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8
9 **UNITED STATES DISTRICT COURT**
10 **NORTHERN DISTRICT OF CALIFORNIA**
11 **SAN FRANCISCO/OAKLAND DIVISION**

11 LYDIA CONSTANTINI

12 Plaintiff,

13 v.

14 SMITH & NEPHEW, INC., a
15 Tennessee Corporation,

16
17 Defendants.

Case No: 3:17-cv-03649

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

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19
20 **COMPLAINT**

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

26 Plaintiff, Lydia Constantini, states the following for her Complaint and jury
27 demand against Defendant, Smith & Nephew, Inc., a Tennessee Corporation:

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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 her place of residence being on Lucas Avenue in Sonoma, California, which lies in Sonoma 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 Northern 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 Northern District of California, and because Defendant conducts substantial business in this District.

INTRADISTRICT ASSIGNMENT

5. Sonoma County, where Plaintiff resides, is furthermore part of the Northern District of the United States District Court for California. Pursuant to Civil L.R. 3-2(d), civil actions which arise in the county of Sonoma shall be assigned to the San Francisco Division or the Oakland Division of the Northern District.

FACTUAL BACKGROUND

6. 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.

1 7. Defendant markets, manufactures, and sells prosthetic hip devices for
2 use in total hip arthroplasty and resurfacing arthroplasty, specifically the hip
3 socket, acetabulum, and the ball, or femoral head. These hip replacement
4 products include the Birmingham Hip Resurfacing System (“BHR”), which Smith
5 & Nephew withdrew from the U.S. market and subsequently recalled on
6 September 10, 2015, due to high failure rates, especially for female patients and
7 for patients with smaller joint sizes.

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

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

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

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

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

7 13. Almost two years after the initial application, the FDA on May 9,
8 2006, finally granted conditional approval to Smith & Nephew to market the BHR
9 based on strict guidelines that required ongoing clinical studies, monitoring,
10 reporting of certain adverse events, post-marketing surveillance and other
11 measures.¹

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

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

24 16. As part of the Study, Defendant agreed to collect data from clinical
25 exams, x-rays, and an annual questionnaire, and compile information on each
26 patient’s Harris Hip Score, including pain, function, movement, revision status

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28 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.

1 and adverse events during a 10-year period following implantation. But at least
2 one of the study surgeons dropped out of the Study, and others failed to notify
3 patients of the health risks of metallosis, even after study subjects reported toxic
4 levels of cobalt and chromium in their blood. Smith & Nephew also failed to
5 enroll the required number of patients in the Study. For example, in May 2013,
6 approximately seven years after PMA approval, the company told the FDA that it
7 had only enrolled 269 out of the planned 350 patients in the Study.² On
8 information and belief, only a small fraction of the required number of patients
9 were enrolled in the Study during the first five years the BHR was available in the
10 U.S., despite tens of thousands of the devices being sold and implanted in patients.

11 17. The Study results also were biased because men, who typically have
12 a lower failure rate in a resurfacing procedure, made up approximately three-
13 quarters of study participants, compared to women who made up only one quarter
14 of participants.³ Smith & Nephew also reported 35 deviations from the study
15 protocol, which resulted in a poor patient follow-up rate, in part due to Smith &
16 Nephew failing to adequately staff the study locations with enough research
17 coordinators.⁴ These and other problems prompted the FDA to write a letter to
18 Debra Gilbert, Senior Clinical Affairs Specialist at Smith & Nephew, on Oct. 26,
19 2012 stating that the FDA was unable to review the adequacy of the BHR studies
20 and reports due to “inadequate” information from Smith & Nephew.⁵

21 18. Despite the fact that the Study was a requirement of the PMA, Smith
22 & Nephew prematurely closed the Study’s U.S. patient database on March 19,
23 2012, before the planned completion date, and thus did not comply with the terms
24 of the PMA. On several occasions, the FDA reported the status of the BHR Study

25 ² Tables 7, BHR System Post-Approval Study, 84-Month Interim Study Status Report, May 6, 2013, obtained via
26 Freedom of Information Act.

³ *Id.*

27 ⁴ BHR System Post-Approval Study, 72-Month Interim Study Status Report, May 12, 2012, obtained via Freedom
of Information Act.

28 ⁵ *Id.* (written by Danica Marinac-Dabic, Director, Division of Epidemiology, Office of Surveillance and
Biometrics).

1 was “progress inadequate” in part because patient enrollment milestones were not
2 met, and because it failed to timely submit scheduled reports to the FDA pursuant
3 to 21 CFR § 814.84, *et. seq.* Mandatory reports for the study were submitted late
4 to the FDA at least three times in the last eleven years — in Nov. 2006, July 2011
5 and May 2017. Documents submitted by Smith & Nephew to the FDA as recently
6 as May 2013 show that of the eight planned “investigational” sites for the PMA
7 study, only four were operational at the time, while a fifth had dropped out due to
8 slow patient enrollment and three others were still “pending site initiation,
9 contract execution and ... approval.”

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

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

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

25 22. Smith & Nephew began a BHR training program for surgeons on
26 Dec. 13, 2006, but it failed to achieve the training milestones it promised to the

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28 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).

1 FDA, and the company in fact did not begin widespread training until late 2009 –
2 more than three years after the BHR became available in the U.S. - when it
3 admitted to the FDA that surgeons were performing resurfacing operations despite
4 having not been trained at all by Smith & Nephew in how to properly perform the
5 procedure.⁷

6 23. Although Smith & Nephew failed to follow its own training protocol,
7 which was a requirement of the PMA, the company and the inventor of the BHR,
8 Dr. Derek McMinn, later did not hesitate to blame those same inadequately
9 trained surgeons for the BHR's high failure rate in subsequent years. For example,
10 in August 2011, four years before the BHR was finally recalled, Dr. McMinn
11 published an article titled "Metal Ions Questions & Answers" in which he
12 attempted to distinguish the BHR from other problematic and failure-prone metal-
13 on-metal hip devices, including the DePuy ASR.⁸ Dr. McMinn placed the blame
14 for these failures on surgeons who improperly placed the device, and on patients
15 themselves, particularly women, whom he claimed are "'pre-sensitised' to metal
16 due to the usage of costume jewellery etc. and their tissues may "over-react" to
17 low levels of nickel released from artificial devices"(sic). Dr. McMinn did not
18 offer any scientific evidence for his theory about the connection between costume
19 jewelry and failure rates for the BHR.

20 24. The DePuy ASR device was recalled in August 2010, giving
21 Smith & Nephew ample warning about the dangers of its similar BHR device.
22 Clinical comparisons of the ASR and BHR devices at the time showed that the
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25 ⁷ Email from Gino Rouss of Smith & Nephew to John Goode of the FDA, Oct. 22, 2009 (stating, in part that "...
26 hip resurfacing arthroplasty has now been utilized since the BHR device was approved in May, 2006, and it is
27 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."

28 ⁸ Dr. Derek McMinn, *Metal Ions Questions & Answers*, available at <http://www.mcmmincentre.co.uk/metal-ions-questions-answers.html>

1 BHR had a similar linear wear rate and generated similar levels of metal ions in
2 patients as the ASR.⁹

3 25. Although Smith & Nephew was aware of the risks associated with
4 the BHR for many years, it did not inform Plaintiff or her healthcare providers
5 until 2015 when it was too late. Nonetheless, Smith & Nephew was aware of
6 information about the BHR's unreasonably high risk of premature failure for
7 certain patient populations as early as 2008, when the Australian Orthopaedic
8 Registry published data from the previous year showing that female resurfacing
9 patients with a femoral head size of less than 50 mm faced a more than three-fold
10 increased risk of revision (HR = 3.22, at 95 percent confidence interval) compared
11 to female patients with a larger head size. Similarly, men with a femoral head size
12 of less than 50 mm faced a far higher risk of revision compared to other male
13 patients with a larger head size (HR = 2.69, at 95 percent confidence interval).¹⁰

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

21 27. Smith & Nephew also was criticized by researchers who found that
22 early safety statistics for the BHR device — the same data Smith & Nephew
23 submitted to the FDA for its PMA approval — could not be duplicated by outside
24 surgeons who did not receive the detailed training of the original designers and
25 surgeons.

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

¹⁰ Hip and Knee Arthroplasty, Australian Orthopaedic Association, 2008 Annual Report.

28 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).

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

12 29. Smith & Nephew also was aware of problems with metal-on-metal
13 hips generally, when it sent a team of employees and/or consultants, including but
14 not limited to Tim Band, Dr. Joseph Daniel and BHR inventor Dr. Derek
15 McMinn, to participate in the FDA's Orthopaedic and Rehabilitation Devices
16 Advisory Panel meeting on metal-on-metal hip implant systems on or about June
17 27-28, 2012, in Gaithersburg, Maryland. The purpose of the meeting was to
18 discuss mounting concerns about the safety of metal-on-metal hip devices, both
19 for total hip arthroplasty and hip resurfacing arthroplasty. It followed an FDA
20 statement in February 2011 about health risks of metal-on-metal systems for both
21 types of procedures.¹⁵

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23
24 ¹² Schuh, R., D. Neumann, et. al., *Revision Rate of Birmingham Hip Resurfacing Arthroplasty: Comparison of*
25 *Published Literature and Arthroplasty Register Data*, Int. Orthop 36(7): 1349-1354 (2012)(stating that "... the
excellent results reported by the development team are not reproducible by other surgeons.")

26 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.

27 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).

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

1 30. After years of complaints and repeated lack of action, on June 4,
2 2015, Smith & Nephew announced the voluntary removal of the BHR device from
3 the U.S. market due to unreasonably high failure rates for certain demographic
4 groups, including all women, all men age 65 or older, and all men with requiring
5 femoral head sizes 46 mm or smaller.¹⁶

6 31. The market withdrawal of the BHR followed numerous other
7 warning signs, including an Urgent Field Safety Notice¹⁷ sent to doctors in
8 November 2014 about high revision rates for the same population groups
9 mentioned above, and for patients with congenital dysplasia, and diagnosed
10 avascular necrosis. But Smith & Nephew knew about these and other problems
11 years before it finally issued a recall, and it continued to promote the BHR device
12 even after well-documented problems with other metal-on-metal hips such as the
13 Zimmer Durom, DePuy ASR, Biomet Magnum, DePuy Pinnacle and Wright
14 Conserve, all of which were removed from the U.S. market earlier.

15 32. Smith & Nephew had numerous chances to follow the lead of its
16 competitors and warn patients of the unreasonable failure rate associated the
17 metal-on-metal BHR device. For example, a February 2012 article in the Journal
18 of Bone and Joint Surgery revealed the BHR has a 26 percent failure rate in
19 women after ten years, and the authors of the article warned that “results in
20 women have been poor and we do not recommend metal-on-metal resurfacing in
21 women.”¹⁸

22 33. In conjunction with the above-mentioned market withdrawal, Smith
23 & Nephew issued a Class 2 recall of the BHR device on September 10, 2015,
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25 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,
26 2017)(stating that “... Smith & Nephew considers that these patient groups may be at a greater risk of revision
27 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.

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

1 covering 5,987 units (Recall Number Z-2745-2015), 10,167 units (Recall Number
2 Z-2746-2015) and 624 units (Recall Number Z-2747-2015) respectively in the
3 stream of commerce, due to “revision rates which were higher than established
4 benchmarks” pursuant to 21 CFR § 7.55e.

5 34. Data published in connection with the recall show a total of 397
6 “device problems” with the BHR, including numerous safety problems related to
7 “metal shedding debris” and other symptoms typical of metal-on-metal device
8 failure.¹⁹ Earlier, in its 2012 post-marketing annual report to the FDA, Smith &
9 Nephew disclosed 356 reportable complaints for the BHR alone between March 1,
10 2011, and February 29, 2012. However, an independent analysis of FDA data
11 shows an additional thirty (30) reported complaints during the same time period,
12 or 8.4 percent more complaints than Smith & Nephew disclosed in its annual
13 report. Numerous complaints also were not logged with the FDA until six months
14 or longer after Smith & Nephew received them, and in some cases they were not
15 logged until several years later.

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

23 36. By this time, in 2013 and 2014, Smith & Nephew did state that at
24 least some of the revision surgeries were due to metallosis. However, in the first
25 several years after the BHR entered the U.S. market, Smith & Nephew failed to
26 report the risk of metallosis in its adverse events to the FDA. According to an

27 _____
28 ¹⁹ A list of the device failures is available through the FDA’s Manufacturer and User Device Experience, or
MAUDE, database.

1 independent analysis of these adverse event reports, the term “metallosis” was not
2 used in these reports until late 2010, even though the company knew of dozens
3 and possibly hundreds of cases where metallosis was found. Instead, Smith &
4 Nephew went to great lengths to blame device failure on other sources, such as the
5 patient’s allergies to metal, or generalized pain. Here is a short list of examples
6 that show how Smith & Nephew avoided responsibility for the BHR’s metal-on-
7 metal risks.

- 8 • Adverse Event Report 1921214 (2010): “the revision surgeon does
9 not fault the devices.
- 10 • Report 1058217 (2008): “it was reported that revision surgery was
11 performed due to metal allergy.”
- 12 • Report 1353825 (2009): “incorrect positioning.”
- 13 • Report 1402939 (2009): “revision surgeon does not fault the device.”
- 14 • Report 960061 (2007): “surgical error.”
- 15 • Report 1626209 (2010): “nickel allergy.”

16
17 37. While Smith & Nephew tried to hide the true cause of the BHR’s
18 failure rate, clinical data continue to pile up showing the real risk for patients
19 including Plaintiff. Data compiled by the National Joint Registry of England and
20 Wales, for example, show the BHR 42 mm femoral head component has a seven-
21 year revision rate of 11.76 percent, well above the normal acceptable failure rate
22 for a device of this type.

23 38. A separate study of the BHR device in England showed that out of
24 319 patients, nearly 30 percent had modified Harris Hip Scores below 90 at their
25 ten-year follow up exam, and approximately 12 percent of patients had scores
26 below 80.²⁰ A score above 90 is considered excellent. Scores below that number
27 are described as either poor, fair, or good.

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

1 39. Contrary to Defendant’s representations and marketing to the medical
2 community and to the patients themselves, Defendant’s BHR resurfacing products
3 have high failure, injury, and complication rates, fail to perform as intended,
4 require frequent and often debilitating re-operations, and have caused severe and
5 sometimes irreversible injuries, conditions, and damage to a significant number of
6 patients, including Plaintiff.

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

11 **PRE-EMPTION AND THE FEDERAL FOOD, DRUG**
12 **AND COSMETIC ACT**

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

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

25 43. A U.S. manufacturer of Class III medical devices with PMA approval
26 must comply with the FDA’s Quality Systems Regulations (“QSR”). 21 CFR §
27 820 *et seq.* The specific QSR promulgated by the FDA are known as Current
28 Good Manufacturing Practices (“CGMP”). 21 CFR § 820.1(a). A manufacturer

1 must satisfy these quality standards in the manufacture and production of medical
2 devices. 21 CFR § 820.1(a).

3 44. These quality standards include the duty to identify and respond to a
4 “nonconforming product.” A manufacturer, such as Smith & Nephew, must
5 “establish and maintain procedures to control product that does not conform to
6 specified requirements,” such as a failure to conform to performance and design
7 standards set forth in the manufacturer’s PMAs and supplements. 21 CFR §
8 820.90. “The procedures shall address the identification, documentation,
9 evaluation, segregation, and disposition of nonconforming product.” CGMP/QSR
10 also require a manufacturer to establish and maintain procedures for implementing
11 corrective actions and preventive actions (“CAPAs”), including investigating the
12 cause of nonconformities in the product, processes and quality systems, and taking
13 corrective action to prevent recurrence of such nonconformities. 21 CFR §
14 820.100.

15 45. FDA’s CGMP/QSR may require a manufacturer to test for, monitor
16 for (through postmarketing surveillance), discover, investigate and remedy issues
17 related to the safe and effective use of a medical device as approved. A part of
18 satisfying these postmarketing surveillance duties can be to formulate and then
19 effectively execute a Postmarketing Surveillance Plan for the purpose of
20 ascertaining any issues regarding the safe and effective use of the device once
21 released to the market. 21 CFR § 822.8.

22 46. Similar to Postmarketing Surveillance Plans, CGMP/QSR require a
23 manufacturer to review and evaluate all complaints regarding the operation of a
24 medical device and determine whether an investigation is necessary. 21 CFR §
25 820.198(b).

26 47. An investigation must be completed when a complaint involves the
27 possible failure of a device, its labeling or its packaging to meet any of its
28 specifications, unless an investigation for a similar complaint has already been

1 performed. 21 CFR § 820.198(c).

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

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

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

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

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

28

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

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

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

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

24 57. The written submission must contain, among other things, a
25 description of the event giving rise to the information reported and the corrective
26 or removal actions taken, and any illness or injuries that have occurred with use of
27 the device, including reference to any device report numbers. A manufacturer
28 must also indicate the total number of devices manufactured or distributed which

1 are subject to the correction or removal and provide a copy of all communications
2 regarding the correction or removal. 21 CFR § 806.10(c).

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

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

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

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

18 62. A device is deemed to be misbranded if, among other things, its
19 labeling is false or misleading in any particular, or if it is dangerous to health
20 when used in the manner prescribed, recommended, or suggested in the labeling
21 thereof. 21 U.S.C. § 352(a) & (j).

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

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1 64. A “misbranded” device is prohibited for introduction into interstate
2 commerce by the FDCA. 21 U.S.C. § 331(a).

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

10 66. Thus, unexpected adverse events or expected adverse events in more
11 frequency than that expected in the original PMA approval and/or any device
12 issue that requires changes in labeling, manufacturing processes or device design
13 are not sanctioned by the FDA in its original approvals, and are subject to further
14 review and action by the agency despite such original approvals.

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

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

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

27 70. Congress anticipated that a manufacturer tasked with post-market
28 surveillance of its PMA approved product’s performance, such as the BHR, would

1 require a voluntary mechanism to be able to quickly update its approved product's
2 manufacturing, labeling and marketing to protect the public and to ensure its own
3 compliance with the Act. Such a mechanism, to be expedient, protect patients and
4 comply with the FDCA, should not be delayed because the FDA has not yet given
5 its formal approval.

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

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

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

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

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

26 76. Hundreds of patients across the United States have sought
27 compensation from Smith & Nephew due to premature failure of the BHR device,
28 based on violations of state common law duties and the federal requirements.

1 Smith & Nephew's attempts to hide behind the veil of preemption have been
2 rejected by numerous other Courts in cases involving the same BHR device.
3 *Comella v. Smith & Nephew, Inc.*, 2013 WL 6504427 (N.D. Ill. 2013); *Elmore v.*
4 *Smith & Nephew, Inc.*, 2013 WL 1707956 (N.D. Ill. 2013); *Gale v. Smith &*
5 *Nephew, Inc.*, 989 F.Supp.2d 243 (S.D.N.Y. 2013); *Herron v. Smith & Nephew,*
6 *Inc.*, 2014 WL 1232224 (E.D.Ca. 2014); *Tillman v. Smith & Nephew*, 2013 WL
7 3776973 (N.D.Ill. 2013); *Laverty v. Smith & Nephew, Inc.*, 1:15-cv-09485 (N.D.
8 Ill. 2015); *Frederick v. Smith & Nephew, Inc.*, 2013 WL 6275644 (N.D. Ohio
9 2013); *Williams v. Smith & Nephew, Inc.*, 2015 U.S. Dist. LEXIS 108670 (D. Md.
10 Aug. 18, 2015); *Raab v. Smith & Nephew, Inc.*, 14-CV-30279 (S.D.W.V., Dec.
11 15, 2015); *Marion v. Smith & Nephew, Inc.*, 2016 U.S. Dist. LEXIS 99449.

12 **GENERAL CLAIMS FOR RELIEF**

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

17 78. Defendant, Smith & Nephew, Inc., is a developer and manufacturer
18 of joint replacement systems. Since 2006, Defendant, Smith & Nephew, Inc., has
19 manufactured, introduced and/or delivered the Birmingham Hip Resurfacing
20 System (hereinafter "BHR") into the stream of interstate commerce. The BHR is
21 a metal-on-metal hip resurfacing prosthesis. It is comprised of the following two
22 (2) components:

- 23 a. Birmingham Resurfacing Femoral Head; and
- 24 b. Birmingham Hip Resurfacing Acetabular Cup.

25 79. Before commercially distributing the BHR in the United States,
26 federal law required Defendant, Smith & Nephew to submit an application for
27 premarket approval ("PMA") of the device to the Secretary of Health and Human
28 Services. On May 9, 2006, the Food and Drug Administration ("FDA")

1 completed its review of Defendant, Smith & Nephew’s PMA application for the
2 BHR. Based on the materials submitted by Defendant, Smith & Nephew, the
3 FDA conditionally approved the BHR for commercial distribution.

4 80. The Approval Order from the FDA stated that “[c]ommercial
5 distribution of a device that is not in compliance with these conditions is a
6 violation of the [Food, Drug and Cosmetic] act, [21 U.S.C. §§301, et seq.]”

7 81. The Approval Order cited many agreements Smith & Nephew made
8 with the FDA, which became part of the approval. Thus, the Approval Order
9 became an outline of the specific post-market obligations and duties Smith &
10 Nephew undertook, in addition to all those existing under Federal Law, when it
11 finally convinced the FDA to conditionally approve the BHR. Those agreements
12 included, but were not limited to, the following:

- 13 a. Smith & Nephew would conduct a post-approval study and
14 submit its reports biannually the first two years and annually
15 for the next eight years following premarket approval, which
16 study was to evaluate the “longer-term safety and
17 effectiveness” of the BHR;
- 18 b. Smith & Nephew would implement a training program of its
19 physicians, which was to include quarterly investigator
20 teleconferences or meeting the first two years “to discuss study
21 issues including adverse events; and to identify
22 recommendations for improvement of the training program or
23 labeling”;
- 24 c. Smith & Nephew would “provide an analysis of adverse events
25 and complaints (including MDRs) received regarding the BHR
26 system”;
- 27 d. Smith & Nephew would advise of the results of its post-
28 approval studies, training program assessment, and adverse

1 event analysis through a supplement in its labeling upon
2 completion of the post-approval study, or at “earlier
3 timepoints, as needed.”

4 82. The Approval Order made clear that each requirement imposed upon
5 Smith & Nephew with respect to its distribution of the BHR system was to
6 “ensure the safe and effective use of the device.”

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

- 11 a. Smith & Nephew received hundreds of adverse reports and
12 complaints regarding the BHR but delayed its reporting to the
13 FDA, and when it did communicate adverse reports, it did not
14 do so properly but, in fact, attempted to blame others for the
15 adverse events;
- 16 b. Smith & Nephew only initiated follow up inquiry on a fraction
17 of adverse event reports by the patients’ surgeons and sales
18 force regarding the BHR;
- 19 c. Smith & Nephew became aware of wide evidence that the
20 BHR systems were wearing down more quickly and severely
21 than anticipated, and failed to take appropriate action to
22 determine the cause and provide a solution, nor did it
23 appropriately advise the FDA;
- 24 d. Smith & Nephew, when it did provide reports to the FDA
25 pursuant to the Approval Order, underreported to and withheld
26 information from the FDA about the likelihood of failure;
27 and/or,

28

1 e. Smith & Nephew also failed to timely supplement its labeling
2 as required in the Approval Order with information pertaining
3 to the various failures of the BHR system, thereby
4 misrepresenting the efficacy and safety of the BHR resurfacing
5 products and actively misleading the FDA, the medical
6 community, patients, and public at large into believing that the
7 BHR system was safe and effective.

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

15 **FRAUDULENT CONCEALMENT**

16 85. Smith & Nephew fraudulently concealed the fact that they did not
17 enjoy legal protection provided as part of device's PMA status. Smith & Nephew
18 failed to disclose information to the scientific and medical communities, as well as
19 consumers, in violation of its duty to disclose. The information purposely
20 withheld was material, and was information that consumers, such as Plaintiff
21 could not have learned without Smith & Nephew's disclosure.

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

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

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

9 **PLAINTIFF'S INJURIES**

10 86. On or about September 22, 2008, Plaintiff, Lydia Constantini, was
11 admitted to the Mercy Medical Center Mount Shasta in Mount Shasta, California,
12 for the purpose of undergoing a right hip resurfacing by Keith J. Ure, M.D. At the
13 time of said surgery, Dr. Ure utilized and implanted the Defendant's Birmingham
14 Hip Resurfacing system. Specifically, the following components of said system
15 were utilized:

- 16 a. Smith & Nephew Birmingham Resurfacing Femoral Head
17 50mm; and
18 b. Smith & Nephew Birmingham Resurfacing Acetabular Cup
19 56mm.

20 87. On or about December 10, 2013, Plaintiff, Lydia Constantini,
21 underwent revision of her right hip due to pain and other complications caused by
22 the failure of the Defendant's Birmingham Hip Resurfacing system. Plaintiff's
23 revision surgery was performed by John N. Diana, M.D. at Queen of the Valley
24 Medical Center in Napa, California.

25 88. In his revision operative note, Dr. Diana described evidence of
26 metallosis, with elevated chromium and cobalt levels in Plaintiff's body and the
27 formation of a pseudotumor in Plaintiff's hip joint as a result of the premature
28 failure of the device. Furthermore, Dr. Diana noted that approximately one-third

1 of Ms. Constantini's abductor muscle had been disrupted and compromised as a
2 result of the pseudotumor formation.

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

9 **FIRST CLAIM FOR RELIEF**
10 **STRICT PRODUCTS LIABILITY BASED ON VIOLATIONS**
11 **OF 21 C.F.R. 820.30 (f) and (g); 21 C.F.R. 820.80 (c) and (d); 21**
12 **C.F.R. 820.100; 21 C.F.R. 820.198**

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

15 91. Defendant designed and/or manufactured the BHR Systems
16 implanted in Plaintiff's right hip, in violation of the Federal Food, Drug and
17 Cosmetic Act ("Act") and regulations promulgated pursuant to it, as well as the
18 duties created by virtue of the agreements in the Approval Order.

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

- 24 a. Failed to accurately establish the in vivo life expectancy of the
25 BHR, in violation of 21 C.F.R. § 820.30(f);
- 26 b. Failed to validate the anticipated wear of the acetabular cup
27 prior to its release into commercial distribution, in violation of
28 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

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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

1 its PMA annual reports to the FDA blamed catastrophic
2 product failures of the BHR on generalized issues such as
3 “pain” or “squeaking” or “allergic reaction”;

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

7 j. Continued to place the BHR into the stream of interstate
8 commerce when it knew, or should have known, that the
9 acetabular component was Malfunctioning [as defined in 21
10 C.F.R. § 803.3] or otherwise not responding to its Design
11 Objective Intent; and/or,

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

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

18 a. Smith & Nephew allowed and encouraged its commission-
19 based salesmen to not report adverse events and complaints
20 such as revision surgeries, thereby substantially reducing the
21 known and reported incidence of product problems;

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

26 c. Smith & Nephew received hundreds of adverse reports
27 regarding the BHR system but delayed its reporting to the
28 FDA;

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- 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;

1 k. Smith & Nephew, as a result of increased demand for the
2 product, failed to properly train all surgeons and Original Core
3 Surgeons using the product as required by the Approval Order
4 by using shortcuts, such as teaching surgeons by satellite
5 instead of hands on as it had assured the FDA and by failing to
6 require those surgeons to receive such training directly from
7 the product designers in the United Kingdom or from Original
8 Core Surgeons;

9 l. Smith & Nephew also misrepresented to the surgeons in the
10 United States that in vivo testing of the BHR had been
11 undertaken when Defendant, in fact, knew or should have
12 known that the testing was invalid and the results unreliable;
13 and,

14 m. Smith & Nephew failed to timely supplement its labeling as
15 required in the Approval Order with information pertaining to
16 the various failures of the BHR system, thereby
17 misrepresenting the efficacy and safety of the BHR resurfacing
18 products to the FDA and actively misleading the FDA, the
19 medical community, patients, and public at large into believing
20 that the BHR system was safe and effective when it was not
21 by, among other things, claiming to have solved the problem of
22 metal-on-metal friction due to a “fluid film” theory that has
23 proven untrue.

24 94. As a direct and proximate result of Defendant’s violations of one or
25 more of these federal statutory and regulatory standards of care, a BHR System,
26 including the acetabular cup and femoral head, was implanted in Plaintiff’s right
27 hip, and failed and such failure directly and proximately caused and/or contributed
28 to the severe and permanent injuries the Plaintiff sustained and endured as defined

1 in 21 C.F.R. § 803.3. As a direct and proximate result, Plaintiff, endured pain and
2 suffering and has required additional and debilitating surgeries and has incurred
3 significant medical expenses in the past and will incur additional medical
4 expenses in the future; both past and future wage loss; both past and future non-
5 economic damages including, but not limited to, physical and mental pain and
6 suffering, inconvenience, emotional distress and impairment of the quality of her
7 life; and permanent impairment and disfigurement.

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

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

18 97. Thus, under California law, a money damages remedy exists for
19 violation of the Act and regulations promulgated thereunder which results in an
20 unreasonably dangerous product proximately causing injuries, and there is no
21 need for the California Legislature to act in order to create such a remedy.

22 98. The Act contains an express preemption provision, 21 U.S.C. §
23 360(k), which in relevant part states: "no state or political subdivision of a state
24 may establish or continue in effect with respect to a device intended for human
25 use any requirement (1) which is different from, or in addition to, any requirement
26 applicable under this Act [21 USCS §§ 301, et seq.] to the device, and (2) which
27 relates to the safety or effectiveness of the device or to any other matter included
28 in a requirement applicable to the device under this Act [21 USCS §§ 301, et

1 seq.]”

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

13 100. As a direct and proximate result of Defendant Smith & Nephew’s
14 aforementioned actions, Plaintiff prays for judgment against Defendant, Smith &
15 Nephew, Inc., in an amount in excess of Seventy Five Thousand Dollars
16 (\$75,000.00).

17 **SECOND CLAIM FOR RELIEF**
18 **NEGLIGENCE BASED ON VIOLATIONS OF 21 C.F.R. 820.30 (f) and**
19 **(g); 21 C.F.R. 820.80 (c) and (d); 21 C.F.R. 820.100; 21 C.F.R. 820.198**

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

22 102. The BHR Systems, including the acetabular cups and femoral heads,
23 implanted in Plaintiff’s right hip were distributed and/or manufactured in violation
24 of the Act and regulations promulgated to it.

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

1 104. Defendant knew, and continues to know, that its disclosures to the
2 public and Plaintiff were and are incomplete and misleading; and that Defendant's
3 BHR resurfacing products were and are causing numerous patients severe injuries
4 and complications. Smith & Nephew suppressed this information, and failed to
5 accurately and completely disseminate or share this and other critical information
6 with the medical community, health care providers, and patients.

7 105. As a result, Smith & Nephew actively and intentionally misled and
8 continues to mislead the public, including the medical community, health care
9 providers, and patients, into believing that the Defendant's BHR resurfacing
10 products were and are safe and effective, leading to the prescription for and
11 implantation of the BHR resurfacing products into patients such as Plaintiff. For
12 example, in its 2015 annual report to the FDA, Smith & Nephew still did not list
13 female patients or smaller bearing sizes in its list of contraindications for the BHR
14 system, even though numerous studies cited those patient groups as being
15 particularly at risk of premature failure.²¹

16 106. Smith & Nephew failed to perform or rely on proper and adequate
17 testing and research in order to determine and evaluate the risks and benefits of
18 Defendant's BHR resurfacing products. As compared to Smith & Nephew's BHR
19 resurfacing products, feasible and suitable alternative designs, procedures, and
20 instruments for implantation and treatment of damaged and worn parts of the hip
21 joint and similar other conditions have existed at all times relevant.

22 107. Smith & Nephew's BHR resurfacing products were at all times
23 utilized and implanted in a manner foreseeable to Defendant. Smith & Nephew
24 failed to warn and provided incomplete, insufficient, and misleading training and
25 information to physicians, in order to increase the number of physicians utilizing
26 Defendant's BHR resurfacing products, thereby increasing the sales of the BHR

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

1 resurfacing products, and also leading to the dissemination of inadequate and
2 misleading information to patients, including Plaintiff and other patients who are
3 female, or who have small femoral head sizes.

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

10 109. Smith & Nephew's failure to comply with the above-stated duties is
11 evident through the non-exhaustive list, *supra* Claim I, of malfeasance,
12 misfeasance, and/or nonfeasance on the part of Defendant. Subsequently, the BHR
13 system implanted in Plaintiff's hip failed and such failure directly caused and/or
14 contributed to the severe and permanent injuries sustained and endured by
15 Plaintiff, as defined in 21 C.F.R. § 803.3. As a direct and proximate result,
16 Plaintiff endured pain and suffering and has required additional and debilitating
17 surgeries and has incurred significant medical expenses in the past and will incur
18 additional medical expenses in the future; both past and future wage loss; both
19 past and future non-economic damages including, but not limited to, physical and
20 mental pain and suffering, inconvenience, emotional distress and impairment of
21 the quality of her life; and permanent impairment and disfigurement.

22 110. This cause of action is based entirely on the contention that
23 Defendant, Smith & Nephew violated federal safety statutes and regulations.
24 Plaintiff does not bring the underlying action as an implied statutory cause of
25 action, but rather she is pursuing parallel state common law claims based upon
26 Smith & Nephew's violations of the applicable federal regulations.

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

1 negligence.

2 112. Thus, under California law, a money damages remedy exists for
3 violation of the Act and regulations promulgated thereunder which results in an
4 unreasonably dangerous product proximately causing injuries, and there is no
5 need for the California Legislature to act in order to create such a remedy.

6 113. The cause of action set forth in this Claim for Relief is not preempted
7 by 21 U.S.C. § 306(k) because the violations alleged are all based on an
8 exclusively federal statutory and regulatory set of requirements which include no
9 “requirement which is different from, or in addition to, any requirement applicable
10 under” the Act and regulations promulgated thereunder. *See; Bausch v. Stryker*,
11 630 F.3d 546, 556 (7th Cir. 2010) (claims for negligence and strict products
12 liability relating to a Class III medical device were not expressly preempted by
13 federal law to the extent they were based on the defendants’ violations of federal
14 law). As such, the claims set forth herein contain requirements that are parallel to
15 the Act and regulations promulgated thereunder.

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

19 **THIRD CLAIM FOR RELIEF**
20 **(Breach of Express Warranties)**

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

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

27 117. Smith & Nephew expressly warranted to Plaintiff, by and through its
28 authorized agents or sales representatives, in publications, package inserts, the

1 internet, and other communications intended for physicians, patients, Plaintiff, and
2 the general public, that the system was safe, effective, fit and proper for its
3 intended use.

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

8 119. Due to the defective and unreasonably dangerous BHR resurfacing
9 products, it was neither of merchantable quality nor fit for the particular purposes
10 for which it was sold, presenting an unreasonable risk of injury to patients,
11 including Plaintiff, during foreseeable use.

12 120. Defendant breached their warranty of the mechanical soundness of
13 the BHR system by continuing sales and marketing campaigns highlighting the
14 safety and efficacy of its product, while Defendant knew or should have known of
15 the defects and risk of product failure and resulting patient injuries.

16 121. Defendant made numerous claims to the general public, and to
17 Plaintiff in particular, that the BHR devices were safe for their intended use and
18 that they did not suffer from the same problems that plague other metal-on-metal
19 hips, even though it was in possession of information to the contrary.

20 122. Instead of warning patients about the dangers of metal toxicity,
21 which were well documented even in 2006 when the BHR was approved, Smith &
22 Nephew as recently as 2013 disseminated unpublished reports from its own design
23 surgeon, Derek McMinn, stating that “there does not appear to be any conclusive
24 evidence that elevated cobalt and chromium levels have any significant
25 detrimental effects in total hip arthroplasty patients.”²² As recently as January,
26

27 ²² McMinn, et. al., *Metal Ion Studies in Patients Treated with the Birmingham Hip Resurfacing, a Comparable*
28 *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).

1 2015, Defendant referred patients with questions about the BHR devices to a
2 website, www.surfacehippy.com, with claims about people with the BHR devices
3 who completed extraordinary physical feats after implantation, including a “sprint
4 triathlon” with their prosthetic BHR devices.²³ The same website, where Smith &
5 Nephew prominently advertises its BHR device, publishes misleading articles by
6 orthopedic surgeons and paid consultants, including but not limited to the BHR
7 designer, Dr. Derek McMinn, downplaying the risks of the failure-prone BHR
8 device, and comparing them favorably to other metal-on-metal devices, even
9 though the BHR is just as failure prone as some of these other devices according
10 to clinical studies.

11 123. Smith & Nephew also enlisted the services of professional athletes
12 and celebrities in its efforts to promote the BHR system, including former NHL
13 hockey player Tim Taylor, former NFL quarterback Steve Beuerlein, and former
14 professional cyclist Floyd Landis.²⁴ The most recent example of these misleading
15 marketing efforts is a campaign by Dr. McMinn himself, modeled after the
16 presidential campaign slogan of Donald Trump, to “Make Resurfacing Great
17 Again,” through the use of a safer resurfacing device that includes a polyethylene
18 acetabular cup, the PHR, which purportedly avoids the problems associated with
19 metal-on-metal articulation in the original BHR system.²⁵ Thus, despite an
20 overwhelming body of clinical literature showing the dangers of cobalt and
21 chromium toxicity, the BHR’s inventor and spokesman continues even today to
22 blame patient “allergy sufferers,” rather than the manufacturer or himself, for
23 widespread metal-on-metal injuries.

24 _____
25 ²³ See Patricia Walter, *MPH’s Hip Resurfacing with Mr. Shimmin*, available at
26 <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.

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

28 ²⁵ Dr. Derek McMinn, Custom Polyethylene Hip Resurfacing, January 17, 2017, available at <http://www.mcmmincentre.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.”).

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](#).

124. 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 it's "warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State Laws."

125. The defective and unreasonably dangerous condition of the BHR products constituted a breach of the Defendant's express warranties under California law.

126. 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.

1 127. Defendant breached their warranty of the mechanical soundness of
2 the BHR system by continuing sales and marketing campaigns highlighting the
3 safety and efficacy of its product, while Defendant knew or should have known of
4 the defects and risk of product failure and resulting patient injuries.

5 128. Defendant made numerous claims to the general public, and to
6 Plaintiff in particular, that the BHR devices were safe for their intended use and
7 that they did not suffer from the same problems that plague other metal-on-metal
8 hips, even though it was in possession of information to the contrary.

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

- 15 • That “... there is no evidence that increased levels of cobalt and
16 chromium ions are associated with any clinical effects.” Smith &
17 Nephew knew about the adverse clinical effects of elevated cobalt
18 and chromium levels, including metallosis, pseudotumor, and tissue
19 and bone necrosis.
- 20 • That the BHR has “outstanding results” that are superior to a total hip
21 replacement for male patients under 55 years of age. Smith &
22 Nephew failed to mention any data for the BHR’s performance in
23 women or in men with smaller joint sizes. Both patient groups have
24 failure rates that are dramatically higher than patients implanted with
25 competing hips devices.
- 26 • Two years later, in 2012, Smith & Nephew’s senior vice president
27 publicly touted the BHR as being “unlike any other metal-on-metal
28 hip implant” with a survivorship rate superior to even traditional non-

1 metal devices due to its “distinctive metallurgy heritage” and other
2 factors.²⁶ The company made these claims, even though it knew as
3 early as 2006 that resurfacing devices such as the BHR posed a
4 serious risk of failure for certain populations, including Plaintiff, all
5 women, and all patients with a small femoral head size.

6 130. As a direct and proximate result of Defendant’s breaches of express
7 warranties, Plaintiff has sustained severe damages and injuries as described
8 elsewhere in this Complaint, including metallosis, tissue damage and necrosis,
9 revision surgery, exposure to toxic levels of chromium and cobalt ions in her
10 body, and unknown long-term consequences that continue to this day and into the
11 future. She has further suffered past and future medical expenses, past and future
12 wage loss; physical pain and suffering, both past and future; mental anguish and
13 emotional distress.

14 **FOURTH CLAIM FOR RELIEF**
15 **(Negligent Misrepresentation)**

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

18 132. Defendant had a duty to accurately and truthfully represent to the
19 medical community, Plaintiff, and the public that BHR products had not been
20 adequately tested and found to be safe and effective for the treatment of damaged
21 and worn parts of the hip joint. Instead, the representations made by Defendant
22 were false.

23 133. Defendant negligently misrepresented to the medical community,
24 Plaintiff, and the public that the BHR products did not have a high risk of
25 dangerous adverse side effects. Defendant made this misrepresentation by

26 _____
27 ²⁶ Smith & Nephew, Press Release, *New Clinical Results Further Distance the BIRMINGHAM*
28 *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.

1 consistently underreporting adverse events for the BHR, delaying reporting of
2 adverse events, and categorizing them in a way that hid the true risk of failure due
3 to metal-on-metal symptoms, in violation of the terms of the PMA and 21 C.F.R.
4 § 822.2 and 21 C.F.R. §§ 814.82 to 814.84.

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

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

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

17 137. As a direct and proximate result of Defendant's negligent
18 misrepresentations, Plaintiff has sustained severe damages and injuries as
19 described elsewhere in this Complaint, including metallosis, tissue damage and
20 necrosis, revision surgery, exposure to toxic levels of chromium and cobalt ions in
21 her body, and unknown long-term consequences that continue to this day and into
22 the future. She has further suffered past and future medical expenses, past and
23 future wage loss; physical pain and suffering, both past and future; mental anguish
24 and emotional distress.

25 **FIFTH CLAIM FOR RELIEF**
26 **(Fraudulent Concealment)**

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

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

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

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

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

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

22 144. As a direct and proximate result of Defendant's fraudulent
23 concealment, Plaintiff has sustained severe damages and injuries as described
24 elsewhere in this Complaint, including metallosis, tissue damage and necrosis,
25 revision surgery, exposure to toxic levels of chromium and cobalt ions in her
26 body, and unknown long-term consequences that continue to this day and into the
27 future. She has further suffered past and future medical expenses, past and future
28

1 wage loss; physical pain and suffering, both past and future; mental anguish and
2 emotional distress.

3
4 **SIXTH CLAIM FOR RELIEF**
5 **(Punitive Damages)**

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

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

11 WHEREFORE, PREMISES CONSIDERED, Plaintiff, Lydia Constantini,
12 prays that this Court enter judgment against the Defendant in an amount in excess
13 of Seventy Five Thousand Dollars (\$75,000.00), together with pre-judgment and
14 post judgment interest, attorneys' fees and costs of this action as may be
15 recoverable, and for such further relief as this Court deems just and reasonable.

16
17 **PLAINTIFF DEMANDS A TRIAL BY JURY.**

18 Dated: June 26, 2017

GOMEZ TRIAL ATTORNEYS

19 /s/ Ahmed S. Diab
20 **AHMED S. DIAB**
21 *adiab@thegomezfirm.com*
22 655 W. Broadway Suite 1700
23 San Diego, California 92101
24 Telephone: (619) 237-3490
25 Facsimile: (619) 237-3496

26
27 *Attorney for Plaintiff Lydia Constantini*
28

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
Lydia Constantini
(b) County of Residence of First Listed Plaintiff Sonoma, CA
(c) Attorneys (Firm Name, Address, and Telephone Number)
Ahmed S. Diab; Gomez Trial Attorneys; 655 W. Broadway, Suite 1700, San Diego, CA 92101; Telephone: 619-237-3490; Fax: 619-237-3496

DEFENDANTS
Smith & Nephew, Inc.
County of Residence of First Listed Defendant Shelby, TN
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
2 U.S. Government Defendant
3 Federal Question (U.S. Government Not a Party)
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)
Citizen of This State
Citizen of Another State
Citizen or Subject of a Foreign Country
PTF DEF
1 1
2 2
3 3
4 4
5 5
6 6

IV. NATURE OF SUIT (Place an "X" in One Box Only) Click here for: Nature of Suit Code Descriptions.

Table with 5 columns: CONTRACT, REAL PROPERTY, TORTS, CIVIL RIGHTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES. Contains various legal categories and codes.

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 - Transfer
8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
28 U.S. § 1332
Brief description of cause:
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 06/26/2017 SIGNATURE OF ATTORNEY OF RECORD s/ Ahmed Diab

FOR OFFICE USE ONLY
RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

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 there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: [Nature of Suit Code Descriptions](#).
- V. Origin.** Place an "X" in one of the seven 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 – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
 Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.
- 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.