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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA

GARY A. LUNSFORD,

Plaintiff,

v.

SMITH & NEPHEW, INC., a Tennessee Corporation,

Defendants.

Case No:

COMPLAINT FOR:
1. **Strict Products Liability**
2. **Negligence**
3. **Breach of Express Warranties**
4. **Negligent Misrepresentation**
5. **Fraudulent Concealment**
6. **Punitive Damages**

DEMAND FOR JURY TRIAL

COMPLAINT

This is a products liability lawsuit related to a defective and recalled prosthetic hip implant. This Complaint is being filed in the Eastern District of California and is related to MDL 2775, *In Re:* Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Products Liability Litigation, in the District of Maryland.

Plaintiff, Gary A. Lunsford, states the following for his Complaint and jury demand against Defendant, Smith & Nephew, Inc., a Tennessee Corporation:

JURISDICTION AND VENUE

1. Plaintiff is, and at all times relevant to this action, was a citizen and resident of the State of California with his place of residence being on Holbrook Drive in Riverbank, California, which lies in Stanislaus County.

2. Defendant, Smith & Nephew, Inc., is and at all times relevant to this action, was a resident and/or corporation 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, the Plaintiff/Defendant had the requisite minimum contacts with the State of California, and the amount in controversy in this action exceeds Seventy Five Thousand Dollars ($75,000.00) exclusive of interest and costs.

4. The Eastern District of California also is the proper venue for this matter pursuant to 28 U.S.C. § 1391 because a substantial number of the events, acts and omissions forming the basis of Plaintiff's claims took place in the Eastern District of California, and because Defendant conducts substantial business in this District. Stanislaus County, where Plaintiff resides, is furthermore part of the Eastern District of the United States District Court for California.

FACTUAL BACKGROUND

5. Defendant Smith & Nephew is a wholly owned subsidiary of Smith & Nephew plc, a public entity incorporated under the laws of England and Wales.

Smith & Nephew is a global medical technology company, with a presence in more than 90 countries worldwide, and total sales of $4.67 billion in 2016.

6. 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 Birmingham Hip Resurfacing System ("BHR"), which Smith & Nephew withdrew from the U.S. market and subsequently recalled on September 10, 2015, due to high failure rates, especially for female patients and for patients with smaller joint sizes.

7. In a resurfacing arthroplasty, the femoral head is not removed but is instead trimmed and capped (resurfaced) with a smooth metal covering. This procedure differs from a total hip replacement, which includes the placement of a prosthetic femoral stem.

8. The BHR device consists of a femoral head component and a hemispherical acetabular cup that is made in a range of 12 sizes. The cup fits into the patient's hip socket, or acetabulum, and then rubs against the femoral head during articulation (movement) of the patient's hip joint. Both components are made of cobalt and chromium metal alloys, and thus are "metal-on-metal" hip implant components.

9. In order to sell the metal-on-metal BHR device in the United States, Defendant submitted an application for Pre-Market Approval ("PMA") to the U.S. Food and Drug Administration on or about July 19, 2004.

10. The U.S. Food and Drug Administration did not approve the application as submitted because the device's PMA was deficient for a number of reasons. The deficiencies in the PMA application forced Smith & Nephew to make as many as eighteen (18) amendments and changes to the application before it was approved. The exact reasons for these deficiencies, and the documents describing them, are solely within the possession of Smith & Nephew and/or the FDA, and can be described in greater detail only with the assistance of discovery in this proceeding.

11. Further evidence of the deficient nature of Smith & Nephew's application is contained in a citizen petition submitted to the FDA on or about February 8, 2006, by one of Smith & Nephew's competitors, Wright Medical Technology, objecting to the PMA application for the BHR and stating that the application lacks "scientifically sound data" to meet the applicable legal standards for Pre-Market Approval.

12. Almost two years after the initial application, the FDA on May 9, 2006, finally granted conditional approval to Smith & Nephew to market the BHR based

on strict guidelines that required ongoing clinical studies, monitoring, reporting of certain adverse events, post-marketing surveillance and other measures.[1]

13. Failure to follow the requirements of the conditional approval of the BHR constitutes a violation of the Federal Food, Drug, and Cosmetic Act ("Act"), pursuant to 21 CFR § 801.19, and furthermore voids any legal protection that Defendant enjoys from tort claims as part of the device's PMA status. For example, Page 4 of the approval letter from the FDA states that "failure to comply with any postapproval requirement constitutes a ground for withdrawal of approval of a PMA. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act."

14. As part of the PMA requirements, Defendant initiated a long-term safety and effectiveness study, based in part on the outcomes of the first 350 patients in the Overall McMinn Cohort in the United Kingdom, as well as individuals implanted with the BHR at locations across the United States.

15. As part of the Study, Defendant agreed to collect data from clinical exams, x-rays, and an annual questionnaire, and compile information on each patient's Harris Hip Score, including pain, function, movement, revision status and adverse events during a 10-year period following implantation. But at least one of the study surgeons dropped out of the Study, and others failed to notify patients of

[1] *See* Center for Drug Evaluation and Research, Food and Drug Administration, *The Clinical Impact of Adverse Event Reporting*, MedWatch, October 1996; *see also* Division of Epidemiology, Office of Surveillance and Biometrics, Food and Drug Administration, *Approval Studies for Medical Devices Workshop*, June 2009.

the health risks of metallosis, even after study subjects reported toxic levels of cobalt and chromium in their blood. Smith & Nephew also failed to enroll the required number of patients in the Study. For example, in May 2013, approximately seven years after PMA approval, the company told the FDA that it had only enrolled 269 out of the planned 350 patients in the Study.[2] On information and belief, only a small fraction of the required number of patients were enrolled in the Study during the first five years the BHR was available in the U.S., despite tens of thousands of the devices being sold and implanted in patients.

16. The Study results also were biased because men, who typically have a lower failure rate in a resurfacing procedure, made up approximately three-quarters of study participants, compared to women who made up only one quarter of participants.[3] Smith & Nephew also reported 35 deviations from the study protocol, which resulted in a poor patient follow-up rate, in part due to Smith & Nephew failing to adequately staff the study locations with enough research coordinators.[4] These and other problems prompted the FDA to write a letter to Debra Gilbert, Senior Clinical Affairs Specialist at Smith & Nephew, on Oct. 26, 2012 stating that the FDA was unable to review the adequacy of the BHR studies and reports due to "inadequate" information from Smith & Nephew.[5]

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[2] Tables 7, BHR System Post-Approval Study, 84-Month Interim Study Status Report, May 6, 2013, obtained via Freedom of Information Act.
[3] *Id*.
[4] BHR System Post-Approval Study, 72-Month Interim Study Status Report, May 12, 2012, obtained via Freedom of Information Act.
[5] I*d.* (written by Danica Marinac-Dabic, Director, Division of Epidemiology, Office of Surveillance and Biometrics).

17. Despite the fact that the Study was a requirement of the PMA, Smith & Nephew prematurely closed the Study's U.S. patient database on March 19, 2012, before the planned completion date, and thus did not comply with the terms of the PMA. On several occasions, the FDA reported the status of the BHR Study was "progress inadequate" in part because patient enrollment milestones were not met, and because it failed to timely submit scheduled reports to the FDA pursuant to 21 CFR § 814.84, *et. seq.* Mandatory reports for the study were submitted late to the FDA at least three times in the last eleven years — in Nov. 2006, July 2011 and May 2017. Documents submitted by Smith & Nephew to the FDA as recently as May 2013 show that of the eight planned "investigational" sites for the PMA study, only four were operational at the time, while a fifth had dropped out due to slow patient enrollment and three others were still "pending site initiation, contract execution and … approval."

18. Further evidence of PMA violations is contained in FDA correspondence to Smith & Nephew dated July 8, 2014, in which the agency issued a deficiency notice and warned the company about bias in its study results because Smith & Nephew had failed to reach the 80 percent target follow-up rate with study participants. Smith & Nephew did not even bother to respond to the FDA's query within the required time frame.[6]

[6] Jeff Sprague, Regulatory Affairs, Smith & Nephew, Letter to FDA Center for Devices and Radiological Health, August 6, 2014 (requesting, in part, a two-week extension to respond).

19. Smith & Nephew also recalled numerous versions of the BHR device in 2007 due to labeling problems and other issues, and it submitted at least twenty-seven (27) proposed supplements to the terms of the PMA from the time of its initial approval in 2006 through May 2014.

20. Smith & Nephew agreed to implement a training program as part of the PMA including quarterly teleconferences with surgeons during the first two years of the U.S. portion of the safety study, and Smith & Nephew agreed to provide the FDA with an analysis of adverse events and complaints related to the BHR system.

21. Smith & Nephew began a BHR training program for surgeons on Dec. 13, 2006, but it failed to achieve the training milestones it promised to the FDA, and the company in fact did not begin widespread training until late 2009 – more than three years after the BHR became available in the U.S. - when it admitted to the FDA that surgeons were performing resurfacing operations despite having not been trained at all by Smith & Nephew in how to properly perform the procedure.[7]

22. Although Smith & Nephew failed to follow its own training protocol, which was a requirement of the PMA, the company and the inventor of the BHR, Dr. Derek McMinn, later did not hesitate to blame those same inadequately trained

[7] Email from Gino Rouss of Smith & Nephew to John Goode of the FDA, Oct. 22, 2009 (stating, in part that "… hip resurfacing arthroplasty has now been utilized since the BHR device was approved in May, 2006, and it is common for surgeons to receive exposure and training through channels other than Smith & Nephew. As such, Smith & Nephew would like to develop a separate training program that would be followed by surgeons that are not associated with the Post-Approval Study."

surgeons for the BHR's high failure rate in subsequent years. For example, in August 2011, four years before the BHR was finally recalled, Dr. McMinn published an article titled "Metal Ions Questions & Answers" in which he attempted to distinguish the BHR from other problematic and failure-prone metal-on-metal hip devices, including the DePuy ASR.[8] Dr. McMinn placed the blame for these failures on surgeons who improperly placed the device, and on patients themselves, particularly women, whom he claimed are "'pre-sensitised' to metal due to the usage of costume jewellery etc. and their tissues may "over-react" to low levels of nickel released from artificial devices"(sic). Dr. McMinn did not offer any scientific evidence for his theory about the connection between costume jewelry and failure rates for the BHR.

23. The DePuy ASR device was recalled in August 2010, giving Smith & Nephew ample warning about the dangers of its similar BHR device. Clinical comparisons of the ASR and BHR devices at the time showed that the BHR had a similar linear wear rate and generated similar levels of metal ions in patients as the ASR.[9]

24. Although Smith & Nephew was aware of the risks associated with the BHR for many years, it did not inform Plaintiff or her healthcare providers until 2015 when it was too late. Nonetheless, Smith & Nephew was aware of information

[8] Dr. Derek McMinn, *Metal Ions Questions & Answers*, available at http://www.mcminncentre.co.uk/metal-ions-questions-answers.html

[9] Underwood, et. al., *A Comparison of Explanted Articular Surface Replacement and Birmingham Hip Resurfacing Components*, J. Bone Joint Surg. 2011 Sep; 93(9); 1169-77.

about the BHR's unreasonably high risk of premature failure for certain patient populations as early as 2008, when the Australian Orthopaedic Registry published data from the previous year showing that female resurfacing patients with a femoral head size of less than 50 mm faced a more than three-fold increased risk of revision (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).[10]

25. Two years after the publication of the Australian joint registry data, one of Smith & Nephew's own paid researchers, Callum W. McBryde, performed a study showing a more than four-fold increased risk of failure (HR = 4.68 times higher) for each 4-mm decrease in the size of the BHR patient's femoral head.[11] McBryde wrote in a 2010 article about the study that the increased risk of revision was unrelated to surgeon technique, and that femoral size was the best indicator of revision rate.

26. Smith & Nephew also was criticized by researchers who found that early safety statistics for the BHR device — the same data Smith & Nephew submitted to the FDA for its PMA approval — could not be duplicated by outside

[10] Hip and Knee Arthroplasty, Australian Orthopaedic Association, 2008 Annual Report.
[11] C.W. McBryde, et. al., The Influence of Head Size and Sex on the Outcome of Birmingham Hip Resurfacing, J. Bone Joint Surg. Am., 2010 (Jan. 92(1) 105-12).

surgeons who did not receive the detailed training of the original designers and surgeons.

27. For example, in a 2012 article in International Orthopaedics, researchers found that the revision rate for the BHR was nearly three times higher for the general patient population than it was for patients treated by the original surgeons who designed the BHR in England (0.27 revisions per 100 observed component years for development team, compared to 0.74 in national registry data).[12] A second study published in 2012 was even more critical, showing that a single surgeon not involved in designing the BHR device experienced a failure rate of 15.4 percent for female patients, and 44.4 percent for all patients with a 42 mm femoral head.[13] Finally, a third study published in 2012 found that seven out of eight revision surgeries in resurfacing patients were due to adverse reaction to metal debris, and that "… overall survival was unsatisfactory."[14]

28. Smith & Nephew also was aware of problems with metal-on-metal hips generally, when it sent a team of employees and/or consultants, including but not limited to Tim Band, Dr. Joseph Daniel and BHR inventor Dr. Derek McMinn, to participate in the FDA's Orthopaedic and Rehabilitation Devices Advisory Panel meeting on metal-on-metal hip implant systems on or about June 27-28, 2012, in

[12] Schuh, R., D. Neumann, et. al., *Revision Rate of Birmingham Hip Resurfacing Arthroplasty: Comparison of Published Literature and Arthroplasty Registere Data*, Int. Orthop 36(7): 1349-1354 (2012)(stating that "… the excellent results reported by the development team are not reproducible by other surgeons.")

[13] J.P. Holland, et. al., Ten-year clinical, Radiological and Metal Ion Analysis of the Birmingham Hip Resurfacing, J. Bone & Joint Surg., 2012; 94-B 471-6.

[14] Reito, et. al., Results of Metal-on-Metal Hip Resurfacing in Patients 40 Years Old and Younger, Arch. Orthop. Trauma Surg (published online Nov. 8, 2012).

Gaithersburg, Maryland. The purpose of the meeting was to discuss mounting concerns about the safety of metal-on-metal hip devices, both for total hip arthroplasty and hip resurfacing arthroplasty. It followed an FDA statement in February 2011 about health risks of metal-on-metal systems for both types of procedures.[15]

29. After years of complaints and repeated lack of action, on June 4, 2015, Smith & Nephew announced the voluntary removal of the BHR device from the U.S. market due to unreasonably high failure rates for certain demographic groups, including all women, all men age 65 or older, and all men with requiring femoral head sizes 46 mm or smaller.[16]

30. The market withdrawal of the BHR followed numerous other warning signs, including an Urgent Field Safety Notice[17] sent to doctors in November 2014 about high revision rates for the same population groups mentioned above, and for patients with congenital dysplasia, and diagnosed avascular necrosis. But Smith & Nephew knew about these and other problems years before it finally issued a recall, and it continued to promote the BHR device even after well-documented problems with other metal-on-metal hips such as the Zimmer Durom, DePuy ASR, Biomet

[15] FDA Statement on Metal-on-Metal Hip Systems, 2011 available at https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetalHipImplants/ucm241601.htm.

[16] Smith & Nephew, *Statement Regarding BHR System*, June 4, 2015, available at http://www.smith-nephew.com/news-and-media/media-releases/news/statement-regarding-bhr-system/ (last visited March 22, 2017)(stating that "… Smith & Nephew considers that these patient groups may be at a greater risk of revision surgery than previously believed, and is therefore removing small sizes and updating the IFU to contraindicate the BHR for women.")

[17] Smith & Nephew, *Urgent Field Safety Notice*, FSCA R-2014-12.

Magnum, DePuy Pinnacle and Wright Conserve, all of which were removed from the U.S. market earlier.

31. Smith & Nephew had numerous chances to follow the lead of its competitors and warn patients of the unreasonable failure rate associated the metal-on-metal BHR device. 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."[18]

32. In conjunction with the above-mentioned market withdrawal, Smith & Nephew issued a Class 2 recall of the BHR device on September 10, 2015, covering 5,987 units (Recall Number Z-2745-2015), 10,167 units (Recall Number Z-2746-2015) and 624 units (Recall Number Z-2747-2015) respectively in the stream of commerce, due to "revision rates which were higher than established benchmarks" pursuant to 21 CFR § 7.55e.

33. Data published in connection with the recall show a total of 397 "device problems" with the BHR, including numerous safety problems related to "metal shedding debris" and other symptoms typical of metal-on-metal device failure.[19] Earlier, in its 2012 post-marketing annual report to the FDA, Smith & Nephew disclosed 356 reportable complaints for the BHR alone between March 1,

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

[19] A list of the device failures is available through the FDA's Manufacturer and User Device Experience, or MAUDE, database.

2011, and February 29, 2012. However, an independent analysis of FDA data shows an additional thirty (30) reported complaints during the same time period, or 8.4 percent more complaints than Smith & Nephew disclosed in its annual report. Numerous complaints also were not logged with the FDA until six months or longer after Smith & Nephew received them, and in some cases they were not logged until several years later.

34. The following year, S&N disclosed 380 reportable complaints between April 1, 2012, and April 1, 2013. But Smith & Nephew failed to accurately report, or conduct follow-up investigations, for more than half of these safety problems to the FDA. For example, it stated "no code available" for 64 of the incidents, and stated "no information" for another 153 incidents, even though many incidents were reported by attorneys, physicians and other parties who easily could have provided additional details.

35. By this time, in 2013 and 2014, Smith & Nephew did state that at least some of the revision surgeries were due to metallosis. However, in the first several years after the BHR entered the U.S. market, Smith & Nephew failed to report the risk of metallosis in its adverse events to the FDA. According to an independent analysis of these adverse event reports, the term "metallosis" was not used in these reports until late 2010, even though the company knew of dozens and possibly hundreds of cases where metallosis was found. Instead, Smith & Nephew went to great lengths to blame device failure on other sources, such as the patient's allergies

to metal, or generalized pain. Here is a short list of examples that show how Smith & Nephew avoided responsibility for the BHR's metal-on-metal risks.

- Adverse Event Report 1921214 (2010): "the revision surgeon does not fault the devices.
- Report 1058217 (2008): "it was reported that revision surgery was performed due to metal allergy."
- Report 1353825 (2009): "incorrect positioning."
- Report 1402939 (2009): "revision surgeon does not fault the device."
- Report 960061 (2007): "surgical error."
- Report 1626209 (2010): "nickel allergy."

36. While Smith & Nephew tried to hide the true cause of the BHR's failure rate, clinical data continue to pile up showing the real risk for patients including Plaintiff. Data compiled by the National Joint Registry of England and Wales, for example, show the BHR 42 mm femoral head component has a seven-year revision rate of 11.76 percent, well above the normal acceptable failure rate for a device of this type.

37. A separate study of the BHR device in England showed that out of 319 patients, nearly 30 percent had modified Harris Hip Scores below 90 at their ten-year follow up exam, and approximately 12 percent of patients had scores below 80.[20] A score above 90 is considered excellent. Scores below that number are described as either poor, fair, or good.

38. Contrary to Defendant's representations and marketing to the medical community and to the patients themselves, Defendant's BHR resurfacing products

[20] FDA Medical Devices, *Post-Approval Studies, PMA P040033*.

have high failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and sometimes irreversible injuries, conditions, and damage to a significant number of patients, including Plaintiff.

39. In addition to the high failure rate of the BHR device, and the Class II recall, Defendant Smith & Nephew also failed to comply with numerous requirements of the PMA, including the safety study, surgeon teleconferences, and adverse event reporting, all of which are described in more detail below.

PRE-EMPTION AND THE FEDERAL FOOD, DRUG AND COSMETIC ACT

40. Manufacturers of the Class III devices such as the BHR are required to obtain premarket approval ("PMA") from the Food and Drug Administration before they can make their products available to patients. 21 U.S.C. § 360(e). The PMA process is part of the regulatory framework of the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act of 1976.

41. The duties of a Class III medical device manufacturer do not end with PMA approval. Instead, the MDA imposes a number of ongoing requirements, including requiring manufacturers to strictly adhere to the design, manufacturing, packaging, storage, labeling, distribution, and advertising specifications in the PMA approval order pursuant to 21 C.F.R. § 814.80, and to conduct ongoing safety studies and notify the FDA of any unexpected serious problems with the device.

42. A U.S. manufacturer of Class III medical devices with PMA approval must comply with the FDA's Quality Systems Regulations ("QSR"). 21 CFR § 820 *et seq*. The specific QSR promulgated by the FDA are known as Current Good Manufacturing Practices ("CGMP"). 21 CFR § 820.1(a). A manufacturer must satisfy these quality standards in the manufacture and production of medical devices. 21 CFR § 820.1(a).

43. These quality standards include the duty to identify and respond to a "nonconforming product." A manufacturer, such as Smith & Nephew, must "establish and maintain procedures to control product that does not conform to specified requirements," such as a failure to conform to performance and design standards set forth in the manufacturer's PMAs and supplements. 21 CFR § 820.90. "The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product." CGMP/QSR also require a manufacturer to establish and maintain procedures for implementing corrective actions and preventive actions ("CAPAs"), including investigating the cause of nonconformities in the product, processes and quality systems, and taking corrective action to prevent recurrence of such nonconformities. 21 CFR § 820.100.

44. FDA's CGMP/QSR may require a manufacturer to test for, monitor for (through postmarketing surveillance), discover, investigate and remedy issues related to the safe and effective use of a medical device as approved. A part of satisfying these postmarketing surveillance duties can be to formulate and then

effectively execute a Postmarketing Surveillance Plan for the purpose of ascertaining any issues regarding the safe and effective use of the device once released to the market. 21 CFR § 822.8.

45. Similar to Postmarketing Surveillance Plans, CGMP/QSR require a manufacturer to review and evaluate all complaints regarding the operation of a medical device and determine whether an investigation is necessary. 21 CFR § 820.198(b).

46. An investigation must be completed when a complaint involves the possible failure of a device, its labeling or its packaging to meet any of its specifications, unless an investigation for a similar complaint has already been performed. 21 CFR § 820.198(c).

47. Also similar to Postmarketing Surveillance Plans, a device manufacturer is required to establish and maintain procedures to identify valid statistical techniques for establishing, controlling and verifying the acceptability of process capability and product characteristics, unless the manufacturer documents justification for not having procedures in place regarding statistical techniques. 21 CFR § 820.250 and 21 CFR § 820.1(a)(3).

48. A medical device manufacturer is required to comply with FDA requirements for records and reports, in order to prevent introduction into the market of medical devices that are adulterated or misbranded, and to assure the continued safety and effectiveness of a medical device.

49. In particular, a manufacturer must keep records and make reports if any medical device may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury. 21 U.S.C. § 360(i). "Serious injury" is defined to mean an injury that "necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure…." *Id.*

50. According to its Congressional mandate, the FDA must establish regulations requiring a manufacturer of a medical device to report promptly to the FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. 21 U.S.C. § 360(i).

51. Adverse events associated with a medical device must be reported to the FDA within 30 days after a manufacturer becomes aware that a device may have caused or contributed to death or "serious injury," or that a device has malfunctioned and would be likely to cause or contribute to death or "serious injury" if the malfunction was to recur. 21 CFR § 803.50(a).

52. This reporting is mandatory and is a condition of continued PMA approval. 21 CFR § 814.82. Such reports must contain all information reasonably known to a manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. 21 CFR § 803.50(b)(1).

53. In addition, a manufacturer is responsible for conducting an investigation of each adverse event and must evaluate the cause of the adverse event. 21 CFR § 803.50(b)(3). A manufacturer must also describe in every individual adverse event report whether remedial action was taken in regard to the adverse event and whether the remedial action was reported to the FDA as a removal or correction of the device. 21 CFR § 803.52(f), (9).

54. A manufacturer must report to the FDA in five (5) business days after becoming aware of any Medical Device Report ("MDR") event or events, including a trend analysis, which necessitates remedial action to prevent an unreasonable risk of substantial harm to public health. 21 CFR § 803.53.

55. This reporting is mandatory and a condition for continued PMA approval. A device manufacturer must report promptly to the FDA any device corrections and removals, and maintain records of device corrections and removals. 21 CFR § 806.10(a). FDA regulations require submission of a written report within ten (10) working days of any correction or removal of a device initiated by a manufacturer to reduce a risk to health posed by the device, or to remedy a violation of the FDCA caused by the device which may present a risk to health. 21 CFR § 806.10(b).

56. The written submission must contain, among other things, a description of the event giving rise to the information reported and the corrective or removal actions taken, and any illness or injuries that have occurred with use of the

device, including reference to any device report numbers. A manufacturer must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal and provide a copy of all communications regarding the correction or removal. 21 CFR § 806.10(c).

57. FDA regulations state: "Recall means a firm's removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure." 21 CFR § 7.3(g).

58. A Recall does not necessarily mean a removal of a marketed device, but may also include its "correction" by "repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location." 21 CFR § 7.3(h).

59. A device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities, or controls used for its manufacture, packing, storage, or installation are not in conformity with the federal requirements. 21 U.S.C. § 351(e) & (h).

60. Devices subject to an FDA recall are, by definition, adulterated and prohibited for introduction into interstate commerce by the Federal Food, Drug, and Cosmetic Act ("FDCA"). 21 U.S.C. § 331(a).

61. 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).

62. 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.

63. A "misbranded" device is prohibited for introduction into interstate commerce by the FDCA. 21 U.S.C. § 331(a).

64. As stated in Smith & Nephew's PMA Approval Letter for its BHR device: "… [T]he manufacturer shall submit the appropriate reports required by the MDR Regulation within the time frames as identified in 21 CFR 803.10(c) … i.e., 30 days after becoming aware of a reportable death, serious injury, or malfunction as described in 21 CFR 803.50 and 21 CFR 803.52 and 5 days after becoming aware that a reportable MDR event requires remedial action to prevent an unreasonable risk of substantial harm to the public health."

65. Thus, unexpected adverse events or expected adverse events in more frequency than that expected in the original PMA approval and/or any device issue that requires changes in labeling, manufacturing processes or device design are not

sanctioned by the FDA in its original approvals, and are subject to further review and action by the agency despite such original approvals.

66. A manufacturer marketing a medical device in the United States under an approved PMA must submit for approval by the FDA a PMA Supplement when proposing any change to the device that affects its safety and effectiveness, including any new indications for use of a device, labeling changes, or changes in the performance or design specifications, circuits, components, ingredients, principle of operation or physical layout of the device. 21 CFR § 814.39(a).

67. A failure to comply with the conditions of PMA approval (especially including violation of FDA Regulations described above) invalidates PMA approval orders.

68. Commercial distribution of a device that is not in compliance with these conditions is a violation of the FDCA.

69. Congress anticipated that a manufacturer tasked with post-market surveillance of its PMA approved product's performance, such as the BHR, would require a voluntary mechanism to be able to quickly update its approved product's manufacturing, labeling and marketing to protect the public and to ensure its own compliance with the Act. Such a mechanism, to be expedient, protect patients and comply with the FDCA, should not be delayed because the FDA has not yet given its formal approval.

70. A manufacturer of an approved PMA may voluntarily implement certain changes to its device, its manufacturing processes or its labeling to enhance the safety of the device prior to obtaining FDA approval.

71. Such changes need not wait for FDA approval but can be implemented immediately. These changes may include, but are not limited to, labeling changes that add or strengthen a contraindication, warning precaution, information about an adverse reaction or information intended to enhance safe use, or changes in quality controls or manufacturing process that add a new specification or test method, or otherwise provides additional assurance of purity, strength or reliability of the device. 21 CFR § 814.39(d)(1) and (2).

72. The PMA regulation (21 CFR § 814) sets forth general criteria for determining when a device manufacturer must submit a PMA supplement and details the various types of supplements available to the device manufacturer.

73. The MDA contains an express preemption provision found at 21 U.S.C. § 360k, so long as the manufacturer follows all of the conditions set forth in the PMA and in the MDA generally.

74. The MDA does not, however, preempt state law claims that are sufficiently parallel to a violation of the above federal requirements, so long as those claims are based on violations of state law duties that predate and operate independently from the federal requirements.

75. Hundreds of patients across the United States have sought compensation from Smith & Nephew due to premature failure of the BHR device, based on violations of state common law duties and the federal requirements. Smith & Nephew's attempts to hide behind the veil of preemption have been rejected by numerous other Courts in cases involving the same BHR device. *Comella v. Smith & Nephew, Inc.*, 2013 WL 6504427 (N.D. Ill. 2013); *Elmore v. Smith & Nephew, Inc.*, 2013 WL 1707956 (N.D. Ill. 2013); *Gale v. Smith & Nephew, Inc.*, 989 F.Supp.2d 243 (S.D.N.Y. 2013); *Herron v. Smith & Nephew, Inc.*, 2014 WL 1232224 (E.D.Ca. 2014); *Tillman v. Smith & Nephew*, 2013 WL 3776973 (N.D.Ill. 2013); *Laverty v. Smith & Nephew, Inc.*, 1:15-cv-09485 (N.D. Ill. 2015); *Frederick v. Smith & Nephew, Inc.*, 2013 WL 6275644 (N.D. Ohio 2013); *Williams v. Smith & Nephew, Inc.*, 2015 U.S. Dist. LEXIS 108670 (D. Md. Aug. 18, 2015); *Raab v. Smith & Nephew, Inc.*, 14-CV-30279 (S.D.W.V., Dec. 15, 2015); *Marion v. Smith & Nephew, Inc.*, 2016 U.S. Dist. LEXIS 99449.

GENERAL CLAIMS FOR RELIEF

76. This is a strict products liability and negligence action arising out of Defendant Smith & Nephew's violations of the Federal Code of Regulations, the State Laws of California and the damages that Plaintiff suffered as a result of a defective hip implant.

77. Defendant, Smith & Nephew, Inc., is a developer and manufacturer of joint replacement systems. Since 2006, Defendant, Smith & Nephew, Inc., has

manufactured, introduced and/or delivered the Birmingham Hip Resurfacing System (hereinafter "BHR") into the stream of interstate commerce. The BHR is a metal-on-metal hip resurfacing prosthesis. It is comprised of the following two (2) components:

a. Birmingham Resurfacing Femoral Head; and

b. Birmingham Hip Resurfacing Acetabular Cup.

78. Before commercially distributing the BHR in the United States, federal law required Defendant, Smith & Nephew to submit an application for premarket approval ("PMA") of the device to the Secretary of Health and Human Services. On May 9, 2006, the Food and Drug Administration ("FDA") completed its review of Defendant, Smith & Nephew's PMA application for the BHR. Based on the materials submitted by Defendant, Smith & Nephew, the FDA conditionally approved the BHR for commercial distribution.

79. The Approval Order 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.]."

80. The Approval Order cited many agreements Smith & Nephew made with the FDA, which became part of the approval. Thus, the Approval Order became an outline of the specific post-market obligations and duties Smith & Nephew undertook, in addition to all those existing under Federal Law, when it finally convinced the FDA to conditionally approve the BHR. Those agreements

included, but were not limited to, the following:

a. Smith & Nephew would conduct a post-approval study and submit its reports biannually the first two years and annually for the next eight years following premarket approval, which study was to evaluate the "longer-term safety and effectiveness" of the BHR;

b. Smith & Nephew would implement a training program of its physicians, which was to include quarterly investigator teleconferences or meeting the first two years "to discuss study issues including adverse events; and to identify recommendations for improvement of the training program or labeling";

c. Smith & Nephew would "provide an analysis of adverse events and complaints (including MDRs) received regarding the BHR system";

d. Smith & Nephew would advise of the results of its post-approval studies, training program assessment, and adverse event analysis through a supplement in its labeling upon completion of the post-approval study, or at "earlier timepoints, as needed."

81. The Approval Order made clear that each requirement imposed upon Smith & Nephew with respect to its distribution of the BHR system was to

"ensure the safe and effective use of the device."

82. After Smith & Nephew received approval of the BHR system on May 9, 2006, Smith & Nephew became aware of defects in the BHR and harm it was causing, as well as deficiencies in surgeon training, but did not respond in accordance with its obligations, including but not limited to, the following:

a. Smith & Nephew received hundreds of adverse reports and complaints regarding the BHR but delayed its reporting to the FDA, and when it did communicate adverse reports, it did not do so properly but, in fact, attempted to blame others for the adverse events;

b. Smith & Nephew only initiated follow up inquiry on a fraction of adverse event reports by the patients' surgeons and sales force regarding the BHR;

c. Smith & Nephew became aware of wide evidence that the BHR systems were wearing down more quickly and severely than anticipated, and failed to take appropriate action to determine the cause and provide a solution, nor did it appropriately advise the FDA;

d. Smith & Nephew, when it did provide reports to the FDA pursuant to the Approval Order, underreported to and withheld

information from the FDA about the likelihood of failure; and/or,

e. Smith & Nephew also 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 and actively misleading the FDA, the medical community, patients, and public at large into believing that the BHR system was safe and effective.

83. Smith & Nephew's failures to follow the requirements of the Approval Order constitute violations of the Federal Food, Drug, and Cosmetic Act, pursuant to 21 CFR § 801.109 and furthermore voids any legal protection that Defendant enjoys from tort claims as part of the device's PMA status. Specifically, Smith & Nephew failed to warn healthcare professionals, the public, and Plaintiff in particular, of the new information it learned about the BHR's risks, and failed to take reasonable efforts to issue an effective post-sale warning.

FRAUDULENT CONCEALMENT

84. Smith & Nephew fraudulently concealed the fact that they did not enjoy legal protection provided as part of device's PMA status. Smith & Nephew failed to disclose information to the scientific and medical communities, as well as consumers, in violation of its duty to disclose. The information purposely withheld

was material, and was information that consumers, such as Plaintiff could not have learned without Smith & Nephew's disclosure.

a. Specifically, Smith & Nephew intentionally withheld from consumers the fact that it no longer enjoyed PMA protection; at minimum, this material fact was intentionally withheld from the public, and consumers such as Plaintiff, until the formal recall in September 2015. Accordingly, consumers, such as Plaintiff, were misled into believing that they had no claim or recourse for the injuries suffered due to the BHR system.

b. Because Smith & Nephew intentionally withheld this material information concerning the PMA status, numerous Plaintiffs were harmed by relying on the nondisclosure, and acted on such reliance.

c. Because Smith & Nephew continues to maintain that it has PMA protection from all claims, and because of the fraudulent concealment of material facts, Plaintiff is well-within the statute of limitations at the time of this filing. Plaintiff's statute of limitations would have begun to run from the recall date in September 2015, or the date of his revision surgery, whichever is later.

PLAINTIFF'S INJURIES

85. On or about September 4, 2010**,** Plaintiff, Gary Lunsford, was admitted to Kaiser Permanente Roseville Medical Center of Roseville, California, for the purpose of undergoing a left hip resurfacing by Rachael Klug, M.D. At the time of said surgery, Dr. Klug utilized and implanted the Defendant's Birmingham Hip

Resurfacing system. Specifically, the following components of said system were utilized:

a. Smith & Nephew Birmingham Resurfacing Femoral Head 36 mm; and

b. Smith & Nephew Birmingham Resurfacing Acetabular Cup 44 mm.

86. On or about October 4, 2016, Plaintiff, Gary Lunsford, underwent revision of his left hip due to pain and other complications caused by the failure of the Defendant's Birmingham Hip Resurfacing system. Plaintiff's revision surgery was performed by Robert M. Cash, M.D. at Doctors Medical Center in Modesto, California.

87. In his revision operative note, Dr. Cash described evidence of metallosis in Plaintiff's body and a pseudotumor formation in Plaintiff's hip joint as a result of the premature failure of the device.

88. At the time of the initial resurfacing procedure, neither Plaintiff nor his surgeon were aware of the myriad of problems associated with the BHR. In fact, as stated below in more detail, Smith & Nephew continued to promote the BHR as a safe alternative to other metal-on-metal hip devices long after it knew or reasonably should have known of the risk of premature metal-on-metal failure, and did not withdraw the device from U.S. markets until 2015.

FIRST CLAIM FOR RELIEF

STRICT PRODUCTS LIABILITY BASED ON VIOLATIONS OF 21 C.F.R. 820.30 (f) and (g); 21 C.F.R. 820.80 (c) and (d); 21 C.F.R. 820.100; 21 C.F.R. 820.198

89. Plaintiff herein incorporates, reasserts and re-alleges the allegations set forth above in paragraphs 1-88 by reference as if fully set forth herein below.

90. Defendant designed and/or manufactured the BHR Systems implanted in Plaintiff's left hip, 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.

91. At the time the BHR Systems, including the Acetabular Cups and Femoral Heads, left the control of Defendant, Smith & Nephew, they were unreasonably dangerous due to Defendant's non-compliance with the Act, and the regulations promulgated pursuant to it and the Approval Order in one or more of the following ways:

a. Failed to accurately establish the in vivo life expectancy of the BHR, 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); 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 implant *in vivo*;

c. Failed to establish and maintain appropriate reliability assurance testing to validate the BHR 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'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, returned BHR, and other quality problems associated with the BHR, 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; For example, instead of adequately investigating these incidents, Smith & Nephew in its PMA annual reports to the FDA blamed catastrophic product failures of the BHR on generalized issues such as "pain" or "squeaking" or "allergic reaction";

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;

j. Continued to place the BHR 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; 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.

92. 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 BHR 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 BHR;

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 had been bribed or paid financial kickbacks or illegal payments and remuneration in order to use and promote the BHR;

j. Smith & Nephew willfully ignored the existence of numerous complaints about failures associated with components of the BHR 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 BHR 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 BHR had been undertaken when Defendant, in fact, knew or should have known that the testing was invalid and the results unreliable; and,

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 BHR 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.

93. As a direct and proximate result of Defendant's violations of one or more of these federal statutory and regulatory standards of care, a BHR System, including the acetabular cup and femoral head, was implanted in Plaintiff's left hip, and failed and such failure directly and proximately caused and/or contributed to the severe and permanent injuries the Plaintiff sustained and endured as defined in 21 C.F.R. § 803.3. 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.

94. 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.

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

96. Thus, under California 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 California Legislature to act in order to create such a remedy.

97. 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.]."

98. The cause of action set forth in this Claim for Relief is not preempted by 21 U.S.C. § 306(k) because the violations alleged 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. *See; Bausch v. Stryker,* 630 F.3d 546, 556 (7th Cir. 2010) (claims for negligence and strict products liability relating to a Class III medical device were not expressly preempted by federal law to the extent they were based on the defendants' violations of federal law). As such, the claims set forth herein contain requirements that are parallel to the Act and regulations promulgated thereunder.

99. As a direct and proximate result of Defendant Smith & Nephew's aforementioned actions, Plaintiff prays for judgment against Defendant, Smith & Nephew, Inc., in an amount in excess of Seventy Five Thousand Dollars ($75,000.00).

SECOND CLAIM FOR RELIEF

NEGLIGENCE BASED ON VIOLATIONS OF 21 C.F.R. 820.30 (f) and (g); 21 C.F.R. 820.80 (c) and (d); 21 C.F.R. 820.100; 21 C.F.R. 820.198

100. Plaintiff herein incorporates, reasserts and re-alleges the allegations set forth above in paragraphs 1-99 by reference as if fully set forth herein below.

101. The BHR Systems, including the acetabular cups and femoral heads, implanted in Plaintiff's left hip on September 4, 2010 were distributed and/or manufactured in violation of the Act and regulations promulgated to it.

102. Smith & Nephew consistently under-reported and withheld information about the likelihood of the BHR to fail and cause injury and complications, and has misrepresented the efficacy and safety of the BHR resurfacing products, actively misleading the medical community, patients, the public at large, and Plaintiff.

103. Defendant knew, and continues to know, that its disclosures to the public and Plaintiff were and are incomplete and misleading; and that Defendant's BHR resurfacing 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.

104. As a result, Smith & Nephew actively and intentionally misled and continues to mislead the public, including the medical community, health care

providers, and patients, into believing that the Defendant's BHR resurfacing products were and are safe and effective, leading to the prescription for and implantation of the BHR resurfacing products into patients such as Plaintiff. For example, in its 2015 annual report to the FDA, Smith & Nephew still did not list female patients or smaller bearing sizes in its list of contraindications for the BHR system, even though numerous studies cited those patient groups as being particularly at risk of premature failure.[21]

105. 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 Defendant's BHR resurfacing products. As compared to Smith & Nephew's BHR resurfacing 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.

106. Smith & Nephew's BHR resurfacing products were at all times utilized and implanted in a manner foreseeable to Defendant. 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 Defendant's BHR resurfacing products, thereby increasing the sales of the BHR resurfacing products, and also leading to the dissemination of inadequate and

[21] Jeff Sprague, Regulatory Affairs Specialist, PMA Annual Report to FDA, May 2, 2015 (obtained via Freedom of Information Act).

misleading information to patients, including Plaintiff and other patients who are female, or who have small femoral head sizes.

107. It was the duty of Defendant, Smith & Nephew, Inc. to comply with the Act, and the regulations promulgated pursuant to it, as well as the conditions established in the Approval Order with which Defendant agreed to comply in order to obtain premarket approval of its device. Yet, notwithstanding this duty, Defendant, Smith & Nephew, Inc. violated the Act in one or more of the following ways identified in the above list *supra* Claim I.

108. Smith & Nephew's failure to comply with the above-stated duties is evident through the non-exhaustive list, *supra* Claim I, of malfeasance, misfeasance, and/or nonfeasance on the part of Defendant. Subsequently, the BHR system implanted in Plaintiff's hip 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. 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.

109. This cause of action is based entirely on the contention that Defendant,

Smith & Nephew violated federal safety statutes and regulations. Plaintiff does not bring the underlying action as an implied statutory cause of action, but rather he is pursuing parallel state common law claims based upon Smith & Nephew's violations of the applicable federal regulations.

110. Under California law, Smith & Nephew's violations of the aforementioned federal statutes and regulations establish a *prima facie* case of negligence.

111. Thus, under California 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 California Legislature to act in order to create such a remedy.

112. The cause of action set forth in this Claim for Relief is not preempted by 21 U.S.C. § 306(k) because the violations alleged are all based on an exclusively federal statutory and regulatory set of requirements which include no "requirement which is different from, or in addition to, any requirement applicable under" the Act and regulations promulgated thereunder. *See; Bausch v. Stryker,* 630 F.3d 546, 556 (7th Cir. 2010) (claims for negligence and strict products liability relating to a Class III medical device were not expressly preempted by federal law to the extent they were based on the defendants' violations of federal law). As such, the claims set forth herein contain requirements that are parallel to the Act and regulations promulgated thereunder.

113. As a direct and proximate result of Smith & Nephew's aforementioned actions, Plaintiff prays for judgment against Smith & Nephew, Inc. in an amount in excess of Seventy Five Thousand Dollars ($75,000.00).

THIRD CLAIM FOR RELIEF
(Breach of Express Warranties)

114. Plaintiff herein incorporates, reasserts and re-alleges by reference as if fully set forth verbatim each and every allegation in the Complaint.

115. Smith & Nephew warranted, both expressly and impliedly, through its marketing, advertising, distributors and sales representatives, that the BHR resurfacing products were of merchantable quality, fit for the ordinary purposes and uses for which it was sold.

116. Smith & Nephew 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 system was safe, effective, fit and proper for its intended use.

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

118. Due to the defective and unreasonably dangerous BHR resurfacing 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.

119. Defendant breached their 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.

120. 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.

121. Instead of warning patients about the dangers of metal toxicity, which were well documented even in 2006 when the BHR was approved, Smith & Nephew as recently as 2013 disseminated unpublished reports from its own design surgeon, Derek McMinn, stating that "there does not appear to be any conclusive evidence that elevated cobalt and chromium levels have any significant detrimental effects in total hip arthroplasty patients."[22] 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

[22] McMinn, et. al., *Metal Ion Studies in Patients Treated with the Birmingham Hip Resurfacing, a Comparable FDA-approved Device and Historic Metal-on-Metal Total Hip Replacements* (original provided in 2006 Summary of Safety and Effectiveness, but recirculated to the FDA and other sources in 2012 and subsequent years in an effort to dispel concerns about metal ion disease).

triathlon" with their prosthetic BHR devices.[23] The same website, where Smith & Nephew prominently advertises its BHR device, publishes misleading articles by orthopedic surgeons and paid consultants, including but not limited to the BHR designer, Dr. Derek McMinn, downplaying the risks of the failure-prone BHR device, and comparing them favorably to other metal-on-metal devices, even though the BHR is just as failure prone as some of these other devices according to clinical studies.

122. Smith & Nephew also enlisted the services of professional athletes and celebrities in its efforts to promote the BHR system, including former NHL hockey player Tim Taylor, former NFL quarterback Steve Beuerlein, and former professional cyclist Floyd Landis.[24] The most recent example of these misleading marketing efforts is a campaign by Dr. McMinn himself, modeled after the presidential campaign slogan of Donald Trump, to "Make Resurfacing Great Again," through the use of a safer resurfacing device that includes a polyethylene acetabular cup, the PHR, which purportedly avoids the problems associated with metal-on-metal articulation in the original BHR system.[25] Thus, despite an overwhelming body of clinical literature showing the dangers of cobalt and

[23] 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.

[24] Smith & Nephew Marketing Campaign, *What Does Your Patient Want To Get Back To?* (October 2008).

[25] Dr. Derek McMinn, Custom Polyethylene Hip Resurfacing, January 17, 2017, available at http://www.mcminncentre.co.uk/custom-polyethylene-hip-resurfacing.html ("Together, this metal-on-polyethylene articulation is an ideal solution for patients, particularly women, who have an allergy to metals.").

chromium toxicity, the BHR's inventor and spokesman continues even today to blame patient "allergy sufferers," rather than the manufacturer or himself, for widespread metal-on-metal injuries.

Friday 20th January 2017 Make Resurfacing Great Again!

This InaugurationDay, Mr McMinn says *'Make Resurfacing Great Again'*, pictured here with Joseph Daniel (McMinn Centre Director of Research) and Terry Smith (Managing Director of Jointmedica).

(Left to Right: Joseph Daniel, Mr Derek McMinn & Terry Smith)

Mr McMinn's latest invention, the Metal-on-Polyethylene PolyMotion® Hip Resurfacing device is now available on a custom basis, click here for more information. The PHR is an ideal solution for metal allergy sufferers who want to reap the same rewards as a standard Hip Resurfacing. For further information, please watch Mr McMinn's latest video lecture available here.

123. 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."

124. The defective and unreasonably dangerous condition of the BHR

products constituted a breach of the Defendant's express warranties under California law.

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

126. Defendant breached their 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.

127. 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.

128. For example, in 2010, Smith & Nephew published a glossy brochure called "Apples to Oranges" which it sent to surgeons and patients. The brochure claimed the BHR was superior to other metal-on-metal devices, including the DePuy ASR, Zimmer Durom, Wright Conserve Plus, and many others. The Apples to Oranges brochure contained a series of voluntary statements that fall outside the PMA, and that were misleading and inaccurate, including:

- That "… there is no evidence that increased levels of cobalt and chromium ions are associated with any clinical effects." Smith &

Nephew knew about the adverse clinical effects of elevated cobalt and chromium levels, including metallosis, pseudotumor, and tissue and bone necrosis.

- That the BHR has "outstanding results" that are superior to a total hip replacement for male patients under 55 years of age. Smith & Nephew failed to mention any data for the BHR's performance in women or in men with smaller joint sizes. Both patient groups have failure rates that are dramatically higher than patients implanted with competing hips devices.
- Two years later, in 2012, Smith & Nephew'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.[26] The company made these claims, even though it knew as early as 2006 that resurfacing devices such as the BHR posed a serious risk of failure for certain populations, including Plaintiff, all women, and all patients with a small femoral head size.

129. As a direct and proximate result of Defendant's breaches of express

[26] 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.

warranties, 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.

FOURTH CLAIM FOR RELIEF
(Negligent Misrepresentation)

130. Plaintiff herein incorporates, reasserts and re-alleges by reference as if fully set forth verbatim each and every allegation in the Complaint.

131. Defendant had a duty to accurately and truthfully represent to the medical community, Plaintiff, and the public that BHR products 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.

132. Defendant negligently misrepresented to the medical community, Plaintiff, and the public that the BHR products did not have a high risk of dangerous adverse side effects. Defendant made this misrepresentation by consistently underreporting adverse events for the BHR, delaying reporting of adverse events, and categorizing them in a way that hid the true risk of failure due to metal-on-

metal symptoms, in violation of the terms of the PMA and 21 C.F.R. § 822.2 and 21 C.F.R. §§ 814.82 to 814.84.

133. Had Defendant accurately and truthfully represented to the medical community, Plaintiff, and the public the material facts relating to the risks of the BHR products, Plaintiff and/or Plaintiff's healthcare providers would not have utilized Defendant's BHR products for Plaintiff's treatment.

134. Defendant effectively deceived and misled the scientific and medical communities and consumers regarding the risks and benefits of the BHR system. Defendant did not inform the public or Plaintiff until, at the earliest, June 2015, when Defendant attempted to pull the product from the market for certain populations, including all women and men with smaller femoral head sizes.

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

136. As a direct and proximate result of Defendant's negligent misrepresentations, 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.

FIFTH CLAIM FOR RELIEF
(Fraudulent Concealment)

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

138. Throughout the relevant time period, Defendant knew that its BHR resurfacing products were defective and unreasonably unsafe for their intended purpose.

139. Defendant was under a duty to disclose to Plaintiff and the medical community the defective nature of the BHR resurfacing products because Defendant was in a superior position to know the true quality, safety, and efficacy of the BHR resurfacing products. Defendant fraudulently concealed the danger of the BHR device by underreporting adverse events for the BHR, delaying reporting of adverse events, and categorizing them in a way that hid the true risk of failure due to metal-on-metal symptoms, in violation of the terms of the PMA and 21 C.F.R. § 822.2 and 21 C.F.R. §§ 814.82 - 814.84.

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

141. 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.

142. Defendant's fraudulent concealment, as complained of herein, constitutes a parallel violation of California common law that predates and operates independently from the above federal requirements.

143. As a direct and proximate result of Defendant's fraudulent concealment, 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.

SIXTH CLAIM FOR RELIEF
(Punitive Damages)

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

145. The acts and omissions of the Defendant as set forth herein constitute intentional, fraudulent, malicious and/or reckless conduct. Accordingly, Plaintiff is entitled to an award of punitive damages.

WHEREFORE, PREMISES CONSIDERED, Plaintiff, Gary A. Lunsford, 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: June 6, 2017

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