IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS---EASTERN DIVISION

CHERYL ELMORE and KEN ELMORE,	)	
Plaintiffs,	)	Case No.
vs.	)	JURY DEMANDED
SMITH & NEPHEW, INC., a Delaware corporation,	)	
Defendant.	)	

COMPLAINT

Plaintiffs, CHERYL ELMORE and KEN ELMORE, by their counsel, David A. Axelrod, Stacey L. Leinheiser, and Jason M. Kleinman, for their Complaint against Defendant, SMITH & NEPHEW, INC., a Delaware corporation, state as follows:

GENERAL ALLEGATIONS

Nature of the Case

1. This is a strict products liability, negligence, and loss of consortium action arising out of Defendant Smith & Nephew's violations of various sections of the Federal Code of Regulations and the damages suffered by Plaintiffs, Cheryl Elmore ("Cheryl") and Ken Elmore ("Ken") as a result thereof. Cheryl had a Smith & Nephew, Inc. Birmingham Hip Resurfacing System ("BHR") implanted in her right hip on October 17, 2008. Due to design and/or manufacturing defects with the BHR, Cheryl endured a tremendous amount of pain and suffering, required the explantation of her BHR implant, and has suffered serious and permanent injuries.

Parties

2. Plaintiff, Cheryl, is a resident and citizen of Montgomery County, Illinois.

3. Plaintiff, Ken, is a resident and citizen of Montgomery County, Illinois.

4. Defendant, Smith & Nephew, Inc. ("Smith & Nephew") is a Delaware corporation with its principal place of business located in Shelby County, Tennessee. Smith & Nephew does business and maintains an agent in Illinois. The address of the registered agent for Smith & Nephew in Illinois is 208 S. LaSalle Street, Suite 814, Chicago, Cook County, Illinois 60604.

Jurisdiction and Venue

5. Jurisdiction in this case arises under 28 U.S.C. § 1332, based on diversity of citizenship between the Plaintiffs and the Defendant, and the amount in controversy exceeding seventy-five thousand dollars ($75,000.00) exclusive of interest and costs.

6. Smith & Nephew has transacted business in Illinois, committed tortious acts in Illinois, made or performed contracts in Illinois, made promises substantially connected to Illinois, and maintains its registered agent in Chicago, Illinois. Therefore, this court has personal jurisdiction over the Defendant pursuant to the Illinois long arm statute, 735 ILCS 5/2-209, subparagraphs (1), (2), and (7).

7. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(a) and (c) because Smith & Nephew conducts business and sales activity in this judicial district and maintains its registered agent in Chicago, Illinois, and thus is subject to personal jurisdiction in this judicial district.

Factual Background

8. Smith & Nephew, among other things, is a developer and manufacturer of joint replacement systems. Smith & Nephew's orthopaedics division is located at 1450 E. Brooks Road, Memphis, Tennessee.

9. Since 2006, Smith & Nephew has manufactured and introduced or delivered for introduction into interstate commerce the BHR.

10. The BHR is a metal-on-metal hip resurfacing prosthesis. It is comprised of two components, a stemmed femoral head and a hemispherical acetabular cup.

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

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

13. On October 6, 2008, Cheryl underwent right hip resurfacing at Memorial Medical Center in Springfield, Illinois ("Memorial Medical"). Ronald R. Romanelli, M.D. ("Dr. Romanelli") performed the procedure. The BHR components used by Dr. Romanelli, and manufactured and introduced or delivered for introduction into interstate commerce by Smith & Nephew, were a size 48 acetabular cup (catalog # 74120148/lot # 079292) and a size 42 femoral head (catalog # 74121142/lot # 078591).

14. On October 15, 2008, Cheryl went in for a post-operative appointment with Dr. Romanelli. X-rays taken at that appointment revealed an aseptic loosening of the femoral component.

15. On October 17, 2008, Dr. Romaneilli performed a revision on Cheryl's right hip. The surgery was performed at Memorial Medical. During the October 17, 2008 surgery, the size 48 acetabular cup was removed and a BHR size 50 acetabular dysplasia cup (catalog # 74120250/lot # 64778) (the "Acetabular Cup"), manufactured and introduced or delivered for introduction into interstate commerce by Smith & Nephew, was inserted. The BHR size 42 femoral head (catalog # 74121142/lot # 078591) previously implanted on October 6, 2008 (the "Femoral Head"), remained in place.

16. By October 2009, Cheryl began having a feeling of looseness and popping in her right hip.

17. By February 2010, Cheryl was experiencing a grinding feeling in her right hip and was having increasing pain localized to the groin and associated with hip flexion.

18. On October 4, 2010, blood serum metal ion testing was performed on Cheryl. The results showed highly elevated levels of chromium and cobalt (14.11 ng/ml and 7.12 ng/ml respectively).

19. On October 29, 2010, an MRI of Cheryl's right hip was performed. The imaging showed a collection of fluid in and around the right hip joint.

20. On December 13, 2010, an ultrasound showed a fluid collection in the anterior of Cheryl's right hip of approximately 3x5 centimeters. The fluid was aspirated under ultrasound guidance and 7 ml of serosanguineous fluid was obtained.

21. On December 21, 2010, at Barnes Jewish Hospital, Robert Barrack, M.D. ("Dr. Barrack") performed a revision surgery on Cheryl's right hip due to the failure of the BHR generally, and the Acetabular Cup and Femoral Head specifically. Dr. Barrack removed the

Acetabular Cup and Femoral Head and performed a right total hip athroplasty implanting a Smith & Nephew R3 multi-hole acetabular component, BIOLOX-forte ceramic 30 +0 head, 36 mm 20 degrees polyethylene liner, five acetabular screws, and Synergy size 10 high offset stem.

22. Since the December 21, 2010 surgery, Cheryl has suffered from repetitive, chronic fractures in her right acetabulum as demonstrated by the following radiographic studies:

a. A post-surgical x-ray taken on December 21, 2010 showed a new medial wall defect in the acetabulum.

b. On January 31, 2011, at a post-operative visit, radiographs revealed that Cheryl had a nondisplaced fracture of the anterior column of her right hip. Because of this, she was restricted to touchdown weightbearing for six to eight weeks.

c. On March 7, 2011, an x-ray was taken of Cheryl's right hip. The x-ray showed a minimally displaced fracture at the junction of the right superior pubic ramus and acetabulum with breach of the quadrilateral plate, unchanged from the prior study.

d. On June 13, 2011, an x-ray of the right hip showed a healing minimally displaced fracture at the junction of the right superior pubic ramus and acetabulum.

e. On June 14, 2011, a CT of Cheryl's pelvis was performed. The CT showed a chronic appearing fracture involving the medial right acetabular wall.

23. Cheryl uses a cane, wheelchair, and/or other assistive device to get around at virtually all times. Her pain is being partially controlled with narcotics. Without narcotics, Cheryl can stand for only approximately ten minutes at a time, for a total of one hour per day, and/or sit for 30 minutes at a time, for a total of two hours per day, before needing to recline to approximately 140°-160° to alleviate her excruciating pain. Without narcotics, she can no longer accompany her children at their school activities and functions, attend church, perform routine household chores without breaking them down into 10-15 minute increments, or participate in other activities that she

used to enjoy. She can no longer exercise, including, but not limited to, horseback riding, swimming and scuba diving, or even simply going for a walk. Cheryl can no long have normal family relations with Ken. Cheryl is unable to perform the duties of her job and has not worked since June 2011.

COUNT I
STRICT PRODUCTS LIABILITY BASED ON VIOLATIONS OF 21 C.F.R. 820.30(f) and (g), 21 C.F.R. 820.30(g), 21 C.F.R. 820.80(c) and (d), 21 C.F.R. 820.100, 21 C.F.R. 820.198
(Cheryl v. Smith & Nephew)

24. Cheryl reasserts and realleges paragraphs 1-23 of the General Allegations as her paragraph 24 of Count I as though fully set forth herein.

25. The BHR, including the Acetabular Cup and Femoral Head, implanted in Cheryl's right hip on October 17, 2008, was designed and/or manufactured in violation of the Federal Food, Drug and Cosmetic Act (the "Act") and regulations promulgated pursuant to it.

26. At the time the BHR, including the Acetabular Cup and Femoral Head, implanted into Cheryl's right hip on October 17, 2008, left the control of Smith & Nephew it was unreasonably dangerous due to non-compliance by Smith & Nephew with the Act, and the regulations promulgated pursuant to it 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, in violation of 21 C.F.R. 820.80(c);

g Failed to correct the component discrepancy, in violation of 21 C.F.R. 820.80(c);

h. Failed to capture the component discrepancy or defect during their Final Acceptance Activities, in violation of 21 C.F.R. 820.80(d);

i. 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;

j. Failed to appropriately respond to adverse incident reports 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;

k. 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,

l. 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.

27. As a direct and proximate result of Smith and Nephew's violations of one or more of these federal statutory and regulatory standards of care, a BHR, including the Acetabular Cup and Femoral Head were implanted in Cheryl and she was caused to endure a serious injury, as defined in 21 C.F.R. 803.3. Cheryl was caused to suffer, and will suffer in the future, injuries including, but not limited to pain, suffering, lost wages, disability, disfigurement, legal obligations for hospital, medical, nursing, rehabilitative, and other medical services and treatment. All of these injuries are permanent.

28. This cause of action is based entirely on the contention that Smith & Nephew has violated federal safety statutes and regulations. Cheryl 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 Smith & Nephew's violations of the applicable federal regulations.

29. Under Illinois law, Smith & Nephew's violations of the aforementioned federal statutes and regulations establish a *prima facie* case of strict liability in tort. See eg. Anderson v. Hyster Company, 74 Ill.2d 364, 368, 385 N.E.2d 690 (1979) (proof a product is "unreasonably dangerous" may come from legislation or government regulation); Baier v. Bostitch, 243 Ill.App.3d 195, 207-208, 611 N.E.2d 1103 (1st Dist. 1993) (allowing OSHA standard to help define "unreasonably dangerous"); Byrne v. SCM Corp., 182 Ill.App.3d 523, 551-552 (4th Dist. 1989) (approving use of modified IPI 60.01, allowing the jury to consider whether the defendant violated a statute on the occasion in question "in determining whether or not the product was unreasonably dangerous at the time of the occurrence.").

30. Thus under Illinois common 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 Illinois Legislature to act in order to create such a remedy.

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

and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act [21 USCS §§ 301 et seq.]."

32. The cause of action set forth in this Count is not preempted by 21 U.S.C. § 360k 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 in this cause of action contain requirements that are parallel to the Act and regulations promulgated thereunder.

WHEREFORE, Plaintiff, CHERYL ELMORE, prays for judgment against Defendant, SMITH & NEPHEW, INC., a Delaware corporation, as follows:

A. For damages in an amount in excess of $75,000.00, exclusive of interest and costs;

B. Plus costs; and,

C. For such other relief as this Court may deem just and proper.

COUNT II
NEGLIGENCE BASED ON VIOLATIONS OF
21 C.F.R. 820.30(f) and (g), 21 C.F.R. 820.30(g), 21 C.F.R. 820.80(c) and (d),
21 C.F.R. 820.100, 21 C.F.R. 820.198
(Cheryl v. Smith & Nephew)

33. Cheryl reasserts and realleges paragraphs 1-23 of the General Allegations as her paragraph 33 of Count II as though fully set forth herein.

34. The BHR, including the Acetabular Cup and Femoral Head, implanted in Cheryl's right hip on October 17, 2008, was designed and/or manufactured in violation of the Act and regulations promulgated pursuant to it.

35. It was the duty of Smith & Nephew to comply with the Act, and the regulations promulgated pursuant to it, yet, notwithstanding this duty, Smith & Nephew 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, in violation of 21 C.F.R. 820.80(c);

g Failed to correct the component discrepancy, in violation of 21 C.F.R. 820.80(c);

h. Failed to capture the component discrepancy or defect during their Final Acceptance Activities, in violation of 21 C.F.R. 820.80(d);

i. 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;

j. Failed to appropriately respond to adverse incident reports 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;

k. 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,

l. 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.

36. As a direct and proximate result of Smith and Nephew's violations of one or more of these federal statutory and regulatory standards of care, a BHR, including the Acetabular Cup and Femoral Head were implanted in Cheryl and she was caused to endure a serious injury, as defined in 21 C.F.R. 803.3. Cheryl was caused to suffer, and will suffer in the future, injuries including, but not limited to pain, suffering, lost wages, disability, disfigurement, legal obligations for hospital, medical, nursing, rehabilitative, and other medical services and treatment. All of these injuries are permanent.

37. This cause of action is based entirely on the contention that Smith & Nephew has violated federal safety statutes and regulations. Cheryl 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 Smith & Nephew's violations of the applicable federal regulations.

38. Under Illinois law, Smith & Nephew's violations of the aforementioned federal statutes and regulations establish a *prima facie* case of common law negligence. Kalata v. Anheuser- Busch Companies, Inc., 144 Ill. 2d 425, 434, 581 N.E.2d 656, 661 (1991) (noting that "[a] violation of a statute or ordinance designed to protect human life or property is *prima facie*

evidence of negligence."). The Illinois Supreme Court has described an Illinois negligence cause of action like this one based solely on statutory violations, as "identical" to a "private cause of action under the Act. . .[which] operates exactly as would a private cause of action." Abbasi v. Paraskevoulakos, 187 Ill.2d 386, 393-395, 718 N.E.2d 181 (1999).

39. Thus, under Illinois common law, a money damages remedy exists for negligent violation of the Act and regulations promulgated thereunder which proximately cause injuries, and there is no need for Illinois' Legislature to act in order to create such a remedy.

40. The Act contains an express preemption provision 21 U.S.C. § 360k, 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.] ."

41. The cause of action set forth in this Count is not preempted by 21 U.S.C. § 360k 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 in this cause of action contain requirements that are parallel to the Act and regulations promulgated thereunder.

WHEREFORE, Plaintiff, CHERYL ELMORE, prays for judgment against Defendant, SMITH & NEPHEW, INC., a Delaware corporation, as follows:

A. For damages in an amount in excess of $75,000.00, exclusive of interest and costs;

B. Plus costs; and,

C. For such other relief as this Court may deem just and proper.

COUNT III
LOSS OF CONSORTIUM 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 (Ken v. Smith & Nephew)

42. Ken reasserts and realleges paragraphs 1-41 as his paragraph 42 of Count III as though fully set forth herein.

43. Prior to the negligence as set forth herein, Ken and Cheryl were lawfully married and enjoyed a normal wife and husband relationship.

44. From about December 21, 2010, through the present, Ken was deprived of the companionship of Cheryl and the valuable services Cheryl would have performed for him had she not been injured by Smith & Nephew.

45. From about December 21, 2010, through the present, Ken and Cheryl have been deprived of normal family relations with each other.

WHEREFORE, Plaintiff, KEN ELMORE, prays for judgment against Defendant, SMITH & NEPHEW, INC., a Delaware corporation, as follows:

A. For damages in an amount in excess of $75,000.00, exclusive of interest and costs;

B. Plus costs; and,

C. For such other relief as this Court may deem just and proper.

JURY DEMAND

Plaintiffs hereby invoke their rights to a trial by jury as to all counts and issues pled against the Defendant in this cause.

CHERYL ELMORE and KEN ELMORE

By: /s/ Stacey L. Leinheiser
One of Plaintiffs' Attorneys

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