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
WILLIAM A. FARNER, Plaintiff, vs. SMITH & NEPHEW, INC., Defendant.	**DIRECT-FILED THA COMPLAINT PURSUANT TO CASE MANAGEMENT ORDER NO. 7** **THA TRACK CASE** Civil Action No.: 1:18-cv-2842

COMPLAINT AND JURY DEMAND

This is a product liability lawsuit relating to an artificial metal-on-metal total hip arthroplasty ("THA") system that was never approved for use in U.S. patients, but was nonetheless marketed and promoted to the medical community and the public for almost a decade, causing hundreds of serious injuries in men and women in almost every U.S. state. Plaintiff, William A. Farner, states the following for his specific and general allegations related to the unapproved and fraudulently marketed THA system.

JURISDICTION AND VENUE

1. Plaintiff, William A. Farner, at all times relevant to this action, was a citizen and resident of the State of Illinois with his place of residence located in Elk Grove Village, which is part of the Northern District of Illinois, U.S. District Court.

2. Defendant Smith & Nephew, Inc. ("Smith & Nephew") 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.

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

4. Plaintiff, William A. Farner, states and brings this civil action in MDL No. 2775, *In re: Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Products Liability Litigation*. Plaintiff is direct filing this Complaint in the District of Maryland pursuant to CMO No. 3, entered by this Court, and pursuant to the Transfer Order of the U.S. Judicial Panel on Multidistrict Litigation of January 31, 2018. But for these orders, Plaintiff's complaint would have been filed in the Northern District of Illinois, U.S. District Court.

5. This action arises out of Smith & Nephew's violations of various sections of the Code of Federal Regulations, the common and statutory law of Plaintiff's home state and the damages suffered by Plaintiff, William A. Farner, as a result thereof.

PLAINTIFF'S INJURIES

6. Plaintiff underwent surgery on or about December 18, 2007 during which a Smith & Nephew BHR Resurfacing System was implanted in his right hip. Plaintiff's surgery was performed by Dr. Eugene Lopez, Jr. at Alexian Brothers Medical Center in Elk Grove Village, Illinois.

7. Plaintiff underwent medically-indicated revision of his right hip joint on or about March 2, 2010, during which a Smith & Nephew total hip arthroplasty system was implanted in his right hip joint. Plaintiff's revision surgery was performed by Dr. Daniel Kuesis at Alexian Brothers Medical Center in Elk Grove Village, Illinois.

8. On or about October 27, 2015, Plaintiff underwent a second medically-indicated

revision of his right hip due to hip pain and other complications caused by the failure of the Defendant's Birmingham Hip Resurfacing ("BHR") metal-on-metal total hip arthroplasty system ("THA"). Plaintiff's revision surgery was performed by Dr. Wayne Paprosky at Central DuPage Hospital in Winfield, Illinois. In his operative note, Dr. Paprosky describes metallosis, elevated cobalt and chromium levels and pseudotumors in Plaintiff's hip joint as a result of the premature failure of the device.

9. At the time of the initial implant procedures, neither Plaintiff nor his surgeon were aware of the myriad problems associated with the BHR when used in a THA operation. In fact, Smith & Nephew continued to promote the THA total hip system as a safe alternative to other metal-on-metal hip devices despite the THA not being a safer alternative and not being approved for sale in the U.S.

FACTUAL BACKGROUND

10. Smith & Nephew is a global medical technology company, with its headquarters in England, a presence in more than 90 countries worldwide, and total sales of $4.8 billion in 2017. Its domestic headquarters are in Memphis, Tenn.

11. Defendant markets, manufactures, and sells prosthetic hip devices for use in total hip arthroplasty and resurfacing arthroplasty, specifically the hip socket, acetabulum, and the ball, or femoral head. These hip replacement products include the BHR resurfacing system, which Smith & Nephew withdrew from the U.S. market and subsequently issued a Class II recall on September 10, 2015, due to high failure rates, especially for women. However, Smith & Nephew never issued a recall for the THA "mix and match" system because it was never approved in the first place.

12. Since 2006, Smith & Nephew has manufactured, introduced and/or delivered the BHR and THA into the stream of interstate commerce. The BHR is a metal-on-metal hip resurfacing prosthesis. It is comprised of a resurfacing femoral head and a matching acetabular cup.

13. The conditional approval letter from the FDA stated that "[c]ommercial distribution of a device that is not in compliance with these conditions is a violation of the [Food, Drug and Cosmetic] act, [21 U.S.C. §§301, et seq.]."

14. The approval order from the FDA was limited to the acetabular BHR cup used in a resurfacing procedure, and was part of a Premarket Approval application ("PMA") submitted by Smith & Nephew to the FDA. This submission is the most stringent type of application and requires clinical testing and other studies to gauge safety and effectiveness.

15. Plaintiff's initial hip implant surgeries included a PMA-approved BHR acetabular cup, but also a modular head and femoral stem that were not approved for use with the cup as part of the above-referenced FDA letter, and all of these components together comprise the THA. Plaintiff's 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.

16. Even though the THA total hip system was not approved by the FDA, the decision to implant Defendant's BHR acetabular component with Smith & Nephew's traditional femoral stem, modular head and modular sleeve was based on specific express and implied representations made by Defendant Smith & Nephew to Plaintiff's surgeon 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 Plaintiff's surgeon and his dealings with Smith & Nephew's sales representative that led him to understand that it was permissible to use Defendant's Femoral Component, modular head sleeve and modular Femoral Head **with** Defendant's BHR acetabular component;

c. Smith & Nephew training courses attended by Plaintiff's surgeon that included written materials and instructional videos that did not advise him that it was not permissible to use Defendant's femoral component,

modular head sleeve and modular femoral head **with** Defendant's BHR acetabular component;

d. Defendant Smith & Nephew's sales representative's conduct of bringing Defendant's Femoral Component, Modular Head Sleeve and Modular Femoral Head to total hip arthroplasty and revision procedures on other patients of Plaintiff's surgeon to be available for use leading him to believe that they were safe to use together;

e. Defendant Smith & Nephew's sales representative's conduct of bringing Defendant's Femoral Component, Modular Head Sleeve and Modular Femoral Head to Plaintiff's initial total hip arthroplasty surgery, and without telling the surgeon that said Class II components could not be safely used with the BHR acetabular component; and/or

f. The fact that if Defendant Smith & Nephew's sales representatives had told Plaintiff's surgeon that the Smith & Nephew BHR acetabular component could not be used with the Femoral Stem, Modular Femoral Head and Modular Head Sleeve and that the BHR acetabular component could only be used with the BHR femoral head and that such use was in violation of the PreMarket Approval granted by the FDA, the surgeon would have never used Smith & Nephew's BHR acetabular component in Plaintiff's total hip arthroplasty.

17. Defendant Smith & Nephew's marketing, distribution, training and/or permitted use of its femoral stem, modular head sleeve and modular femoral head with its BHR acetabular cup violate the Federal Food, Drug and Cosmetic Act ("Act"), the regulations promulgated to it and the PMA order granted to Smith & Nephew by the FDA. Specifically, the conduct of Smith & Nephew's sales representatives, including the training it provided to surgeons such as Plaintiff's, and its marketing materials resulted in Plaintiff's surgeon 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.

18. Smith & Nephew's marketing, distribution, training and/or permitted use of its Modular Femoral Head with its BHR acetabular cup also violates, among other things, the modular femoral head's 510(k) approval by the FDA 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 an artificial 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).[1]

19. The FDA did not approve the combination of these two 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. Plaintiff's unapproved total hip system 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.

20. Because the THA system is not approved by the FDA, its safety and efficacy are difficult to study. However, the system suffers from many of the same problems that plague the BHR resurfacing device, and all metal-on-metal hips, especially in women and in patients with smaller femoral head sizes. 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]

21. Plaintiff's THA fails in part because metal ions created by the metal components

[1] 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).

[2] D.W. Murray, et. al., The Ten-Year Survival of the Birmingham Hip Resurfacing, J. Bone & Joint Surg., 2012;94-B.

rubbing together entered the Plaintiffs bloodstream, destroyed tissue, created an adverse reaction and caused the THA to fail and require revision. The metal ions produced by the THA include metal ions from the BHR cup and from the femoral head placed inside that cup.

22. It was the duty of Defendant Smith & Nephew, Inc. to comply with the Act, the regulations promulgated pursuant to it, and the PMA order from the FDA, yet, notwithstanding this duty, Defendant Smith & Nephew violated the Act and the PMA 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. Defendant Smith & Nephew sold, distributed and permitted use of its 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 BHR acetabular cup with the BHR femoral head. 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 BHR system as required by the PMA Order and in violation of the Act;

f. Failed to properly train surgeons using Defendant's BHR system on the permitted use of the BHR system and its 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 510k.

FIRST CLAIM FOR RELIEF – STRICT PRODUCTS LIABILITY

23. Plaintiff herein incorporates, reasserts and realleges the allegations set forth above as if fully set forth herein below.

24. Defendant designed and/or manufactured the THA system implanted in Plaintiff's hips in violation of the Act and regulations promulgated pursuant to it, 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.

25. At the time the THA system left the control of Defendant, Smith & Nephew, it was 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 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.

26. 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 salesmen to not report adverse events and complaints such as revision surgeries, 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 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 THA system but delayed its reporting to the FDA;

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 THA;

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 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, 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.

27. As a direct and proximate result of Defendant's violations of one or more of these federal statutory and regulatory standards of care, a THA system was implanted in Plaintiff's left and right hip, and their subsequent failures 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.

28. This cause of action is based entirely on the contention that Defendant, Smith & Nephew violated federal safety statutes and regulations, as well as the conditions established in the Approval Order with which Defendant agreed to comply to obtain premarket approval of the device. Plaintiff does not bring the underlying action as an implied statutory cause of action, but rather he is pursuing parallel state law claims based upon Defendant, Smith & Nephew's violations of the applicable federal regulations and Approval Order.

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

30. Thus, under Illinois 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.

31. 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.]."

32. However, the cause of action set forth here is not preempted by 21 U.S.C. §306(k)

because the 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).

SECOND CLAIM FOR RELIEF - NEGLIGENCE

33. Plaintiff herein incorporates, reasserts and realleges the allegations set forth above as if fully set forth herein below.

34. The THA system, including the acetabular cup and modular femoral head implanted in Plaintiff's left and right hips, were not approved by the FDA for sale in the U.S., but Smith & Nephew nonetheless negligently promoted and marketed them as being safe for patients such as Plaintiff.

35. The THA system implanted in Plaintiff was negligently designed and/or manufactured and marketed in violation of the Act and regulations promulgated to it.

36. It was the duty of Defendant, Smith & Nephew, Inc. to comply with the Act, 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.

37. 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.

38. As a direct and proximate result of Smith & Nephew's aforementioned actions, Plaintiff was injured by a Class III medical device that was never approved by the FDA for sale to surgeons and Plaintiff.

THIRD CLAIM FOR RELIEF – BREACH OF EXPRESS WARRANTY

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

40. Smith & Nephew warranted, both expressly and impliedly, through its 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.

41. Defendant expressly warranted to Plaintiff, by and through its authorized agents or sales representatives, in publications, package inserts, the internet, and other communications intended for physicians, patients, Plaintiff, 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.

42. The Defendant is aware that health care providers and patients, including the Plaintiff, rely upon the representations made by Smith & Nephew when choosing, selecting and purchasing its products, including the THA system products.

43. Due to the defective and unreasonably dangerous and unapproved THA system

products, it was neither of merchantable quality nor fit for the particular purposes for which it was sold, presenting an unreasonable risk of injury to patients, including Plaintiff, during foreseeable use.

44. Smith & Nephew breached its warranty of the mechanical soundness of the BHR system by continuing sales and marketing campaigns highlighting the safety and efficacy of its product, while Defendant knew or should have known of the defects and risk of product failure and resulting patient injuries.

45. Defendant made numerous claims to the general public, and to Plaintiff in particular, that the BHR devices were safe for their intended use and that they 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, almost four years after Plaintiff's initial surgeries, Defendant's 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.[3]

46. 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 the BHR devices who completed extraordinary physical feats after implantation, including a "sprint triathlon" with their prosthetic BHR devices.[4]

47. 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

[3] 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.

[4] 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.

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.

48. Pursuant to 21 U.S.C. §360k, the above statements constitute a violation of the PMA 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."

49. The defective and unreasonably dangerous condition of the BHR products also constituted a breach of the Defendant's express warranties under Illinois law, in part because the THA system device was never approved by the FDA for sale in the configuration in which it was implanted in Plaintiff, even though Smith & Nephew led surgeons and patients to believe it was approved and was safe.

50. As a direct and proximate result of Defendant's breaches of express warranties, Plaintiff has sustained severe damages and injuries as described elsewhere in this Complaint, including metallosis, tissue damage and necrosis, revision surgeries, exposure to toxic levels of chromium and cobalt ions in his body, and unknown long-term consequences that continue to this day and into the future. He has 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.

FOURTH CLAIM FOR RELIEF – BREACH OF IMPLIED WARRANTY

51. Plaintiff incorporates by reference as if fully set forth verbatim each and every

allegation in the Complaint.

52. Defendant impliedly warranted that the THA system was merchantable and was fit for the particular purposes for which they were intended.

53. 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."

54. 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 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.

55. When the 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.

56. Plaintiff, individually and/or by and through Plaintiff's healthcare provider, relied upon Defendant's implied warranties of merchantability and fitness for a particular purpose, in consenting to have the 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.

57. Plaintiff also relied on Smith & Nephew's 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.

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

59. Defendant's breaches of their implied warranties resulted in the implantation of an unreasonably dangerous and defective product in the body of Plaintiff, placing Plaintiff's health and safety in jeopardy.

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

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

FIFTH CLAIM FOR RELIEF – NEGLIGENT MISREPRESENTATION

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

63. Defendant had a duty to accurately and truthfully represent to the medical community, Plaintiff, and the public that 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 Defendant were false.

64. Smith & Nephew negligently misrepresented to the medical community, Plaintiff,

and the public that the THA system did not have a high risk of dangerous adverse side effects. Defendant made this misrepresentation by consistently underreporting adverse events for both the BHR and for the THA system, delaying reporting of adverse events, and promoting the 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.

65. Smith & Nephew caused physicians, the medical community and the general public to believe that the 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.

66. 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 THA system, Plaintiff and/or Plaintiff's healthcare providers would not have utilized the BHR or the THA system for Plaintiff's treatment.

67. Defendant effectively deceived and misled the scientific and medical communities and consumers regarding the risks and benefits of the 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.

68. 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.

69. As a direct and proximate result of Defendant's negligent misrepresentations, Plaintiff has sustained severe damages and injuries as described elsewhere in this Complaint.

SIXTH CLAIM FOR RELIEF – UNFAIR AND DECEPTIVE TRADE PRACTICES

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

71. Plaintiff purchased and used Defendant's THA system primarily for personal use and thereby suffered ascertainable losses as a result of Defendant's violations of the PMA Letter for the BHR cup, and the 510(k) approval order for the various other components including the modular femoral head, which constitutes parallel violations under state consumer protection laws.

72. Had Smith & Nephew not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for Defendant's unapproved and fraudulently marketed THA system products, and would not have incurred related medical costs and injuries.

73. Defendant engaged in wrongful conduct while at the same time obtaining, under false pretenses, monies from Plaintiff for the THA system that would not have been paid had Defendant not engaged in unfair and deceptive conduct.

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

82. 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.

SEVENTH CLAIM FOR RELIEF – FRAUDULENT CONCEALMENT

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

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

85. Smith & Nephew was under a duty to disclose to Plaintiff and the medical community the defective nature of the THA system products, including the fact that 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 THA, 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.

86. Defendant fraudulently concealed from and/or failed to disclose to Plaintiff, 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.

87. 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.

88. As a direct and proximate result of Defendant's fraudulent concealment, Plaintiff has sustained severe damages and injuries as described elsewhere in this Complaint.

EIGHTH CLAIM– NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

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

90. Defendant carelessly and negligently manufactured, developed, tested, labeled, marketed, and sold the THA system products to Plaintiff, carelessly and negligently concealing the harmful effects from Plaintiff, and carelessly and negligently misrepresented the quality, safety, and efficacy of the products, in violation of the terms of its PMA Letter and federal regulations, as described in greater detail above.

91. Plaintiff was directly impacted by Defendant's carelessness and negligence in that Plaintiff purchased the BHR products and THA system and has therefore sustained and will continue to sustain emotional distress, physical injuries, economic losses, and other damages.

92. Defendant's actions, as complained of herein, negligently inflicted emotional distress upon the Plaintiff. The above-mentioned violations and failures and failures to comply with federal regulations constitute a parallel violation of common law that predates and operates independently from the above federal requirements, including both the PMA and 510(k) approvals for the various components, which are furthermore not approved to be used in combination with each other. Common law furthermore allows this cause of action on Plaintiff's behalf because the BHR and THA came into contact with his body, and his injuries were severe.

93. As a direct and proximate result of Defendant's negligent infliction of emotional distress, Plaintiff has sustained severe damages and injuries as described elsewhere in this Complaint, including metallosis, tissue damage and necrosis, revision surgery, exposure to toxic levels of

chromium and cobalt ions in his body, and unknown long-term consequences that continue to this day and into the future. He has 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.

94. As a direct and proximate result of Defendant Smith & Nephew's improper training and marketing to U.S. surgeons on the implantation of the BHR cup with its modular femoral head and modular head sleeve and femoral stem in violation of one or more of these federal statutory and regular standards, an unreasonably dangerous BHR acetabular cup and an unreasonably dangerous combination of Smith & Nephew products in a THA system which were not approved for use with one another, were implanted in Plaintiff and failed, and such failure directly caused and/or contributed to the severe and permanent injuries sustained and endured by Plaintiff, as defined in 21 C.F.R. 803.3.

NINTH CLAIM FOR RELIEF – PUNITIVE DAMAGES

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

96. 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.

97. Because the 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, Plaintiff is entitled to an award of punitive damages.

WHEREFORE, Plaintiff prays that this Court enter judgment against the Defendant in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), 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.

PLAINTIFF DEMANDS A TRIAL BY JURY.

Dated: September 12, 2018

Respectfully submitted,

JONES WARD PLC

s/ Alex C. Davis
Alex C. Davis
Jasper D. Ward IV
The Pointe
1205 E. Washington St., Suite 111
Louisville, KY 40206
Phone: (502) 882 6000
Facsimile: (502) 587-2007
alex@jonesward.com
jasper@jonesward.com
Alex C. Davis Bar ID No.: 94899
Jasper D. Ward Bar ID No.: 92160
Counsel for Plaintiff

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

William A. Farner

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Alex C. Davis, Jasper D. Ward IV, Jones Ward PLC, 1205 E. Washington Street, Suite 111, Louisville, Kentucky 40206; 502-882-6000

DEFENDANTS

Smith & Nephew, Inc.

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

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

Attorneys *(If Known)*

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

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

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

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

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

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☒ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

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

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

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

Brief description of cause:
MDL product liability

VII. REQUESTED IN COMPLAINT:

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

DEMAND $

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

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Catherine C. Blake DOCKET NUMBER MDL 2775

DATE 9/12/2018

SIGNATURE OF ATTORNEY OF RECORD s/ Alex C. Davis

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

Print Save As... Reset

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

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

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

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

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

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

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

IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. Origin. Place an "X" in one of the six boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

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

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

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

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