UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF MICHIGAN

ROSETTA VENTIMIGLIA,

Plaintiff,

vs.

SMITH & NEPHEW, INC.,

Defendant.

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COMPLAINT AND JURY DEMAND

Jurisdiction

Rosetta Ventimiglia, by counsel, John A. Zick, states the following complaint against the defendant:

1. Rosetta Ventimiglia is a citizen of the state of Michigan, residing in Macomb County, Michigan.

2. Smith & Nephew, Inc. (Smith & Nephew) is a corporation organized under the laws of the State of Delaware, with its principal place of business in the Commonwealth of Massachusetts.

3. The amount in controversy exceeds the sum of $75,000, exclusive of interest and costs.

4. This Court has original diversity jurisdiction of this action pursuant to Title 28 U.S.C. § 1332(a).

THE FDA'S PREMARKET APPROVAL OF SMITH & NEPHEW'S BIRMINGHAM HIP RESURFACING SYSTEM AND SMITH & NEPHEW'S ONGOING RESPONSIBILITIES

5. Smith & Nephew is a global medical technology company, with its headquarters in England, a presence in more than 90 countries world-wide, and total revenue of $4.6 billion in 2015.

6. The 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 on June 4, 2015, and issued a Class II Recall on September 10, 2015, due to high failure rates, especially for women and for patients with small bearing 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. The BHR System is a Class III medical device under the Medical Device Amendments of 1976 (MDA).

10. Smith & Nephew submitted an application and several amended applications for Pre-Market Approval of the BHR System to the United States Food and Drug Administration (FDA) from 2004 to 2006.

11. On May 9, 2006, the FDA issued an Order conditionally approving the BHR System for commercial distribution. As a condition of distribution, however, the FDA imposed a number of requirements:

a. Smith & Nephew was only allowed to sell, distribute, and promote the BHR System for prescription use in accordance with 21 CFR 801.109 and § 520(e) of the Federal Food, Drug, and Cosmetic Act;

b. Smith & Nephew was only allowed to sell, distribute, or promote the BHR System for use in compliance with § 502(q) and (r) of the Federal Food, Drug, and Cosmetic Act;

c. Smith & Nephew was required to conduct a study of the longer-term safety and effectiveness of the BHR System in the United Kingdom based upon the experiences of the first 350 consecutive patients in the initial study (the Overall McMinn Cohort) reported in its application - Smith & Nephew was required to monitor and report the pain, function, movement, revision status, and adverse events experienced by these patients annually from the fifth year post-implantation (year five) to the tenth year post-implantation (year ten);

d. Smith & Nephew was required to conduct a study of the longer-term safety and effectiveness of the BHR System in the United States based upon the experiences of 350 patients from up to 8 geographically and professionally diverse settings - Smith & Nephew was to monitor and report the clinical and radiographic data for each of the 350 patients annually from implantation (surgery, year 0) to the fifth year post-implantation (year five), send postcard questionnaires to each of the 350 patients and report their experiences annually from the sixth year post-implantation (year six) to the ninth year post-implantation (year nine), and monitor and report the clinical and radiological data for each of the 350 patients in the tenth year post-implantation (year ten);

e. Smith & Nephew was required to implement a training program including quarterly

teleconferences or meetings for the first two years of the United States Study to provide clinical updates to investigators, discuss study issues including adverse events, and identify recommendations for the improvement of the training program and labeling and to report the findings of these conferences or meetings to the FDA;

f. Smith & Nephew was required to submit annual post-approval reports under 21 CFR 814.84 that included a bibliography and summary of unpublished reports of data from clinical investigations and non-clinical laboratory studies involving the BHR and reports in the scientific literature concerning the device;

g. Smith & Nephew was required to submit adverse reaction and device defect reports to the FDA within 10 days after receiving or having knowledge of a mix-up of the device or its labeling, any adverse reactions, side effects, injury, toxicity, or sensitivity reactions attributable to the device; or any significant chemical, physical, or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling;

h. Smith & Nephew was required to submit a medical device report under the Medical Device Reporting (MDR) Regulation whenever it received or otherwise became aware of information that reasonably suggested that the BHR System may have caused or contributed to a

death or serous injury or malfunctioned and a recurrence would be likely to cause or contribute to a death or serious injury;

i. Smith & Nephew was required to provide an analysis of adverse events and complaints related to the BHR System;

j. Smith & Nephew was required to issue a supplemental label that reflected the results of the post-approval studies, training program assessment, and adverse event analysis; and

k. Smith & Nephew was required to submit a supplemental PMA when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitated a labeling, manufacturing, or device modification.

12. When the FDA issued the PMA approval order for the BHR System, it warned Smith & Nephew that its failure to comply with any of the conditions outlined above and/or imposed by federal regulation would constitute grounds for withdrawal of approval of the PMA and commercial distribution of a device that was not in compliance with these conditions was a violation of the Federal Food, Drug, and Cosmetic Act.

13. After receiving FDA approval, Smith & Nephew introduced the BHR System into the stream of commerce.

ROSETTA VENTIMIGLIA AND THE SMITH & NEPHEW BIRMINGHAM HIP RESURFACING SYSTEM

14. On April 8, 2014, Rosetta Ventimiglia, then age 56, went to Huron Valley Sinai Hospital in Commerce Township, Michigan, for a right hip resurfacing procedure. Her surgeon, Philip T. Schmitt, D.O., implanted a Smith & Nephew BHR System with a size 50 cup and a size 44 femoral head.

15. Thereafter, Ms. Ventimiglia experienced hip pain, limited range of motion, and "clunking" and "locking" sensations in her right hip. Blood tests revealed elevated metal levels of cobalt 10.9 and chromium 19.8.

16. Removal of the BHR system was medically necessary.

17. On November 14, 2016, Ms. Ventimiglia underwent right hip revision surgery by Brian R. Hallstrom, M.D. at the University of Michigan Medical Center in Ann Arbor, Michigan.

18. In the revision surgery, the Smith & Nephew components were removed, and a total hip replacement was performed, using components from another implant manufacturer.

19. In the revision surgery, the tissues in the area were found to be stained with metal, and cloudy fluid was present, consistent with a metal reaction. There was extensive metallosis around the acetabular

component, including a defect in the medial wall of the pelvis, from the materialization of the resurfacing component.

20. Following the revision surgery, Ms. Ventimiglia suffered a femoral fracture while she was being positioned by one of the physicians at the University of Michigan Medical Center.

21. After her discharge from the hospital, Ms. Ventimiglia underwent a lengthy recovery including months of physical therapy. She was disabled from her employment and her activities were significantly limited.

22. As a direct and proximate result of the failure of the Smith & Nephew BHR System, Rosetta Ventimiglia experienced pain and suffering, emotional distress and inconvenience.

23. As a further result of the failure of the Smith & Nephew BHR System, Ms. Ventimiglia suffered special damages including medical expenses and lost income.

Count I - Negligence

24. The plaintiff repeats the allegations of paragraphs 1 through 23, the same as if set forth verbatim.

25. Smith & Nephew had a duty to comply with and not deviate from the PMA requirements contained in the BHR System's FDA approval

order.

26. Pursuant to 21 C.F.R. 814.80, Smith & Nephew, as the manufacturer of a Class III medical device, also had a duty and was required to manufacture, package, store, label, distribute, and advertise it in a manner consistent with the conditions for approval specified by the FDA in the device's PMA approval order. Any deviation from the PMA approval order, without authorization from the FDA, was a violation of federal law.

27. Additionally, Smith & Nephew had a duty and was required to comply with and not deviate from other federal statutory and regulatory requirements that applied to the BHR System.

28. Pursuant to 21 C.F.R. 814.82 and 814.84, Smith & Nephew, as the manufacturer of a Class III medical device, also had a duty and was required to provide all of the post-approval reports and information identified by the FDA in the device's PMA approval order. Any deviation from the PMA approval order, or failure to provide the material known or knowable to Smith & Noble, was a violation of federal law.

29. Pursuant to 21 CFR. 820.80, Smith & Nephew, as the manufacturer of a Class III medical device, also had a duty and was required to establish and maintain procedures for device acceptance, meaning that

they are responsible for ensuring that each production run, lot, or batch meets the in-process and final acceptance criteria for the device. Failure to do so was a violation of federal law.

30. Pursuant to 21 C.F.R. 820.100 and 820.198, Smith & Nephew, as the manufacturer of a Class III medical device, also had a duty and was required to establish and maintain procedures for ongoing quality reviews of its devices and for implementing corrective and preventative action if processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned products, and other sources of quality data identify potential causes of nonconforming product or other quality problems. Smith & Nephew was required to be pro-active and investigate the cause of nonconformities and implement effective corrective action. Failure to do so was a violation of federal law.

31. In parallel with federal law, Michigan law imposed post-sale duties upon Smith & Nephew. The defendant owed a common law duty to monitor the sale, development, and use of the BHR System, to discover defects or hazards associated with the use of the BHR System, to warn the government, doctors, and users of these defects and hazards, and to take other actions to protect those exposed to these defects and hazards.

32. Further, in parallel with federal law, Michigan law treats violations of federal statutes and regulations as evidence of common law negligence and Smith & Nephew, as a manufacturer, seller, and distributor of products in Michigan, owed a common law duty to comply with all applicable laws and regulations.

33. Despite its duties, the defendant directly and by and through its actual and apparent agents, servants, and/or employees, was negligent and careless in the following ways:

a. Smith & Nephew failed to comply with and not deviate from the conditions set in the PMA approval order, in violation of the order, 21 C.F.R. 814.82 and 814.84, and Michigan common law in that it failed to warn Ms. Ventimiglia, her physicians, and the larger medical community of physicians of the risk of cobalt and chromium poisoning and other complications. Smith & Nephew was aware or should have been aware that many patients were experiencing pain, dysfunction, movement problems, revisions, and adverse events at a greater level than it had predicted. Smith & Nephew was aware or should have been aware that many of these patients were experiencing higher than anticipated wear and tear of their metal-on-metal components and were at increased risk of metal ion

release into their blood stream. Smith & Nephew was also aware or should have been aware that many of these patients had highly elevated and unsafe levels of cobalt and metal ions in their blood stream and were experiencing tissue infiltration, pain, and other signs and symptoms associated with cobalt and metal poisoning and other harmful side effects. Despite its awareness, Smith & Nephew negligently and carelessly failed to properly notify and warn Ms. Ventimiglia, her physicians, and the larger medical community of physicians who were making decisions and speaking to patients about them.

b. Smith & Nephew failed to comply with and not deviate from the conditions set in the PMA approval order, in violation of the order, 21 C.F.R. 814.82 and 814.84, and Michigan common law in that it failed to warn Ms. Ventimiglia, her physicians, and the larger medical community of physicians of the risk of cobalt poisoning and other complications as adverse event reports began and continued to come in. Through September 2011, Smith & Nephew received roughly 610 Adverse Event Reports which it produced to the FDA. Smith & Nephew, however, delayed the production of these reports and erroneously blamed the vast majority of the adverse events on non-product problems. Contrary to its

duties, Smith & Nephew followed-up on only a very small percentage (roughly 2%) of all field-reported (patient-reported) adverse events. Based upon information sent from customers and doctors in the field, Smith & Nephew knew or should have known of adverse reactions and device defect claims raised by numerous patients and information that its BHR Systems were prematurely and excessively wearing down and progressively releasing cobalt and metal ions into patients' blood streams as time and wear and tear mounted. Other manufacturers of metal-on-metal hip implants were having similar problems, and Smith & Nephew knew or should have known that the incidence of cobalt and other metal poisoning in its patients were on the rise and patients were having adverse reactions and symptoms caused by and associated with cobalt and other metal poisoning. Despite its awareness, Smith & Nephew negligently and carelessly failed to properly notify and warn Ms. Ventimiglia, her physicians, and the larger medical community of physicians who were making decisions and speaking to patients about them.

c. Smith & Nephew was otherwise careless and negligent and failed to comply with and not deviate from the conditions set in the PMA approval order and/or applicable federal regulatory and statutory law.

34. If Smith & Nephew, directly and by and through its agents, servants, and/or employees, had complied with its responsibilities under the PMA approval order, federal regulatory and statutory law, and Michigan common law, the FDA, doctors implanting BHR systems, and the public would have known about the difficulties American doctors were having implanting the BHR System, the potential for excessive wear and tear leading to cobalt and other metal ion release and poisoning, the increased number and frequency of adverse events, complaints, and complications being experienced in the United States, and the dangers patients were being exposed to and the injuries that were resulting as a result of the BHR System. The FDA's awareness of any of these matters would have led the FDA to take appropriate and timely actions including, but not limited to, changing the labeling for the BHR System, issuing warnings about cobalt and other metal poisoning, reviewing the full range of data to make decisions that would have prevented Ms. Ventimiglia and others from longstanding exposure to high levels of cobalt and other metals in their blood, ordering a halt in sales to conduct an impartial investigation into these issues, and/or ordering a recall of the BHR System. This, in turn, would have prevented or greatly minimized the exposure Ms.

Ventimiglia and other patients with implanted BHR System components had to cobalt and other metal ions and prevented her and them from suffering from metal poisoning, metallosis and other injuries.

35. Similarly, if Smith & Nephew, directly and by and through its agents, servants, and/or employees, had complied with its responsibilities under the PMA approval order, federal regulatory and statutory law, and Michigan common law, the physicians who treated Ms. Ventimiglia and the larger medical community would have known about the difficulties American doctors were having implanting the BHR System, the potential for excessive wear and tear leading to cobalt and other metal ion release and poisoning, the increased number and frequency of adverse events, complaints, and complications being experienced in the United States, and the dangers patients were being exposed to and the injuries that were resulting as a result of the BHR System. This awareness would have led Ms. Ventimiglia's physicians and the larger medical community to take appropriate and timely actions including, but not limited to, closely monitoring the cobalt and other metal ion levels of patients for any sign of elevation or poisoning; surgically removing the BHR Systems before they subjected Ms. Ventimiglia and other patients to the release of cobalt and other metal

ions or at a time when the exposure would cause no or very limited harm; and/or taking other action to protect Ms. Ventimiglia and other patients, all actions that would have prevented or greatly minimized the exposure Ms. Ventimiglia and other patients with implanted BHR System components had to cobalt and other metal ions and prevented her and them from suffering from metal poisoning, metallosis and other injuries.

36. Finally, if Smith & Nephew, directly and by and through its agents, servants, and/or employees, had complied with its responsibilities under the PMA approval order, federal regulatory and statutory law, and Michigan common law, Ms. Ventimiglia and other patients would have been fully informed of the risks associated with the BHR System and cobalt and metal ion poisoning and could have and would have taken actions to protect themselves including the removal of their BHR Systems and regular monitoring of the cobalt and metal ion levels in their blood. This, in turn, would have prevented Ms. Ventimiglia and others from suffering from metal poisoning, metallosis and other injuries.

37. As a direct and proximate result of the negligence of Smith & Nephew, directly and by and through its agents, servants, and/or employees, which amounted to a deviation from the PMA approval order,

violation of federal regulatory and statutory law, and violation of Michigan common law, Ms. Ventimiglia was implanted with the BHR System on April 8, 2014 and it remained in place until it was removed on November 16, 2016. Throughout this time, the BHR System released high levels of cobalt and other metal ions into Ms. Ventimiglia's bloodstream and caused her to develop metal poisoning, metallosis and other injuries.

38. This count is based solely on Smith & Nephew's failure to comply with the PMA approval order and the conditions and requirements set by federal regulatory and statutory law. The violation of these conditions and requirements constitutes common law negligence under Michigan law and Ms. Ventimiglia is seeking a traditional damages remedy for violations of these common law duties to the extent, and only to the extent, that they run parallel to the federal conditions and requirements.

WHEREFORE, Rosetta Ventimiglia demands judgment against Smith & Nephew, Inc. for that sum in excess of $75,000 which is justified by the evidence brought forth at trial, together with costs, interest and attorney fees.

Count II - Breach of Express Warranty

39. The plaintiff repeats the allegations of paragraphs 1 through 38, the same as if set forth verbatim.

40. When Smith & Nephew released the BHR System into the stream of commerce, Ms. Ventimiglia agreed to have the BHR System implanted, and throughout the time Ms. Ventimiglia' BHR System was in place, Smith & Nephew, directly and by and through its sales representatives who worked with Ms. Ventimiglia's doctor and interaction with Ms. Ventimiglia, expressly warranted that the BHR System was a safe medical device, free from known or knowable defects and hazards. Smith & Nephew's sales materials and brochures contained numerous references to the BHR System's effectiveness and safety. Smith & Nephew's sales representatives, who worked closely with Ms. Ventimiglia's doctors, continually touted the effectiveness, durability, and safety of the BHR System from the time the BHR System was released into the stream of commerce until it was removed from Ms. Ventimiglia's body.

41. Smith & Nephew violated its express warranties to Ms. Ventimiglia and the public, in that the BHR System was not a safe medical device, it was not free from known or knowable defects and hazards, it

experienced the same types of wear and tear that other hip replacement and resurfacing systems experienced, and it released cobalt and other metal ions in Ms. Ventimiglia's and other patients' blood, causing serious health problems.

42. As a direct and proximate result of Smith & Nephew's breach of its express warranties, high levels of cobalt and other metal ions were released into Ms. Ventimiglia's blood stream over a period of time and caused her to develop metal poisoning, metalosis and other injuries. It was necessary for her to undergo revision surgery on November 14, 2016. She suffered the other damages previously set forth.

43. This count is based solely on Smith & Nephew's representations made in voluntary communications with the medical profession and the public. This count is not based on warranties in FDA-approved labeling.

44. The defendant's breach of these express warranties is actionable under Michigan law, and Ms. Ventimiglia is seeking a remedy for this breach of warranties only to the extent that the same run parallel to federal law.

WHEREFORE, Rosetta Ventimiglia demands judgment against Smith & Nephew, Inc. for that sum in excess of $75,000 which is justified

by the evidence brought forth at trial, together with costs, interest and attorney fees.

Count III - Misrepresentation

45. The plaintiff repeats the allegations of paragraphs 1 through 44, the same as if set forth verbatim.

46. Smith & Nephew had a duty to accurately and truthfully represent to the medical community, Ms. Ventimiglia, her physicians and the public that the BHR System had not been adequately tested and found to be safe and effective for the treatment of damaged and worn parts of the hip joint.

47. The defendant negligently misrepresented to the medical community, Ms. Ventimiglia, her physicians and the public, that the BHR System did not have a high risk of dangerous adverse side effects.

48. The defendant made this misrepresentation by consistently under-reporting adverse events for the BHR System, delaying reporting of adverse events, and categorizing them in a way that concealed 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. Had the defendant accurately and truthfully represented to the medical community,

Ms. Ventimiglia, her physicians and the public, the material facts relating to the risks of the BHR System, Ms. Ventimiglia and her health care providers would not have utilized the BHR System for her treatment.

49. By its misrepresentations regarding the efficacy of the BHR System, the defendant effectively deceived and misled the scientific and medical communities and consumers regarding the risks and benefits of the BHR System.

50. Smith & Nephew did not inform the public or Ms. Ventimiglia until, at the earliest, June 2015, when the defendant attempted to withdraw the BHR System from the market for certain populations, including all women.

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

52. As a direct and proximate result of the defendant's negligent misrepresentations, Ms. Ventimiglia has suffered severe damages and injuries as described elsewhere in this complaint.

WHEREFORE, Rosetta Ventimiglia demands judgment against Smith & Nephew, Inc. for that sum in excess of $75,000 which is justified

by the evidence brought forth at trial, together with costs, interest and attorney fees.

/s/ John A. Zick
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Dated: April 20, 2017

JURY DEMAND

The Plaintiff demands a trial by jury.

/s/ John A. Zick
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