephew allowed and encouraged their commission-based salesmen to not report adverse events and complaints such as revision surgeries for the THA system, thereby substantially reducing the known and reported incidence of product problems;

b. Smith & Nephew willfully ignored the existence of numerous adverse events and complaints, such as revision surgeries, which they knew or should have known were not being reported to the company or the FDA;

c. Smith & Nephew received hundreds of adverse reports regarding the BHR-THA system but delayed their reporting to the FDA, or did not report the events at all;

d. Smith & Nephew failed to properly communicate adverse events to the FDA when they did report them, and when doing so, wrongly attempted to blame others for the adverse events;

e. Smith & Nephew also failed to analyze the adverse events and revision surgeries of which they was aware to determine why so many revisions were required so soon after implantation;

f. Smith & Nephew failed to investigate and report on "unanticipated events," i.e., any adverse event not listed on the label;

g. Smith & Nephew failed to investigate all Device Failures;

h. Smith & Nephew failed to revise their instructions to doctors and its surgical techniques documents to reflect the true problematic experience with the THA;

i. Smith & Nephew also knew but failed to disclose that some of the surgeons – both overseas and domestically - upon whose data they relied to boast a high success rate for the THA had been given financial incentives in order to use the THA;

j. Smith & Nephew willfully ignored the existence of numerous complaints about failures associated with components of the THA that were being used in illegal combinations throughout the United States when, in fact, those revision surgeries should have been thoroughly investigated because such usage constitutes an unlawful design change and would provide insight into possible problems that may not be readily seen when the THA system was used as a completed, unaltered system;

k. Smith & Nephew, as a result of increased demand for the product and a desire to conceal widespread off-label use, failed to properly train all surgeons and Original Core Surgeons using the product as required by the Approval Order by using shortcuts, such as teaching surgeons by satellite instead of hands on as it had assured the FDA and by failing to require those surgeons to receive such training directly from the product designers in the United Kingdom or from Original Core Surgeons;

l. Smith & Nephew also misrepresented to the surgeons in the United States that *in vivo* testing of the THA had been undertaken when Defendant, in fact, knew or should have known that the testing was invalid and the results unreliable.

m. Smith & Nephew &failed to timely supplement its labeling as required in the Approval Order with information pertaining to the various failures of the BHR system, thereby misrepresenting the efficacy and safety of the BHR resurfacing products to the FDA and actively misleading the FDA, the medical community, patients, and public at large into believing that the THA system was safe and effective when it was not by, among other things, claiming to have

> solved the problem of metal-on-metal friction due to a "fluid film" theory that has proven untrue.

133. As a direct and proximate result of Defendants' violations of one or more of these federal statutory and regulatory standards of care, a THA system was implanted in Plaintiffs' hip joints, and its subsequent failure directly and proximately caused and/or contributed to the severe and permanent injuries the Plaintiff sustained. As a direct and proximate result, Plaintiff endured pain and suffering and has required additional and debilitating surgeries and has incurred significant medical expenses in the past and will incur additional medical expenses in the future; both past and future wage loss; both past and future non-economic damages including, but not limited to, physical and mental pain and suffering, inconvenience, emotional distress and impairment of the quality of his life; and permanent impairment and disfigurement.

134. This cause of action is based entirely on the contention that Defendants, Smith & Nephew, violated federal safety statutes and regulations, as well as the conditions established in the Approval Orders with which Defendants agreed to comply to obtain PMA and 510(k) approval of the device components, respectively. Plaintiffs do not bring the underlying action as an implied statutory cause of action, but insofar as the BHR component is implicated in their claims, they are pursuing parallel state law claims based upon Defendant, Smith & Nephew's violations of the applicable federal regulations and Approval Order.

135. Further, because the BHR cup was only approved for use in resurfacing procedures, any use with other components as part of a THA procedure are not provided the same express preemption protections as PMA devices.

136. Under the law of the various states where Plaintiffs reside and where their implants and revisions took place, Defendants' violations of the aforementioned federal statutes and regulations establish a *prima facie* case of strict liability in tort.

137. Thus, under these various states' laws, a money damages remedy exists for violation of the Act and regulations promulgated thereunder which results in an unreasonably dangerous product proximately causing injuries.

138. The Act contains an express preemption provision, 21 U.S.C. §360(k), which in relevant part states: "no state or political subdivision of a state may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this Act [21 USCS §§301, et seq.] to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act [21 USCS §§301, et seq.]."

139. However, the cause of action set forth here is not preempted by 21 U.S.C. §306(k) because the BHR-THA system was not approved for sale in the U.S. under either 510(k) or PMA guidelines, and because the violations alleged here are all based on an exclusively federal statutory and regulatory set of requirements and express agreements with the FDA which include no "requirement which is different from, or in addition to, any requirement applicable under" the Act and regulations promulgated thereunder, and because Plaintiff was injured by metal debris from components that are not subject to express preemption under 21 U.S.C. §360(k).

140. According to duties imposed by the PMA and 510(k) orders, Smith & Nephew had the on-going duty to provide the FDA with adverse event and defective device reports regarding the BHR-THA system components. In the majority of states where Plaintiffs reside, there is a parallel state duty to monitor the sale and use of the BHR and/or BHR-THA products, to discover defects associated with the products, and to warn the medical community, consumers, and Plaintiffs of any dangers associated with the device after the original implantation of the device. As discussed above and incorporated herein, Smith & Nephew made numerous representations to the medical community, the general

public, and potential patients, touting the safety of Smith & Nephew's BHR-THA products over the course of several years.

141. Smith & Nephew left the impression with surgeons and the medical community that the failure rate of the BHR was lower than it really was - and that the BHR was safe - by failing to provide updated studies and survivorship, including Smith & Nephew's own PMA-mandated studies.

142. Specifically, Smith & Nephew had actual and constructive knowledge of the risks associated with the BHR device, and failed to post-sale warn the medical community, consumers, and Plaintiff in particular:

a. Smith & Nephew was obligated and failed to take reasonable efforts to issue a post-sale warning to the medical community, consumers, and the Plaintiff of the defective and unreasonably dangerous condition associated with the BHR-THA system that was available either at the time of distribution or in sufficient time before Plaintiffs' injury so that an effective and reasonable supplemental warning could have been given; and/or

b. Smith & Nephew was obligated and failed to take reasonable efforts to warn the medical community, consumers, and Plaintiff of the defective and unreasonably dangerous condition associated with the BHR-THA system that was unknown at the time of sale but which was subsequently discovered after the sale of the device; and/or

c. Smith & Nephew failed to take reasonable efforts to issue a post-sale warning after learning of the BHR-THA system's high failure rates and risks associated with metal ions when a reasonable person in Smith & Nephew's position would have provided such a warning to the medical community, consumers, and Plaintiffs in particular; and/or

d. Smith & Nephew had the obligation to and failed to take reasonable efforts to issue a post-sale warning when it knew or should have known of significant hazards associated

with misuse or alteration of the BHR-THA system. The foreseeable use of the system was unreasonably unsafe and Smith & Nephew was required to warn the medical community, consumers, and Plaintiffs; and/or

e. Smith & Nephew had the obligation and failed to take reasonable efforts to issue a post-sale warning after the initial sale of the BHR-THA system because it commenced and/or had knowledge of safety-related research sufficient to induce the medical community, consumers, and Plaintiffs to reasonably expect Smith & Nephew to disseminate hazard information.

143. Smith & Nephew's failure to carry out its duty to post-sale warn caused Plaintiffs' injuries.

144. Smith & Nephew's failure to carry out its duty to post-sale warn was a proximate cause of Plaintiffs' injuries; and/or

145. Smith & Nephew's failure to carry out its duty to warn post-sale was a direct cause of Plaintiffs' injuries; and/or

146. Smith & Nephew's failure to carry out its duty to post-sale warn was a substantial factor resulting in Plaintiffs' injuries.

147. Smith & Nephew designed and/or manufactured the BHR-THA system implanted in Plaintiffs' bodies, in violation of the Federal Food, Drug and Cosmetic Act ("Act") and regulations promulgated pursuant to it, as well as the duties created by virtue of the agreements in the Approval Order.

148. At the time the BHR-THA system, including the BHR cup, MFH, modular neck sleeve and traditional femoral stem, left the control of Smith & Nephew, they were unreasonably dangerous

due to Defendant's non-compliance with the Act, and the regulations promulgated pursuant to it and the PMA and 510(k) approval orders in one or more of the following ways:

a. Failed to accurately establish the in vivo life expectancy of the BHR-THA system, in violation of 21 C.F.R. § 820.30(f);

b. Failed to validate the anticipated wear of the acetabular cup, MFH, and modular neck sleeve and traditional femoral stem prior to their release into commercial distribution, in violation of 21 C.F.R. § 820.30(g). For example, as recently as 2012, Smith & Nephew admitted to the FDA that *in vitro* wear data from machine simulators had little clinical relevance to the performance of the BHR-THA system *in vivo*;

c. Failed to establish and maintain appropriate reliability assurance testing to validate the BHR-THA system design both before and after its entry into the marketplace, in violation of 21 C.F.R. § 820.30 (g);

d. Failed to conduct adequate bio-compatibility studies to determine the BHR-THA system's latent propensity to effuse metallic contaminants into the human blood and tissue. Instead of conducting adequate studies, Smith & Nephew attempted to blame bio-compatibility studies on, among other things, patients who wear costume jewelry;

e. Failed to identify the component discrepancy, in violation of 21 C.F.R. § 820.80(c);

f. Failed to capture the component discrepancy or defect during their Final Acceptance Activities, in violation of 21 C.F.R. § 820.80(d);

g. Failed to establish and maintain procedures for implementing corrective and preventative action in response to, *inter alia*, complaints regarding the BHR-THA system, returned BHR-THA system components, and other quality problems associated with the BHR-THA system, in violation of 21 C.F.R. § 820.100;

h. Failed to appropriately respond to adverse incident reports and complaints that strongly indicated the BHR-THA system was malfunctioning [as defined in 21 C.F.R. § 803.3], or otherwise not responding to its Design Objective Intent, in violation of 21 C.F.R. § 820.198. For example, instead of adequately investigating these incidents, Smith & Nephew in its reports to the FDA blamed catastrophic product failures of the BHR on generalized issues such as "pain" or "squeaking" or "allergic reaction," or it blamed surgeons for implanting the BHR-THA system off-label;

i. Failed to conduct complete device investigations on returned BHR-THA system components, in violation of 21 C.F.R. § 820.198;

j. Continued to place the BHR-THA system into the stream of interstate commerce when it knew, or should have known, that the components were Malfunctioning [as defined in 21 C.F.R. § 803.3] or otherwise not responding to its Design Objective Intent; and/or,

k. Failed to investigate reports of User Error so as to determine why User Error was occurring and to try to eliminate User Error in the future through improved physician training, or any training at all;

149. Smith & Nephew's failure to comply with the above-stated requirements is evident through the following non-exhaustive list of malfeasance, misfeasance, and/or nonfeasance on the part of Defendant:

a. Smith & Nephew allowed and encouraged its commission-based salesforce to not report adverse events and complaints such as revision surgeries, thereby substantially reducing the known and reported incidence of product problems, which is in part illustrated by the trend that the majority of adverse events were only reported to the FDA after Plaintiffs filed lawsuits against Smith & Nephew;

b. Smith & Nephew willfully ignored the existence of numerous adverse events and complaints, such as revision surgeries, which it knew or should have known were not being reported to the company or the FDA;

c. Smith & Nephew received hundreds of adverse reports regarding the BHR-THA system but delayed its reporting to the FDA or did not report at all;

d. Smith & Nephew failed to properly communicate adverse events to the FDA, when it did report them, and when doing so, wrongly attempted to blame others for the adverse events;

e. Smith & Nephew also failed to analyze the adverse events and revision surgeries of which it was aware to determine why so many revisions were required so soon after implantation;

f. Smith & Nephew failed to investigate and report on "unanticipated events," i.e., any adverse event not listed on the label;

g. Smith & Nephew failed to investigate all Device Failures;

h. Smith & Nephew failed to revise its instructions to doctors and its surgical techniques documents to reflect the true problematic experience with the BHR-THA system;

i. Smith & Nephew also knew but failed to disclose that some of the surgeons — both overseas and domestically — upon whose data it relied to boast a high success rate for the BHR-THA system had been paid financial remuneration in order to use and promote the BHR-THA system;

j. Smith & Nephew, as a result of increased demand for the product, failed to properly train all surgeons using the products as required by the PMA and/or 510(k) approval orders, or by using shortcuts, such as teaching surgeons by satellite instead of hands on

as it had assured the FDA and by failing to require those surgeons to receive such training directly from the product designers in the United Kingdom or from Original Core Surgeons;

k. Smith & Nephew also misrepresented to the surgeons in the United States that *in vivo* testing of the BHR-THA system had been undertaken when Defendants, in fact, knew or should have known that the testing was invalid and the results unreliable;

l. Smith & Nephew represented to medical professionals and Plaintiffs that the BHR-THA system was safer than other metal-on-metal devices, had a low revision/failure rate, and was safe for use by communicating statistics and actions from health authorities, but failing to update the medical community and Plaintiffs when additional information became available and as new risks arose, leaving a false impression in the minds of the medical community and Plaintiffs about the safety of the BHR-THA system; and

m. Smith & Nephew failed to timely supplement its labeling as required in the approval orders with information pertaining to the various failures of the BHR-THA system, thereby misrepresenting the efficacy and safety of the products to the FDA and actively misleading the FDA, the medical community, patients, and public at large into believing that the system was safe and effective when it was not by, among other things, claiming to have solved the problem of metal-on-metal friction due to a "fluid film" theory that has proven untrue.

150. As a direct and proximate result of Defendants' violations of one or more of these federal statutory and regulatory standards of care, a BHR-THA system, including the acetabular cup and MFH, with a modular neck sleeve and traditional femoral stem, was implanted in Plaintiffs' body,

either as part of a primary or revision surgery, and failed and such failure directly and proximately caused and/or contributed to the severe and permanent injuries Plaintiffs sustained and endured as defined in 21 C.F.R. § 803.3. As a direct and proximate result, Plaintiffs endured pain and suffering and has required additional and debilitating surgeries and has incurred significant medical expenses in the past and will incur additional medical expenses in the future; both past and future wage loss; both past and future non-economic damages including, but not limited to, physical and mental pain and suffering, inconvenience, emotional distress and impairment of the quality of his life; and permanent impairment and disfigurement.

151. This cause of action is based in part on the contention that Smith & Nephew's actions that violated the state statutes and common laws listed below also violated parallel federal safety statutes and regulations, as well as the conditions established in the PMA Approval Order and/or 510(k) clearance, with which Defendants agreed to comply to obtain approval of the BHR-THA system.

152. Smith & Nephew violated each state's laws regarding unsafe and dangerous products, and those claims are viable for all Plaintiffs because there is no express preemption for the THA devices.

153. Under Alabama law, the Alabama Extended Manufacturer's Liability Doctrine (AEMLD), Al. Civ. Pr. § 6-5-501, the BHR-THA system reached Plaintiffs without substantial change in the condition in which it was sold and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described above, which made the product unreasonably dangerous.

154. Under Alaska law, the BHR-THA system reached Plaintiffs without substantial change in the condition in which it was sold, and was used without inspection for defects and created a

dangerous scenario for Plaintiffs and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described above, which made the product unreasonably dangerous.

155. Under Arizona law, the risks of the BHR-THA system outweighed the potential benefit, and the products reached Plaintiffs without substantial change in the condition in which it was sold and was unreasonably dangerous when it left the Defendant's possession, and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described above.

156. Under Arkansas law, the BHR-THA system products reached Plaintiffs without substantial change in the condition in which it was sold and was unreasonably dangerous when it left the Defendants' possession, and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described above.

157. Under California law, the BHR-THA system designed, manufactured and sold by Defendants were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein, and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described here and above.

158. Under Colorado law, the BHR-THA system designed, manufactured, and sold by Defendant, reached Plaintiffs without substantial change in the condition in which it was sold and was unreasonably dangerous when it left the Defendants' possession, and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described herein and above.

159. Under Connecticut law, the BHR-THA system designed, manufactured, and sold by Defendants, reached Plaintiffs without substantial change in the condition in which it was sold and was unreasonably dangerous when it left the Defendant's possession, and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described herein and above.

160. Under District of Columbia law, the BHR-THA system designed, manufactured and sold by Defendants were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein, reached Plaintiffs without substantial change in the condition in which it was sold and was unreasonably dangerous when it left the Defendants' possession, and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described herein and above.

161. Under Florida law, the BHR-THA system designed, manufactured and sold by Defendants were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein, reached Plaintiffs without substantial change in the condition in which it was sold and was unreasonably dangerous when it left the Defendant's possession, and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described herein and above.

162. Under Georgia law, the BHR-THA system when sold, was not merchantable and reasonably suited to its intended use, and reached Plaintiffs without substantial change in the condition in which it was sold, and was unreasonably dangerous when it left the Defendants' possession, and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described herein and above.

163. Under Hawaii law, the BHR-THA system designed, manufactured and sold by Defendants were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein, and reached Plaintiffs without substantial change in the condition in which it was sold and was unreasonably dangerous when it left the Defendants' possession, and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described herein and above.

164. Under Idaho law, the BHR-THA system designed, manufactured and sold by Defendant were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein, and reached Plaintiffs without substantial change in the condition in which it was sold and was unreasonably dangerous when it left the Defendant's possession, and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described herein and above.

165. Under Illinois law, the BHR-THA system designed, manufactured and sold by Defendant were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein. The risks inherent in the system outweighed the benefits, beyond the expectations of an ordinary consumer, such as Plaintiffs, and the system products reached Plaintiffs without substantial change in the condition in which it was sold and was unreasonably dangerous when it left the Defendant's possession, and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described herein and above.

166. Under the Indiana Product Liability Law, Ind. Code § 34-20-4-1, the BHR-THA system reached Plaintiffs without substantial change in the condition in which it was sold and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described above, which made the product unreasonably dangerous.

167. Under Iowa law, the BHR-THA system designed, manufactured and sold by Defendants was defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein. The risks inherent in the system outweighed the benefits, beyond the expectations of an ordinary consumer, such as Plaintiffs, and the system reached Plaintiffs without substantial change in the condition in which it was sold and was

unreasonably dangerous when it left the Defendants' possession, and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described herein and above.

168. Under Kansas law, the BHR-THA system designed, manufactured and sold by Defendants was defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein. The risks inherent in the system outweighed the benefits, beyond the expectations of an ordinary consumer, such as Plaintiffs, and the system reached Plaintiffs without substantial change in the condition in which it was sold and was unreasonably dangerous when it left the Defendants' possession, and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described herein and above.

169. Under the Kentucky Product Liability Act: Ky. Rev. Stat. Ann. § 411.300, the BHR-THA system reached Plaintiffs without substantial change in the condition in which it was sold and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described above, which made the product unreasonably dangerous.

170. Under the Louisiana Products Liability Act (LPLA), La. Rev. Stat. Ann. §9:2800.51-.53(7), the BHR-THA system reached Plaintiffs without substantial change in the condition in which it was sold and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described above, which made the product unreasonably dangerous.

171. Under Maine law, the BHR-THA system products designed, manufactured and sold by Defendant were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein. The risks inherent in the system outweighed the benefits, beyond the expectations of an ordinary consumer, such as Plaintiffs, and the system reached Plaintiffs without substantial change in the condition in which it was sold and was

unreasonably dangerous when it left the Defendants' possession, and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described herein and above.

172. Under Maryland law, the BHR-THA system designed, manufactured and sold by Defendants were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein, and reached Plaintiffs without substantial change in the condition in which it was sold and was unreasonably dangerous when it left the Defendant's possession, and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described herein and above.

173. Under Massachusetts law, the BHR-THA system, when sold by Defendants, was not merchantable and reasonably suited to its intended use, and reached Plaintiffs without substantial change in the condition in which it was sold, and was unreasonably dangerous when it left the Defendant's possession, and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described herein and above.

174. Under Michigan law, the BHR-THA system, when sold, was not merchantable and reasonably suited to its intended use, and reached Plaintiffs without substantial change in the condition in which it was sold, and was unreasonably dangerous when it left the Defendants' possession. Moreover, at the time of distribution, a safer alternative design was available, was practicable, and would have reduced the risk of injury posed by the BHR-THA system. Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described herein and above. The likelihood of the injuries here was foreseeable by Defendants at the time the product left the Defendants' control.

175. Under Minnesota law, the BHR-THA system designed, manufactured and sold by Defendants were defectively designed and failed to include sufficient instructions and warnings of the

potential safety hazards and failure modes, as alleged herein, and reached Plaintiffs without substantial change in the condition in which it was sold and was unreasonably dangerous when it left the Defendants' possession, and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described herein and above.

176. Under the Mississippi Product Liability Act (MPLA), Miss. Code Ann. § 11-1-63(a)(iii), the BHR-THA system reached Plaintiffs without substantial change in the condition in which it was sold and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described above, which made the product unreasonably dangerous.

177. Under Missouri law, the BHR-THA system products designed, manufactured and sold by Defendant were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein, and reached Plaintiffs without substantial change in the condition in which it was sold and was unreasonably dangerous when it left the Defendant's possession. Plaintiffs' use of the device was entirely reasonable and foreseeable, and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described herein and above.

178. Under Mont. Code Ann. § 27-1-719, the BHR-THA system reached Plaintiffs without substantial change in the condition in which it was sold and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described above, which made the product unreasonably dangerous.

179. Under Nebraska law, the BHR-THA system designed, manufactured and sold by Defendants were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein, and reached Plaintiffs without substantial change in the condition in which it was sold, were used without inspection for defect, and was

unreasonably dangerous when it left the Defendant's possession. Plaintiffs' use of the device was entirely reasonable and foreseeable, and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described herein and above.

180. Under Nevada law, the BHR-THA system designed, manufactured and sold by Defendants were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein, and reached Plaintiffs without substantial change in the condition in which it was sold, were used without inspection for defect, and was unreasonably dangerous when it left the Defendants' possession. Plaintiffs' use of the device was entirely reasonable and foreseeable, and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described herein and above.

181. Under New Hampshire law, the BHR-THA system designed, manufactured and sold by Defendants were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein, and reached Plaintiffs without substantial change in the condition in which it was sold, were used without inspection for defect, and was unreasonably dangerous when it left the Defendants' possession. Plaintiffs' use of the device was entirely reasonable and foreseeable, and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described herein and above.

182. Under the NJPLA, N.J. Stat. Ann. § 2A:58C-1 through 58C-11, the BHR-THA system reached Plaintiffs without substantial change in the condition in which it was sold and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described above, which made the product unreasonably dangerous.

183. Under New York law, the BHR-THA system, when sold, was not merchantable and reasonably suited to its intended use, and reached Plaintiffs without substantial change in the condition

in which it was sold, and was unreasonably dangerous when it left the Defendant's possession. Moreover, at the time of distribution, a safer alternative design was available, was practicable, and would have reduced the risk of injury posed by the system. Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described herein and above. The likelihood of the injuries here was foreseeable by Defendant at the time the product left the Defendant's control.

184. Under New Mexico law, the BHR-THA system designed, manufactured and sold by Defendants were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein, and reached Plaintiffs without substantial change in the condition in which it was sold, were used without inspection for defect, and was unreasonably dangerous when it left the Defendants' possession. Plaintiffs' use of the device was entirely reasonable and foreseeable, and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described herein and above.

185. Under North Carolina Gen. St. § 99B-1-B-12, the BHR-THA system reached Plaintiffs without substantial change in the condition in which it was sold and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described above, which made the product unreasonably dangerous and presented a latent defect that would only manifest in Plaintiffs' bodies numerous years after implantation.

186. Under North Dakota law, the BHR-THA system designed, manufactured and sold by Defendant were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein, and reached Plaintiffs without substantial change in the condition in which it was sold, were used without inspection for defect, and was unreasonably dangerous when it left the Defendant's possession. Plaintiffs' use of the device was

entirely reasonable and foreseeable, and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described herein and above.

187. Under the Ohio Product Liability Act, Ohio Rev. Code Ann. §§ 2307.73(A) – 2307.77, the BHR-THA system reached Plaintiffs without substantial change in the condition in which it was sold and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described above, which made the product unreasonably dangerous.

188. Under Oklahoma law, the BHR-THA system, when sold, was not merchantable and reasonably suited to its intended use, and reached Plaintiffs without substantial change in the condition in which it was sold, and was unreasonably dangerous when it left the Defendant's possession. Moreover, at the time of distribution, a safer alternative design was available, was practicable, and would have reduced the risk of injury posed by the system. The risks of the BHR-THA system because of these defects outweighed their benefits. Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described herein and above. The likelihood of the injuries here was foreseeable by Defendant at the time the product left the Defendant's control.

189. Under Oregon law, Ore. Rev. Stat. §§ 30.920(1)(a) – (1)(b), the BHR-THA system reached Plaintiffs without substantial change in the condition in which it was sold and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described above, which made the product unreasonably dangerous.

190. Under Pennsylvania law, the BHR-THA system, when sold, was not merchantable and reasonably suited to its intended use, and reached Plaintiffs without substantial change in the condition in which it was sold, and was unreasonably dangerous when it left the Defendant's possession. Moreover, at the time of distribution, a safer alternative design was available, was practicable, and would have reduced the risk of injury posed by the system. The risks of the system because of these

defects outweighed their benefits. Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described herein and above. The likelihood of the injuries here was foreseeable by Defendant at the time the product left the Defendants' control.

191. Under Rhode Island law, the BHR-THA system, when sold, was not merchantable and reasonably suited to its intended use, and reached Plaintiffs without substantial change in the condition in which it was sold, and was unreasonably dangerous when it left the Defendant's possession. Moreover, at the time of distribution, a safer alternative design was available, was practicable, and would have reduced the risk of injury posed by the system. The risks of the system because of these defects outweighed its benefits. Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described herein and above. The likelihood of the injuries here was foreseeable by Defendants at the time the product left the Defendants' control.

192. Under the South Carolina Defective Products Act, S.C. Code Ann. § 15-73-10, the BHR-THA system reached Plaintiffs without substantial change in the condition in which it was sold and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described above, which made the product unreasonably dangerous.

193. Under South Dakota law, the BHR-THA system designed, manufactured and sold by Defendant were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein, and reached Plaintiffs without substantial change in the condition in which it was sold, were used without inspection for defect, and was unreasonably dangerous when it left the Defendants' possession. Plaintiffs' use of the device was entirely reasonable and foreseeable, and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described herein and above.

194. Under Tenn. Code Ann. § 29-28-102(2), the BHR-THA system reached Plaintiffs without substantial change in the condition in which it was sold and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described above, which made the product unreasonably dangerous.

195. Under Tex. Civ. Prac. & Rem. Code Ann. § 82.005(a) – (a)(2), the BHR-THA system reached Plaintiffs without substantial change in the condition in which it was sold and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described above, which made the product unreasonably dangerous.

196. Under Utah law, the BHR-THA system designed, manufactured and sold by Defendant were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein, and reached Plaintiffs without substantial change in the condition in which it was sold, were used without inspection for defect, and was unreasonably dangerous when it left the Defendants' possession. Plaintiffs' use of the device was entirely reasonable and foreseeable, and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described herein and above.

197. Under Vermont law, the BHR-THA system designed, manufactured and sold by Defendants were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein, and reached Plaintiffs without substantial change in the condition in which it was sold, were used without inspection for defect, and was unreasonably dangerous when it left the Defendants' possession. Plaintiffs' use of the device was entirely reasonable and foreseeable, and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described herein and above.

198. In Virginia, the BHR-THA system was unreasonably dangerous either for the use to which it would ordinarily be put and/or for some other reasonably foreseeable purpose, and the unreasonably dangerous condition existed when the goods left the defendant's hands.

199. Under the Washington Product Liability Act (WPLA), Wash. Rev. Code §§7.72.030(1), .030(2), .040(1), the BHR-THA system reached Plaintiffs without substantial change in the condition in which it was sold and Plaintiffs suffered injury and damages to themselves because of the system's defective condition, as described above, which made the product unreasonably dangerous.

200. Under the above states' laws, and under similar laws of states and jurisdictions not specifically mentioned above, Smith & Nephew's violations of the aforementioned federal statutes and regulations establish a *prima facie* case of strict liability in tort.

201. Thus, pursuant to these states' laws, a money damages remedy exists for violation of the Act and regulations promulgated thereunder which results in an unreasonably dangerous product proximately causing injuries, and there is no need for the varying state Legislatures to act in order to create such a remedy.

202. Under the above states' law, Smith & Nephew's violations of the aforementioned federal statutes and regulations establish a *prima facie* case of strict liability in tort.

203. Thus, under above states' law, a money damages remedy exists for violation of the Act and regulations promulgated thereunder which results in an unreasonably dangerous product proximately causing injuries, and there is no need for the Legislatures to act in order to create such remedies.

204. The Act contains an express preemption provision, 21 U.S.C. § 360(k), which in relevant part states: "no state or political subdivision of a state may establish or continue in effect with

respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this Act [21 USCS §§ 301, et seq.] to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act [21 USCS §§ 301, et seq.]."

205. The cause of action set forth in this Claim for Relief is not preempted by 21 U.S.C. § 360(k) because the violations alleged are all based on an exclusively on state law claims that parallel federal statutory and regulatory set of requirements and express agreements with the FDA which include no "requirement which is different from, or in addition to, any requirement applicable under" the Act and regulations promulgated thereunder.

206. In addition, express or implied preemption does not apply to the extent Plaintiffs' injuries were caused by the articulation, metal debris and failure of the 510(k) components such as the modular neck sleeve, MFH and traditional femoral head.

207. Finally, Smith & Nephew was not given pre-market approval for the BHR to be used with components such as the stem and MFH, and therefore 360(k) does not cover THA cases.

COUNT II
NEGLIGENCE AND NEGLIGENT FAILURE TO WARN

208. Plaintiffs incorporate, reassert and reallege the allegations set forth above as if fully set forth herein below.

209. The modular THA system, including the BHR acetabular cup and MFH implanted in Plaintiffs, were not approved by the FDA for sale in the U.S. as part of the same hip system, but Smith & Nephew nonetheless negligently promoted, sold, allowed to be sold and marketed them as being safe for patients including Plaintiffs.

210. The THA systems implanted in Plaintiffs were negligently designed and/or manufactured and/or marketed in violation of federal regulations, various state statutes and common law.

211. It was the duty of Defendants to comply with the regulations and laws for medical devices, as well as the conditions established in the 510(k) and PMA approval orders for the various components, and Smith & Nephew agreed to comply with those requirements.

212. The designer of the BHR acetabular cup, Derek McMinn, stated that the learning curve for the BHR was more than 1,000 surgeries, and Smith & Nephew promoted the BHR to hundreds of U.S. surgeons even though it knew most of them would never perform enough hip resurfacings to master the learning curve. Smith & Nephew never informed the FDA of this steep learning curve for the BHR, and to the extent Smith & Nephew was not aware of this learning curve, the failure to discover this learning curve was in whole or in part because Smith & Nephew failed to carry out the PMA conditions requiring a surgeon training program and a study of the surgeon training program.

213. Smith & Nephew also failed to train surgeons in how to implant the BHR cup with the MFH in a total hip arthroplasty, because the THA procedure was not approved in the U.S. Because of this lack of approval, Smith & Nephew failed to provide any instructions whatsoever that would show surgeons how to combine these devices in a THA procedure, even though it actively promoted and marketed this configuration for off-label use through its sales representatives.

214. Smith & Nephew breached their duties of reasonable care to Plaintiffs by the actions detailed above, including, but not limited to, failing to warn Plaintiffs and the medical community of the true risks of the BHR and the MFH, misrepresenting the true safety of the BHR and MFH, failing to comply with the terms of the PMA and 510(k) orders, failing to update the medical community and

patients when it learned or discovered new information about the risks and safety of the BHR and MFH, and otherwise failing to recall the BHR and MFH in a timely manner.

215. Defendant's breach of their duties caused Plaintiffs' injuries.

216. The MFH system, including the BHR acetabular cup, MFH, modular neck sleeve and traditional femoral stems, implanted in Plaintiffs' hip were distributed and/or manufactured in violation of the state and federal and regulations specifically designed to protect patients against the type of harm they suffered.

217. Defendants consistently under-reported and withheld information about the likelihood of the BHR and MFH to fail and cause injury and complications, and have misrepresented the efficacy and safety of the BHR and MFH products, actively misleading the medical community, patients, the public at large, and Plaintiffs.

218. Defendants knew, and continue to know, that their disclosures to the public and Plaintiffs were and are incomplete and misleading; and that Defendants' unapproved MFH system products were and are causing numerous patients severe injuries and complications. Smith & Nephew suppressed this information, and failed to accurately and completely disseminate or share this and other critical information with the medical community, health care providers, and patients.

219. As a result, Smith & Nephew actively and intentionally misled and continue to mislead the public, including the medical community, health care providers, and patients, into believing that the MFH system was safe and effective, leading to the prescription for and implantation of the illegal and off-label THA system into patients such as Plaintiffs. Defendants continued this misrepresentation, despite the FDA warning them numerous times that the MFH was not approved for sale in the U.S. as part of a THA procedure.

220. Smith & Nephew failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the MFH system. As compared to the MFH system, feasible and suitable alternative designs, procedures, and instruments for implantation and treatment of damaged and worn parts of the hip joint and similar other conditions have existed at all times relevant.

221. The MFH total hip system was at all times utilized and implanted in a manner foreseeable to Defendants, and in fact promoted by Defendants even though it was not approved by the FDA in a total hip arthroplasty. Smith & Nephew failed to warn and provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing their BHR and MFH products, thereby increasing the sales of the products, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiffs.

222. It was the duty of Defendant to comply with all federal and state regulations that applied to the sale of medical devices, as well as state common laws, as well as the conditions established in the PMA and 510(k) orders with which Defendants agreed to comply in order to obtain approval of the MFH and BHR devices. Yet, notwithstanding this duty, Defendants violated these regulations and laws as described in detail above.

223. Subsequently, the unapproved MFH systems implanted in Plaintiffs' hips failed and such failure directly caused and/or contributed to the severe and permanent injuries sustained and endured by Plaintiffs, as defined in 21 C.F.R. § 803.3. As a direct and proximate result, Plaintiffs endured pain and suffering and has required additional and debilitating surgeries and has incurred significant medical expenses in the past and will incur additional medical expenses in the future; both past and future wage loss; both past and future non-economic damages including, but not limited to,

physical and mental pain and suffering, inconvenience, emotional distress and impairment of the quality of their lives; and permanent impairment and disfigurement.

224. Under Alabama law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws, as described above, and Defendants breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

225. Under Alaska law, Smith & Nephew owed a foreseeable duty to Plaintiffs to comply with the act and protect others from unreasonable risks as described above, and Defendants breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

226. Under Arizona law, Smith & Nephew owed a foreseeable duty to Plaintiffs to comply with the regulations and laws described above, and Defendants breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

227. Under Arkansas law, Smith & Nephew owed a foreseeable duty to Plaintiffs to comply with the regulations and laws described above, and Defendants breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

228. Under California law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws described above, and Defendant breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

229. Under Colorado law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws described above, and Defendant breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

230. Under Connecticut law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws described above, and Defendants breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

231. Under Delaware law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws described above, and Defendants breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

232. Under District of Columbia law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws described above, and Defendants breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

233. Under Florida law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws described above, and Defendants breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

234. Under Georgia law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws described above, and Defendants breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

235. Under Hawaii law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws described above, and Defendants breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

236. Under Idaho law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws described above, and Defendants breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

237. Under Illinois law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws described above, and Defendants breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

238. Under Indiana law Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws described above, and Defendants breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

239. Under Iowa law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws described above, and Defendants breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

240. Under Kansas law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws described above, and Defendants breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

241. Under Kentucky law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws described above, and Defendants breached that duty. The breach of such duty was the actual, legal cause of the Plaintiffs' injuries as described herein.

242. Under Louisiana law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws described above, and Defendant failed to conform its conduct to the appropriate standard. The Defendants' substandard conduct was a breach of its duty. The breach of this duty caused the Plaintiffs' injuries as described herein.

243. Under Maine law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws described above, and Defendants breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

244. Under Maryland law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws described above, and Defendants breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

245. Under Massachusetts law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws including the PMA and 510(k) orders, and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendants breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

246. Under Michigan law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws described above, and Defendants breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

247. Under Minnesota law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws for medical devices as a reasonable device manufacturer would and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendants breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

248. Under Mississippi law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws governing medical devices and to take steps to prevent exposing Plaintiffs to an unreasonable risk of harm as described above, and Defendants breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

249. Under Missouri law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws governing medical devices and to take steps to prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendants breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

250. Under Montana law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws governing medical devices and to take steps to prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendants breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

251. Under Nebraska law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws governing medical devices and to take steps to prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendants breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

252. Under Nevada law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with regulations and laws governing medical devices and to take steps to prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendants breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

253. Under New Hampshire law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws governing medical devices and to take steps to prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendants breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

254. Under New Jersey law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws governing medical devices and to take steps to prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendants breached that duty. The breach of such duty was the actual and proximate cause of the Plaintiffs' injuries as described herein.

255. Under New Mexico law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws governing medical devices and to take steps to prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendants breached that duty. The breach of such duty was the actual and proximate cause of the Plaintiffs' injuries as described herein.

256. Under New York law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws governing medical devices and to take steps to prevent exposing

plaintiffs to an unreasonable risk of harm as described above, and Defendants breached that duty. The breach of such duty was the actual and proximate cause of the Plaintiffs' injuries as described herein.

257. Under North Carolina law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws governing medical devices and to take steps to prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendants breached that duty. The breach of such duty was the actual and proximate cause of the Plaintiffs' injuries as described herein.

258. Under North Dakota law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws governing medical devices and to take steps to prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendants breached that duty. The breach of such duty was the proximate cause of the Plaintiffs' injuries as described herein.

259. Under Ohio law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws governing medical devices and to take steps to prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendants breached that duty. The breach of such duty was the proximate cause of the Plaintiffs' injuries as described herein.

260. Under Oklahoma law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws governing medical devices and to take steps to prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendants breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

261. Under Oregon law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws governing medical devices and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendants breached that duty by failing to comply. Plaintiffs are within the class of individuals that could be injured by Defendants' lack of compliance.

The breach of such duty was the actual and proximate cause of the Plaintiffs' injuries as described herein.

262. Under Pennsylvania law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendant breached that duty. The breach of such duty was the proximate cause of the Plaintiffs' injuries as described herein.

263. Under Rhode Island law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws governing medical devices and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendants breached that duty. The breach of such duty was the proximate cause of the Plaintiffs' injuries as described herein.

264. Under South Carolina law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws governing medical devices and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendants breached that duty. The breach of such duty was the proximate cause of the Plaintiffs' injuries as described herein.

265. Under the laws of South Dakota, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws governing medical devices and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendants breached that duty. The breach of such duty was the proximate cause of the Plaintiffs' injuries as described herein.

266. Under Tennessee law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws governing medical devices and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendants breached that duty by failing to comply. Plaintiffs are within the class of individuals that could be injured by Defendant's lack of compliance.

The breach of such duty was the actual and proximate cause of the Plaintiffs' injuries as described herein.

267. Under Texas, law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws governing medical devices and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendant breached that duty by failing to comply. Plaintiffs are within the class of individuals that could be injured by Defendants' lack of compliance. The breach of such duty was the actual and proximate cause of the Plaintiffs' injuries as described herein.

268. Under Utah law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws governing medical devices and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendants breached that duty. The breach of such duty was the proximate cause of the Plaintiffs' injuries as described herein.

269. Under Vermont law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws governing medical devices and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendants breached that duty. The breach of such duty was the proximate cause of the Plaintiffs' injuries as described herein.

270. Under Virginia law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws governing medical devices and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendants breached that duty. The breach of such duty was the proximate cause of the Plaintiffs' injuries as described herein.

271. Under Washington law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws governing medical devices and prevent exposing plaintiffs to

an unreasonable risk of harm as described above, and Defendants breached that duty. The breach of such duty was the proximate cause of the Plaintiffs' injuries as described herein.

272. Under West Virginia law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws governing medical devices and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendants breached that duty by failing to comply. Plaintiffs are within the class of individuals that could be injured by Defendants' lack of compliance. The breach of such duty was the actual and proximate cause of the Plaintiffs' injuries as described herein.

273. Under Wisconsin law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the regulations and laws governing medical devices and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendants breached that duty. Plaintiffs are within the class of individuals that could be injured by Defendants' lack of compliance. The breach of such duty was the actual and proximate cause of the Plaintiffs' injuries as described herein.

274. Under Wyoming law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendant breached that duty. The breach of such duty was the proximate cause of the Plaintiffs' injuries as described herein.

275. Under the above states' laws, and all other state and federal regulations not specifically mentioned but relevant to Plaintiffs' claims, S&N's and PLC's violations of the aforementioned federal statutes and regulations establish a *prima facie* case of negligence.

276. Thus, under state laws, a money damages remedy exists for violation of the PMA and 510(k) regulations and all other applicable regulations promulgated thereunder which results in an

unreasonably dangerous and unapproved product proximately causing injuries, and there is no need for the above states' Legislatures to act in order to create such a remedy.

277. These state laws treat violations of federal statutes and regulations, among other things, as evidence of common law negligence.

278. Defendants also undertook a duty under the above states' law to comply with the terms of the PMA and 510(k) orders and to truthfully communicate safety information about the BHR and MFH systems.

279. In addition to the details set forth above, Smith & Nephew breached their duties under the above states' laws by:

a. failing to correctly monitor its products to ensure that it complied with appropriate quality control procedures and to track nonconforming products;

b. failing to conduct regular risk analysis of its BHR and MFH products, including a Design Failure Analysis, and failing to include and consider known complications from the device as part of its risk analysis processes and failing to exercise appropriate post-market quality controls;

c. failing to provide the FDA with timely post-approval reports for its six month, one year, eighteen month, and two-year report schedules for the PMA, and failing to inform the FDA that it was marketing the MFH for use in a THA procedure;

d. failing to comply with applicable federal and state regulations;

e. failing to monitor the sale and use of the BHR and MFH devices; discover defects associated with their use; and warn the government, doctors, and users about those defects;

f. failing to adequately train Defendants' employees and sales representatives who provided recommendations and advice to physicians who implanted the device in an off-label manner;

g. failing to comply with the terms of the PMA and 510(k) orders;

h. failing to recall the BHR before September 2015, and failing to recall the MFH device entirely or earlier than it did so;

i. failing to provide truthful and accurate information in its voluntary statements to the medical community outside the labeling;

j. failing to update the medical community as it learned of new or additional risks;

k. failing to update the medical community with information about the real-world survivorship rate of the BHR and MFH products, government actions about monitoring metal ion levels, and similarity between the MFH total hip system and other MOM devices, including the Biomet and Wright Medical predicate devices for the MFH;

l. failing to update patients with information about the real-world survivorship rate of the BHR and MFH products and their associated matching components, government actions about monitoring metal ion levels, and similarity between the MFH total hip system and other MOM devices after originally providing this information through marketing materials, websites and other direct-to-consumer statements;

m. promoting the MFH device off-label for use with the BHR; and

n. failing to properly train and educate physicians on the use of the MFH device when used in a total hip arthroplasty system. Defendants accepted a duty even to the Plaintiffs' physicians to train them to implant the MFH device correctly, and

Defendants did not fulfil their duty to provide all necessary information to physicians, in part because the MFH was not approved for use in a THA procedure in the first place. These claims are not expressly or impliedly preempted as Smith & Nephew voluntarily agreed to accept this duty to train physicians after they became aware of the MFH being used in a total hip system, in part due to their own off-label promotion of this device without accompanying training or instructions.

280. These simple common law negligence duties are parallel to the duties under federal law, and are not preempted by any federal law. Alternatively, they are not subject to a preemption analysis whatsoever because the products fail due to articulation of and metal ions produced by the components that are only subject to a 510(k) approval, including the modular neck sleeve, MFH, and traditional femoral stem.

281. Smith & Nephew's breach of these duties caused Plaintiffs' injuries.

282. Defendants also made false, inaccurate and misleading statements concerning the properties and effects of the BHR Resurfacing product and the MFH when used in combination with a modular neck sleeve, BHR cup, and traditional femoral stem such as the Synergy, Anthology and Echelon.

283. Smith & Nephew for years made voluntary statements outside the labeling of the MFH system and directly to surgeons and patients, including Plaintiffs, that the BHR cup and MFH and associated components were safe in a THA procedure. Indeed, any statement made by Defendants whatsoever regarding the use of the MFH device in a THA procedure was made outside the device's labeling, because the labeling did not contemplate this type of indication. This message was delivered explicitly and implicitly, was designed to convey that the products were safe, went beyond mere descriptive puffery and was a material factor in patients choosing a MFH metal on metal system and/or

choosing to agree to their doctor's recommendation (which was also secured by Smith & Nephew through false and misleading representations beyond the FDA-approved labeling) to undergo total hip replacement surgery using the MFH.

284. Had Smith & Nephew been truthful in their statements to patients, and included material information that they actually omitted, patients would not have chosen the MFH total hip system and would have chosen a safer option, including but not limited to total hip replacement devices and/or total hip replacement devices using ceramic and polyethylene materials.

285. Smith & Nephew made voluntary statements outside the FDA-approved labeling to surgeons and the medical community about the safety of the MFH when used in a THA procedure. These statements both explicitly and implicitly conveyed the message the MFH was safer, was safer than other metal-on-metal devices, was safer than other total hip replacement systems, and was safer than ceramic or polyethylene hip devices. None of those statements were true, and had Smith & Nephew made true statements and included material information that they had omitted regarding the safety of the MFH system, surgeons would not have recommended to their patients, including Plaintiffs, that they undergo hip replacement using the unapproved MFH system. Further, Defendants provided information from sources that, over time, published new and updated information. They failed to provide this new and updated information which cast doubt or definitively proved that the BHR and MFH products, as well as all metal-on-metal hips, were not safe. All of these voluntary statements and representations went beyond the information included in the FDA-approved labeling, which restricted the MFH to only being used in a hemi-arthroplasty.

286. Defendants disseminated this false information, as referred to above, to physicians, the medical community, and the public with the intention to deceive physicians and their patients and to induce the physicians to prescribe the MFH for use in a THA procedure, even though this was not part

of the approved indications. These misrepresentations violated Defendants' obligations pursuant to 21 C.F.R. § 201.6(a), the PMA and 510(k) orders for the THA components.

287. Plaintiffs and/or Plaintiffs' physicians did in fact reasonably rely on Defendants' negligent misrepresentations, as Defendants intended. Specifically, Plaintiffs would have never had the MFH product implanted in a THA procedure had they been aware of the falsity of the representations specifically delineated in the preceding paragraphs, and if they had been aware that the MFH was not approved for use in a THA procedure.

288. Defendants knew or should have known that consumers such as Plaintiffs would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

289. Had Defendants exercised ordinary care, and complied with the then existing standards of care, Plaintiffs would not have been injured.

290. As a direct and proximate result of Defendants' aforementioned actions, Plaintiffs were injured by a medical device that was never approved by the FDA for sale to surgeons or to Plaintiffs as part of a THA procedure.

COUNT III
NEGLIGENCE PER SE

291. Plaintiffs incorporate by reference as if fully set forth verbatim each and every allegation in the Complaint.

292. Smith & Nephew had a duty to exercise reasonable care and comply with existing standards in the researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, labeling and/or distribution of BHR-THA system products, and post-market vigilance regarding same, and to comply with the terms of the PMA and 510(k) approvals for the respective components.

293. Defendants failed to exercise reasonable care and failed to comply with existing laws in the researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, labeling and/or distribution of the BHR-THA system products, and post-market vigilance regarding same, and by failing to comply with the terms of the PMA and 510(k) approvals for the respective components.

294. Under federal law governing labeling for the BHR-THA system products, Defendants were required to "describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur." 21 C.F.R. § 201.57(e) (amended and recodified on June 30, 2006 at 21 C.F.R. § 201.80(e)), for devices approved before June 30, 2001, including BHR-THA system products). Defendants also were required to list adverse reactions that occurred with other products in the same class as the BHR-THA system products. *Id.* at § 201.57(g) (re-codified on June 30, 2006 at 21 C.F.R. § 201.80(g), for drugs approved before June 30, 2001). Breaches of these duties constitute independent acts of negligence under state law.

295. Defendants failed to exercise reasonable care and violated 21 U.S.C. §§ 331, 352; 42 U.S.C. § 1320a-7b, and 21 C.F.R. §§ 201.57, 201.80, and 201.128, in particular. The violations constitute independent violations of state negligence law.

296. The BHR-THA system products also were misbranded under federal law as described in the BHR-MACC.

297. The BHR-THA system also was misbranded because Smith & Nephew intended the system to be sold to U.S. end users, but did not warn about the risks of metallosis and did not instruct surgeons in how to implant the device, among other failures.

298. A device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular, or if it is dangerous to health when used in the manner prescribed, recommended, or suggested in the labeling thereof. 21 U.S.C. § 352(a) & (j). The BHR-THA fits both

of these categories because it did not contain any labeling instructing surgeons that it was a metal-on-metal device, but Smith & Nephew marketed the system as a metal-on-metal construct anyway through its sales representatives and through public statements and marketing materials.

299. The "labeling" of a device pursuant to the FDCA and FDA regulations includes not only labeling specifically approved by the FDA but also includes all written, published or other material which the manufacturer publishes or distributes relating to the device in addition to materials specifically approved by the FDA. Such material may include advertising or promotional material distributed in relation with the device.

300. A "misbranded" device is prohibited for introduction into interstate commerce by the FDCA. 21 U.S.C. § 331(a). Ironically, the BHR-THA system was already prohibited from being introduced into interstate commerce because the FDA had not approved the combination of the components.

301. The BHR-THA System did not include a "Patient Information" document for patients, but instead Smith & Nephew published different warnings and contraindications for each separate component. These documents constitute "labeling" under 21 U.S.C. § 321(m).

302. The "Patient Information" document failed to reference the risk of metallosis in its "Potential Risks" section for years, even though S&N knew or should have known of the risk of metallosis based on the studies it submitted or referenced as part of its PMA application and documents it provided to implanting physicians.

303. The laws, regulations and terms of the PMA and 510(k) orders violated by Defendants were designed to protect Plaintiffs and similarly situated persons and protect against the risks and hazards that have actualized in this case. Therefore, Defendants' conduct constitutes negligence per se.

304. Defendants knew or should have known that consumers, such as Plaintiffs and their minor children, would foreseeably suffer injury as a result of Defendant's failures to exercise reasonable care, as set forth above.

305. Defendants' negligence was the proximate cause of Plaintiffs' harm, and economic loss, which Plaintiffs suffered and/or will continue to suffer.

306. As a direct and proximate result of the foregoing acts and omissions, Plaintiffs suffered physical pain, additional surgeries, mental anguish, and diminished enjoyment of life, and will require lifelong medical treatment, monitoring and/or medications.

COUNT IV
BREACH OF EXPRESS WARRANTY

307. Plaintiffs incorporate by reference as if fully set forth verbatim each and every allegation in the Complaint.

308. Smith & Nephew warranted, both expressly and impliedly, through their marketing, advertising, distributors and sales representatives, that the THA system was of merchantable quality, fit for the ordinary purposes and uses for which it was sold, and that its components could be used together in a safe and effective way when in fact they were not safe and effective and were not approved for sale in the U.S.

309. Defendants expressly warranted to Plaintiffs, by and through their authorized agents or sales representatives, in publications, package inserts, the internet, covert advertising and other communications intended for physicians, patients, Plaintiffs, and the general public, that the BHR system and its "mix and match" components were safe, effective, fit and proper for their intended use, even though they were not approved for sale in the first place in that combination.

310. As evidence of Defendants' intention to market the MFH for use in a THA procedure, Smith & Nephew conducted extensive wear testing on the MFH in July 2006 to determine the amount

of metal ion particles that would be released if the MFH was used in tandem with a BHR cup, modular neck sleeve and traditional femoral stem. This testing was performed at the University of Durham Centre for Biomedical Engineering.

311. Smith & Nephew performed the wear testing just two months after the approval for the BHR Resurfacing System in the U.S. The testing would not have been necessary if Defendant had intended to market the MFH for use in only a hemiarthroplasty, as they told the FDA, because in a hemiarthroplasty the MFH would be articulating against the natural acetabulum, and not another metal surface such as the BHR. Tellingly, even this wear testing that Defendants conducted was insufficient to capture the full range of motion that a patient with a metal-on-metal hip system would experience during the normal activities of daily life, and several years later Defendants admitted this shortcoming in a study that they performed. Kamali, et. al., *Tribological Performance of Various CoCr Microstructures in Metal-on-Metal Bearings: the Development of a More Physiological Protocol in Vitro*, J. Bone Joint Surg. Br. (May 2010)("Hip simulators have been used for ten years to determine the tribological performance of large-head metal-on-metal devices using traditional test conditions. However, the hip simulator protocols were originally developed to test metal-on-polyethylene devices.")

312. Defendants likewise conducted metal serum tests on the MFH, and compared the results of these serum tests with those done for the Zimmer Durom device, which was subsequently withdrawn from the U.S. market in 2008 due to unreasonably high failure rates. Similarly, Defendants used the Biomet M2a Magnum and Wright Conserve metal-on-metal systems as predicate devices for the MFH, in part because both of these other systems are used exclusively in total hip arthroplasty procedures. Defendants would not have focused on these other devices had they not intended to market and promote the MFH for use in a THA procedure. Defendants instead compared the MFH side by side

with these other metal-on-metal hip systems, because they intended to market the MFH as a device to be used in a THA procedure, regardless of FDA approval which they ultimately did not receive.

313. Defendants are aware that health care providers and patients, including Plaintiffs, rely upon the representations made by Smith & Nephew when choosing, selecting and purchasing its products, including the THA system products.

314. Even though Smith & Nephew knew about the dangers and risks of the MFH, it continued to tell patients in the U.S. that everything was fine. For example, in its March 2015 Advisory Notice, described *supra*, Smith & Nephew stated that the BHMH had never been marketed in the U.S., and that there was no equivalent data available for MFH patients in the U.S., even though it was aware of hundreds of adverse events and hundreds of lawsuits related to the MFH at that time.

315. Due to the defective and unreasonably dangerous and unapproved BHR-THA system products, they were neither of merchantable quality nor fit for the particular purposes for which they were sold, presenting an unreasonable risk of injury to patients, including Plaintiffs, during foreseeable use.

316. Smith & Nephew breached their warranty of the mechanical soundness of the MFH total hip system by continuing sales and marketing campaigns highlighting the safety and efficacy of their product, while Defendants knew or should have known of the defects and risk of product failure and resulting patient injuries. Specifically, Smith & Nephew continued to market the MFH for use in a THA procedure long after they knew that the predicate devices made by Biomet and Wright Medical had been withdrawn from the U.S. market, and long after they should have recalled the MFH system. They continued to do so because the FDA had not approved the MFH for use in a THA procedure in the first place, and Defendants knew the FDA would not pressure them to recall the MFH system because the FDA was not aware it was being implanted in patients in a THA procedure.

317. Defendants made numerous claims to the general public, and to Plaintiffs in particular, that the BHR-THA system was safe and that it did not suffer from the same problems that plague other metal-on-metal hips, even though it was in possession of information to the contrary. For example, S&Ns senior vice president publicly touted the BHR as being "unlike any other metal-on-metal hip implant" with a survivorship rate superior to even traditional non-metal devices due to its "distinctive metallurgy heritage" and other factors.[21] The BHR was an integral part of the BHR-THA system. The only warnings that S&N issued about the BHR-THA system were the 2014 and 2015 correspondences, supra. Plaintiffs lack any meaningful documents related to the BHR-THA system even after years of litigation, because Defendants have not provided documents covering the last decade of MFH use in the U.S. since 2008 as of the date this pleading was filed. This includes, but is not limited to, discovery regarding surgeon training, sales representative strategies, promotional and marketing information for the MFH, adverse event reporting for the MFH, correspondence with the FDA about the MFH, internal correspondence at Smith & Nephew about marketing of the MFH off-label, and efforts to silently recall the MFH from the U.S. market.

318. As recently as January, 2015, Defendant referred patients with questions about the BHR devices to a website, www.surfacehippy.com, with claims about people with BHR and/or BHR-THA system devices who completed extraordinary physical feats after implantation, including a "sprint triathlon" with their prosthetic BHR devices.[22] Alternatively, for BHR-THA patients, Smith & Nephew referred U.S. surgeons to a website http://BHMH.Smith-Nephew.com, that no longer exists.

[21] Smith & Nephew, Press Release, *New Clinical Results Further Distance the BIRMINGHAM HIP Resurfacing System from Failed Metal-on-Metal Hip Implants*, February 9, 2012. Smith & Nephew published similar press releases on its Web site on Dec. 7, 2007, and again on May 4, 2010.

[22] See Patricia Walter, *MPH's Hip Resurfacing with Mr. Shimmin*, available at http://www.surfacehippy.info/hipresurfacing/hip-stories/additional-stories/760-mph-s-hip-resurfacing-with-mr-shimmin-2015 (describing a BHR recipient who completed a triathlon in December 2014, exactly 11 months after being implanted with a BHR); the website has been promoted to Smith & Nephew patients by company executives, including but not limited to Tunja Carter, Senior Clinical Affairs Specialist.

319. The designer of the BHR acetabular cup, Derek McMinn, stated that the learning curve for the BHR was more than 1,000 surgeries, and Smith & Nephew promoted the BHR to hundreds of U.S. surgeons even though it knew most of them would never perform enough hip resurfacings to master the learning curve. S&N never informed the FDA of this steep learning curve for the BHR, and to the extent Smith & Nephew was not aware of this learning curve, the failure to discover this learning curve was in whole or in part because S&N failed to carry out the PMA conditions requiring a surgeon training program and a study of the surgeon training program. On information and belief, the learning curve for the BHR-THA system was also steep, in part because Smith & Nephew failed to provide any training whatsoever to U.S. surgeons showing them how to implant the MFH in a THA procedure. The only way to perform this operation was by a surgeon following the recommendation of S&N's sales reps to use the device in an off-label, unapproved THA.

320. Pursuant to 21 U.S.C. §360k, the above statements constitute a violation of the PMA for the BHR because the FDA's conditional approval of the BHR devices warned Defendant that its "warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State Laws." Smith & Nephew similarly violated the 510(k) approval for the MFH by marketing it for use in an off-label THA procedure. Smith & Nephew actively promoted this off-label use, and did not tell the FDA that they were doing so because it was not legally allowed. Smith & Nephew continued this promotion in the U.S., even after it notified surgeons and patients in England, Australia, and New Zealand about high revision rates.

321. The defective and unreasonably dangerous condition of the BHR and MFH products also constituted a breach of the Defendants' express warranties under various state laws, in part because the THA system device was never approved by the FDA for sale in the configuration in which

it was implanted in Plaintiffs, even though Smith & Nephew led surgeons and patients to believe it was approved and was safe.

322. As a direct and proximate result of Defendants' breaches of express warranties, Plaintiffs have sustained severe damages and injuries as described elsewhere in this Master Complaint, including metallosis, tissue damage and necrosis, revision surgery, neck-stem corrosion, trunnionosis, exposure to toxic levels of chromium and cobalt ions in their bodies, and unknown long-term consequences that continue to this day and into the future. They have further suffered past and future medical expenses, past and future wage loss; physical pain and suffering, both past and future; mental anguish and emotional distress.

COUNT V
BREACH OF IMPLIED WARRANTY

323. Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

324. Defendant impliedly warranted that the BHR-THA system was merchantable and fit for the particular purposes for which they were intended, despite the fact that the system was never approved by the FDA for use by surgeons in the U.S.

325. Defendant had reason to know the particular purpose for which its BHR products were required, and that Plaintiff was relying on Defendant's skill and judgment to furnish suitable goods. For example, the PMA Letter approving the BHR device noted that it is particularly well suited for younger or more active patients who "may not be suitable for traditional total hip arthroplasty due to an increased possibility of requiring future ipsilateral hip joint revision."

326. The THA system was not suitable for young and active patients, especially women and those with smaller femoral head sizes, and unlike the BHR resurfacing cup, the MFH total hip system

did not receive the scrutiny of the PMA process, and in fact was not approved for sale in the U.S. at all as part of a total hip system.

327. When the BHR-THA system was implanted in Plaintiff to treat Plaintiff's damaged and worn hip joints, Plaintiff and Plaintiff's surgeons reasonably thought that the THA system was being used for the particular purposes for which they were intended, and they were particularly intended for Plaintiff.

328. Plaintiff, individually and/or by and through Plaintiff's healthcare provider, relied upon Defendants' implied warranties of merchantability and fitness for a particular purpose, in consenting to have the BHR-THA system implanted, with the hope and expectation that the metal-on-metal device would last longer than a traditional polyethylene or ceramic prosthetic device and thus not require a painful revision surgery.

329. Plaintiffs also relied on Defendants' representations that the THA system was a "bone conserving" device and that it would be a less invasive procedure, when in fact the THA system is not a bone conserving device system at all, and is just as invasive and damaging as other metal-on-metal hip systems made by competing manufactures such as the DePuy ASR, Zimmer Durom, Biomet M2a Magnum and Wright Conserve, all of which have been removed or recalled from the U.S. market due to premature and catastrophic failure in patients.

330. Defendants breached these implied warranties of merchantability and fitness for a particular purpose because the BHR-THA system implanted in Plaintiffs was neither merchantable nor suited for the intended uses as warranted, because it carried a high risk of premature failure due to metallosis.

331. Defendants' breaches of their implied warranties resulted in the implantation of an unreasonably dangerous and defective product in the body of Plaintiffs, placing Plaintiffs' health and safety in jeopardy.

332. The above-mentioned violations and failures constitute a parallel violation of state common law and statutory law that predates and operates independently from the above federal requirements.

333. As a direct and proximate result of Defendants' breaches of these implied warranties, Plaintiff has sustained severe damages and injuries as described elsewhere in this Complaint.

COUNT VI
NEGLIGENT MISREPRESENTATION

334. Plaintiffs incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

335. Smith & Nephew had a duty to accurately and truthfully represent to the medical community, Plaintiffs, and the public that the BHR-THA system had not been adequately tested and found to be safe and effective for the treatment of damaged and worn parts of the hip joint. Instead, the representations made by Defendants were false.

336. Smith & Nephew also had a duty under the laws of the individual states and a parallel federal duty as described above and in the BHR-MACC to accurately and truthfully represent to the FDA, the medical community, Plaintiffs, and the public the facts about the safety of the BHR. Instead, the representations made by Defendants were false, misleading, omitted material information or otherwise left a false impression about the safety of the BHR.

337. Smith & Nephew consistently under-reported and withheld information about the likelihood of the BHR and the other BHR-THA components to fail and cause injury and complications,

and has misrepresented the efficacy and safety of the same products, actively misleading the FDA, medical community, patients, the public at large, and Plaintiffs.

338. Smith & Nephew negligently misrepresented to the medical community, Plaintiff, and the public that the BHR-THA system did not have a high risk of dangerous adverse side effects such as metallosis. Defendant made this misrepresentation by consistently underreporting adverse events for both the BHR and for the BHR-THA systems, delaying reporting of adverse events, not reporting adverse events, and promoting the BHR-THA system as if it were a safe and effective medical device approved by the FDA, when in fact it was not approved at all.

339. Smith & Nephew caused physicians, the medical community and the general public to believe that the BHR-THA system received the same scrutiny that its BHR cup received in the PMA order, when in fact Smith & Nephew never received any approval for the THA system, which requires a physician to remove the acetabular cup in a revision, even if it is well-fixed to the natural acetabulum, as illustrated in the below warning.

Currently, in the USA, Smith & Nephew, Inc. does not have a commercially available modular metal femoral head for use with a BHR resurfacing shell. Therefore, if the BHR resurfacing head must be revised to a total hip arthroplasty, the acetabular shell should also be revised, even if well fixed.

340. Had Defendant accurately and truthfully represented to the medical community, Plaintiff, and the public the material facts relating to the risks of the BHR and the BHR-THA system, Plaintiff and/or Plaintiff's healthcare providers would not have combined the BHR with the MFH and a modular neck-sleeve and traditional femoral stem for Plaintiffs' treatment.

341. Defendants effectively deceived and misled the scientific and medical communities and consumers regarding the risks and benefits of the BHR-THA system by intentionally and

surreptitiously marketing the total hip system as being safe and effective, despite the system never having been approved for use in U.S. patients.

342. The above-mentioned violations and failures constitute a parallel violation of common law that predates and operates independently from the above federal requirements, and violates both the PMA and 510(k) approval orders for the various components, which carry an unreasonably high risk of premature failure when used in combination with each other.

343. Smith & Nephew, through its voluntary statements made outside the labeling of these devices, negligently misled and continue to mislead the public, including the medical community, health care providers, and patients, into believing that the products were and are safe and effective, leading to the prescription for and implantation of the products into patients such as Plaintiffs.

344. Smith & Nephew failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the BHR and BHR-THA products. Feasible and suitable alternative designs, procedures, and instruments for implantation and treatment of damaged and worn parts of the hip joint and similar other conditions have existed at all times relevant.

345. Smith & Nephew's BHR and MFH products were at all times utilized and implanted in a foreseeable manner. Smith & Nephew failed to warn and provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing the products, thereby increasing the sales of the unapproved BHR-THA system, and also leading to the dissemination of inadequate and misleading information to patients.

346. Smith & Nephew's failure to comply with the above-stated duties for both the BHR and the BHR-THA components is evident through the non-exhaustive facts detailed above of malfeasance, misfeasance, and/or nonfeasance on the part of Defendant. Subsequently, the BHR-THA system implanted in Plaintiffs' hips failed and such failure directly caused and/or contributed to the

severe and permanent injuries sustained and endured by Plaintiffs, as defined in 21 C.F.R. § 803.3. As a direct and proximate result, Plaintiffs endured pain and suffering and has required additional and debilitating surgeries and has incurred significant medical expenses in the past and will incur additional medical expenses in the future; both past and future wage loss; both past and future non-economic damages including, but not limited to, physical and mental pain and suffering, inconvenience, emotional distress and impairment of the quality of his life; and permanent impairment and disfigurement.

347. Plaintiffs are pursuing this parallel state common law claim for negligent misrepresentation based upon Smith & Nephew's violations of the applicable federal regulations as described above, or based on acts and omissions by Smith & Nephew that are not explicitly or impliedly preempted by federal law. These claims relate to the function of both the BHR device and the MFH device and related components, and they relate to the interaction of the BHR device with the MFH device, and separately to the interaction of the MFH with the modular neck-sleeve and traditional femoral stem. Express and implied preemption do not apply to this latter set of neck-stem failure claims, which only involve devices approved through the 510(k) process.

348. Prior to, on, and after the date the devices were implanted in Plaintiffs, and at all relevant times, Defendants negligently and carelessly represented to Plaintiffs, their health care providers, and the general public that certain material facts were true. The representations include, in addition to the detailed allegations above, the allegations described in the Master Amended Consolidated Complaint for BHR Plaintiffs, which are adopted herein.

349. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiffs have sustained severe damages and injuries as described elsewhere in this Complaint.

COUNT VII
UNFAIR AND DECEPTIVE TRADE PRACTICES

350. Plaintiffs incorporate by reference as if fully set forth verbatim each and every allegation in the Complaint.

351. Plaintiffs purchased and used Defendants' BHR-THA systems primarily for personal use and thereby suffered ascertainable losses as a result of Defendants' violations of the PMA Letter for the BHR cup, and the 510(k) approval order for the various other components including the MFH, which constitutes parallel violations under state consumer protection laws.

352. Had Smith & Nephew not engaged in the deceptive conduct described herein, Plaintiffs would not have purchased and/or paid for Defendants' unapproved and fraudulently marketed BHR-THA system products, and would not have incurred related medical costs and injuries.

353. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, monies from Plaintiffs for the BHR-THA system that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

354. Defendants' actions, as complained of herein, and as suppliers, manufacturers, advertisers, and sellers, constitute unfair, unconscionable, deceptive, and/or fraudulent acts or trade practices.

355. As a direct and proximate result of Defendant's unfair and deceptive trade practices, Plaintiff has sustained severe damages and injuries as described elsewhere in this Complaint.

COUNT VIII
FRAUDULENT CONCEALMENT

356. Plaintiffs incorporate by reference as if fully set forth verbatim each and every allegation in the Complaint.

357. Throughout the relevant time period, Defendant knew that its BHR-THA system products were defective and unreasonably unsafe for their intended purpose.

358. Smith & Nephew was under a duty to disclose to Plaintiffs and the medical community the defective nature of the BHR-THA system products, including the fact they were not FDA approved, because Smith & Nephew was in a superior position to know the true quality, safety, and efficacy of the THA system products. Defendant fraudulently concealed the danger of the THA system by underreporting adverse events for the BHR and the MFH, delaying reporting of adverse events, categorizing them in a way that hid the true risk of failure due to metal-on-metal symptoms, and surreptitiously and intentionally promoting them as if they were FDA approved and safe.

359. Defendant fraudulently concealed from and/or failed to disclose to Plaintiffs, Plaintiff's healthcare providers, and the medical community that its BHR resurfacing products and THA system were defective, unsafe, and unfit for the purposes intended, and that they were not of merchantable quality.

360. The facts concealed and/or not disclosed to Plaintiff and the medical community were material facts that a reasonable person would have considered important in deciding whether to utilize Defendant's BHR resurfacing products and THA system.

361. Smith & Nephew's fraudulent concealment and failure to recall the BHR-THA system also made it impossible for many Plaintiffs to know that they had viable legal claims. Plaintiffs are therefore well-within the statute of limitations at the time of this filing. Plaintiffs' statute of limitation would have begun to run from the date of their discovery of the defective nature of the BHR-THA system, or the date of their revision surgery, whichever is later.

362. As a direct and proximate result of Defendants' fraudulent concealment, Plaintiffs have sustained severe damages and injuries as described elsewhere in this Complaint.

COUNT IX
PUNITIVE DAMAGES

363. Plaintiffs incorporate by reference as if fully set forth verbatim each and every allegation in the Complaint.

364. The acts and omissions of Smith & Nephew as set forth herein constitute intentional, fraudulent, malicious and/or reckless conduct. Among other things, Smith & Nephew knew that its BHR-THA system was not approved for sale in the U.S., but it nonetheless intentionally and surreptitiously marketed the system as being similar to the PMA-approved BHR resurfacing system, even though Smith & Nephew knew that it was not.

365. The acts and omissions of the Defendant as set forth herein constitute intentional, fraudulent, malicious and/or reckless conduct. Among other things, Smith & Nephew knew that its THA system was not approved for sale in the U.S., but it nonetheless intentionally and surreptitiously marketed the system as being similar to the PMA-approved BHR resurfacing system, even though Smith & Nephew knew that it was not.

366. Because the BHR-THA system was not approved by any regulatory agency in the U.S, Smith & Nephew intentionally delayed reporting failures of the system to the FDA, and concealed information about the widespread use of the unapproved system in thousands of patients in almost every state in the U.S. Accordingly, Plaintiffs are entitled to an award of punitive damages.

WHEREFORE, Plaintiffs pray that this Court enter judgment against Defendants in an amount in excess of Seventy Five Thousand Dollars ($75,000.00) for each Plaintiff, together with pre-judgment and post judgment interest, attorneys' fees and costs of this action as may be recoverable, and for such further relief as this Court deems just and reasonable.

PLAINTIFFS DEMAND A TRIAL BY JURY.

Dated: August 14, 2018

Respectfully Submitted,

/s/ Robert K. Jenner

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