IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WISCONSIN

STEVEN A. ZINGLER,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**CASE NO.:**
	)	
SMITH & NEPHEW, INC.,	)	
a Tennessee Corporation,	)	
	)	
Defendant.	)	

COMPLAINT

COMES NOW, the Plaintiff, Steven A. Zingler, and for his claims for relief against the Defendant, Smith & Nephew, Inc., a Tennessee Corporation, alleges and states as follows:

JURISDICTION

1. Plaintiff is, and at all times relevant to this action, was a citizen and resident of the State of Wisconsin with his place of residence being on Nicolet Drive in, Green Bay, which lies in Brown 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 residence and/or business in a state other than the State of Wisconsin.

3. Complete diversity of citizenship exists within the purview of 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 Wisconsin, and the amount in controversy in this action exceeds Seventy Five Thousand Dollars ($75,000.00) exclusive of interest and costs.

GENERAL CLAIMS FOR RELIEF

4. This is a strict products liability and negligence action arising out of Defendant, Smith & Nephew's violations of various sections of the Federal Code of Regulations, the State Laws of Wisconsin and the damages Plaintiff, Steven A. Zingler suffered as a result thereof.

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

a. Birmingham Resurfacing Femoral Head; and

b. Birmingham Hip Resurfacing Acetabular Cup.

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

7. The Approval Order from the FDA stated that "[c]ommercial distribution of a device that is not in compliance with these conditions is a violation of the [Food, Drug and Cosmetic] act, [21 U.S.C. §§301, et seq.]." (*See*, Approval Order attached hereto as Exhibit "1").

8. The Approval Order required Smith & Nephew to, among other things:

a. Submit a PMA supplement "when unanticipated adverse effects, increases

in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing or device modification";

b. Submit an "'Adverse Reaction Report' or 'Device Defect Report' within 10 days after [Smith & Nephew] receives or has knowledge of information concerning…Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and…has been addressed by the device's labeling but is occurring with unexpected severity or frequency";

c. "[R]eport to the FDA whenever they receive or otherwise become aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer or importer:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer…would be likely to cause or contribute to a death or serious injury if the malfunction were to recur."

9. Additionally, the Approval Order cited many agreements Smith & Nephew made with the FDA, which became part of the approval. (*See*, Exhibit "1"). Thus, the Approval Order became an outline of the specific post-market obligations and duties Smith & Nephew undertook, in addition to all those existing under Federal Law, when it finally convinced the FDA to conditionally approve the BHR. Those agreements included, but were not limited to, the following:

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

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

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

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

10. The Approval Order made clear that each requirement imposed upon Smith & Nephew with respect to its distribution of the BHR system was to "ensure the safe and effective use of the device."

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

a. Smith & Nephew received hundreds of adverse reports and complaints

regarding the BHR but delayed its reporting to the FDA, and when it did communicate adverse reports, it did not do so properly but, in fact, attempted to blame others for the adverse events;

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

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

d. Smith & Nephew, when it did provide reports to the FDA pursuant to the Approval Order, underreported to and withheld information from the FDA about the likelihood of failure;

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

12. Smith & Nephew's failures to follow the requirements of the Approval Order constitute violations of the Federal Food, Drug, and Cosmetic Act, pursuant to 21 CFR 801.109 and furthermore voids any legal protection that Defendant enjoys from tort claims as part of the device's PMA status.

PLAINTIFF'S INJURIES

13. On or about March 16, 2011**,** Plaintiff, Steven A. Zingler, was admitted to Bellin Health System Hospital in Green Bay, Wisconsin for the purpose of undergoing a right hip resurfacing by Marc H. Anderson, M.D. At the time of said surgery, Dr. Anderson utilized and implanted the Defendant's Birmingham Hip Resurfacing system. Specifically, the following components of said system were utilized:

a. Smith and Nephew Birmingham Resurfacing Femoral Head 52 mm; and

b. Smith and Nephew Birmingham Hip Resurfacing Acetabular Cup 58 mm.

14. On or about January 26, 2016, Steven A. Zingler underwent revision of his right hip due to right hip pain and other complications caused by the failure of the Defendant's Birmingham Hip Resurfacing system. Plaintiff's revision surgery was performed by Michael Schnaubelt, M.D. at Aurora BayCare Medical Center in Green Bay, Wisconsin.

15. At the time of the resurfacing procedure in 2011, neither Plaintiff nor his surgeon were aware of the myriad of problems associated with the BHR.

FIRST CLAIM FOR RELIEF

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

Plaintiff herein incorporates, reasserts and re-alleges the allegations set forth above in paragraphs 1-15 by reference as if fully set forth herein below.

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

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

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

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

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;

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;

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

j. Continued to place the BHR into the stream of interstate commerce

when it knew, or should have known, that the acetabular component was Malfunctioning [as defined in 21 C.F.R. 803.3] or otherwise not responding to its Design Objective Intent.

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

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

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

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

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

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

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

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

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

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

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

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

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

Original Core Surgeons;

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

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

19. As a direct and proximate result of Defendant's violations of one or more of these federal statutory and regulatory standards of care, a BHR System, including the acetabular cup and femoral head, was implanted in Plaintiff's right hip, and failed and such failure directly and proximately caused and/or contributed to the severe and permanent injuries the Plaintiff sustained and endured as defined in 21 C.F.R. 803.3. As a direct and proximate result, Plaintiff endured pain and suffering and has required additional and debilitating surgeries and has incurred significant medical expenses in the past and will incur additional medical expenses in the future; both past and future wage loss; both past and future non-economic damages including, but not limited to, physical and mental pain and suffering, inconvenience, emotional distress and impairment of the quality of his life; and permanent impairment and disfigurement.

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

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

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

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

24. The cause of action set forth in this Claim for Relief is not preempted by 21 U.S.C. §306(k) because the violations alleged are all based on an exclusively federal statutory and regulatory set of requirements and express agreements with the FDA which include no "requirement which is different from, or in addition to, any requirement applicable under" the

Act and regulations promulgated thereunder. *See; Bausch v. Stryker*, 630 F.3d 546, 556 (7th Cir. 2010) (claims for negligence and strict products liability relating to a Class III medical device were not expressly preempted by federal law to the extent they were based on the defendants' violations of federal law). As such, the claims set forth herein contain requirements that are parallel to the Act and regulations promulgated thereunder.

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

SECOND CLAIM FOR RELIEF

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

Plaintiff herein incorporates, reasserts and re-alleges the allegations set forth above in paragraphs 1-25 by reference as if fully set forth herein below.

26. The BHR Systems, including the acetabular cups and femoral heads, implanted in Plaintiff, Steven A. Zingler's right hip on March 16, 2011 were designed and/or manufactured in violation of the Act and regulations promulgated to it.

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

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

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

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;

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;

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

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

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

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

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

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

c. Smith & Nephew received hundreds of adverse reports regarding the BHR system but delayed reporting them to the FDA without any justification or excuse for such delays;

d. Smith & Nephew failed to properly communicate adverse events to the FDA, when it did, in fact, 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 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 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 User Error and would provide insight into possible problems that may not be readily seen when the BHR system was used as a completed, unaltered system;

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

United Kingdom or from Original Core Surgeons;

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

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

n. On June 4, 2015, Smith & Nephew announced the voluntary removal of the BHR device from the U.S. market due to unreasonably high failure rates for certain demographic groups, including all women, all men age 65 or older, and all men with requiring femoral head sizes 46 mm or smaller.[1]

o. The market withdrawal of the BHR followed numerous other warning signs, including an Urgent Field Safety Notice[2] sent to doctors in November 2014 about high revision rates for the same population groups mentioned above, and for patients with congenital dysplasia, and diagnosed avascular necrosis.

[1] 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/ (stating that "… Smith & Nephew considers that these patient groups may be at a greater risk of revision surgery than previously believed, and is therefore removing small sizes and updating the IFU to contraindicate the BHR for women.")

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

p. In addition to the above-mentioned market withdrawal, Smith & Nephew issued a Class 2 of the BHR device on September 10, 2015, covering more than 10,000 units of the device in the stream of commerce. The reason for the recall was described as "revision rates which were higher than established benchmarks" pursuant to 21 CFR §7.55.

q. Data published in connection with the recall show a total of 288 "device problems" with the BHR, including numerous safety problems related to "metal shedding debris" and other symptoms typical of metal-on-metal device failure.[3]

r. Data published in connection with the recall show a total of 288 "device problems" with the BHR, including numerous safety problems related to "metal shedding debris" and other symptoms typical of metal-on-metal device failure.[4]

s. Data compiled by the National Joint Registry of England and Wales show the BHR 42 mm femoral head component has a seven-year revision rate of 11.76 percent, well above the normal acceptable failure rate for a device of this type.

t. Additional data compiled by the National Joint Replacement Registry of Australia in 2015 show the BHR has a ten-year revision rate of 14.5 percent for women, well above the normal acceptable failure rate for a device of this type.

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[3] Many of the failures have been reported to Smith & Nephew in the last 18 months, suggesting that additional failure reports due to metallosis will continue in the future. A list of the device failures is available through the FDA's Manufacturer and User Device Experience, or MAUDE, database, available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=NXT (last visited Nov. 17, 2016).

[4] Many of the failures have been reported to Smith & Nephew in the last 18 months, suggesting that additional failure reports due to metallosis will continue in the future. A list of the device failures is available through the FDA's Manufacturer and User Device Experience, or MAUDE, database, available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=NXT (last visited Nov. 17, 2016).

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

29. As a direct and proximate result of Defendant, Smith and Nephew's violations of one or more of these federal statutory and regulatory standards of care, and the Approval Order, a BHR System, including the acetabular cup and femoral head, was implanted in Plaintiff's right hip on March 16, 2011 and failed and such failure directly caused and/or contributed to the severe and permanent injuries sustained and endured by Plaintiff, as defined in 21 C.F.R. 803.3. As a direct and proximate result, Plaintiff endured pain and suffering and has required additional and debilitating surgeries and has incurred significant medical expenses in the past and will incur additional medical expenses in the future; both past and future wage loss; both past and future non-economic damages including, but not limited to, physical and mental pain and suffering, inconvenience, emotional distress and impairment of the quality of her life; and permanent impairment and disfigurement.

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

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

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

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

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

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

THIRD CLAIM FOR RELIEF
(Breach of Express Warranties)

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

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

38. Defendant expressly warranted to Plaintiff, by and through Defendant and/or its authorized agents or sales representatives, in publications, package inserts, the internet, and other communications intended for physicians, patients, Plaintiff, and the general public, that the system was safe, effective, fit and proper for its intended use.

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

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

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

42. Defendant made numerous claims to the general public, and to Plaintiff in particular, that the BHR devices were safe for their intended use and that they did not suffer from the same problems that plague other metal-on-metal hips, even though it was in possession of information to the contrary. For example, more than three years before Plaintiff's revision surgery, Defendant's senior vice president publicly touted the BHR as being "unlike any other metal-on-metal hip implant" with a survivorship rate superior to even traditional non-metal devices due to its "distinctive metallurgy heritage" and other factors.[5]

43. As recently as January, 2015, Defendant referred patients with questions about the BHR devices to a website, www.surfacehippy.com, with claims about people with the BHR devices who completed extraordinary physical feats after implantation, including a "sprint triathlon" with their prosthetic BHR devices.[6]

44. Pursuant to 21 U.S.C. §360k, the above statements constitute a violation of the PMA because the FDA's conditional approval of the BHR devices warned Defendant that its "warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State Laws."

45. The defective and unreasonably dangerous condition of the BHR products constituted a breach of the Defendant's express warranties under Wisconsin law. The above-

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

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

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

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

FOURTH CLAIM FOR RELIEF
(Breach of Implied Warranties)

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

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

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

50. When the BHR products were implanted in Plaintiff to treat her damaged and worn hip joints, the BHR products were being used for the particular purposes for which they

were intended, and they were particularly intended for Plaintiff because he was only 56 years old at the time of implantation in March 2011.

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

52. Defendant breached these implied warranties of merchantability and fitness for a particular purpose because the BHR products implanted in Plaintiff were neither merchantable nor suited for the intended uses as warranted, because they carried a high risk of premature failure due to metallosis.

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

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

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

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

FIFTH CLAIM FOR RELIEF
(Unfair and Deceptive Trade Practices)

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

57. Plaintiff purchased and used Defendant's BHR resurfacing products primarily for personal use and thereby suffered ascertainable losses as a result of Defendant's violations of the PMA Letter and various federal regulations governing the BHR device, which also constitute parallel violations of Wisconsin consumer protection laws and the Wisconsin Deceptive Trade Practices Act, Wis. Stat. § 100.18 et seq., ("WDTPA"). In particular, Defendant's failure to report adverse events in a timely manner, and failure to adequately disclose the high risk of premature failure of the BHR device, as described in more detail above, constitutes a violation of federal law and FDA regulations.

58. Had Defendant not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for Defendant's BHR resurfacing products, and would not have incurred related medical costs and injuries.

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

60. Defendant's actions, as complained of herein, and as suppliers, manufacturers, advertisers, and sellers, constitute unfair, unconscionable, deceptive, and/or fraudulent acts or trade practices, in violation of the MPA, which prohibits "[t]he act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice

or the concealment, suppression or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce" and declares such acts or practices as unlawful.

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

SIXTH CLAIM FOR RELIEF
(Fraudulent Concealment)

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

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

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

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

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

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

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

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

PLAINTIFF DEMANDS A TRIAL BY JURY.

Dated this 2nd day of December, 2016.

Respectfully submitted,

By: */s/ Anthony J. Nemo*

Anthony J. Nemo (MN #221351)
MESHBESHER & SPENCE, LTD.
1616 Park Avenue South
Minneapolis, MN 55404
Telephone: (612) 339-9121
Email: tnemo@meshbesher.com

JONES WARD PLC

Jasper D. Ward IV
Alex C. Davis
(*Pro Hac Vice* pending)
Marion E. Taylor Building
312 S. Fourth Street, Sixth Floor
Louisville, Kentucky 40202
Tel. (502) 882-6000
Fax (502) 587-2007
jasper@jonesward.com
alex@jonesward.com
Counsel for Plaintiff

JS 44 (Rev. 08/16)

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
Steven A. Zingler

(b) County of Residence of First Listed Plaintiff Brown, WI
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Alex Davis and Jasper Ward, Jones Ward PLC, 312 S. Fourth St., 6th Fl
Louisville KY 40202, Tel. 502-882-6000

DEFENDANTS
Smith & Nephew, Inc.

County of Residence of First Listed Defendant Shelby, TN
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

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

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

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

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

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

Click here for: Nature of Suit Code Descriptions.

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

TORTS

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

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

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

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

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

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

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

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

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

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

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

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

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

PRISONER PETITIONS

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

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

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 $ 75,000.00

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

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
12/02/2010

SIGNATURE OF ATTORNEY OF RECORD
/s/Anthony Nemo

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

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UNITED STATES DISTRICT COURT

for the

Eastern District of Wisconsin

Steven A. Zingler *Plaintiff(s)* v. Smith & Nephew, Inc. *Defendant(s)*	)	Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Smith & Nephew, Inc.
c/o CT Corporation System
8020 Excelsior Dr., Suite 200
Madison, WI 53717

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Alex C. Davis and Jasper D. Ward IV
Jones Ward PLC
312 S. Fourth St., 6th Floor
Louisville, KY 40202

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

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