

Smith & Nephew Hip Implant MDL Presents Unusual Showdown Involving Off Label Cases

The Smith & Nephew Hip Implant MDL¹ has been an unusual one from its beginning back in early 2017, and the monthly MDL Hearing in Baltimore on Wednesday, January 30 will highlight one of the most unusual and important aspects of this particular hip implant MDL.²

Let's take a look at what's going on in the Smith & Nephew Hip Implant MDL this month. It may surprise you to see what is happening to very good products liability cases in this MDL because all the necessary parties have not been sued.

I. The Smith & Nephew MDL and Its Devices

The total hip replacement surgery (“THR”)³ cases in this hip implant MDL are unusual because they all involve cases where the implanting surgeon is *never* sued, but the surgeon *always* ignored the obvious fact that the implanted parts were not intended for use together. You cannot have a THR case in this MDL unless your surgeon ignored very obvious limitations on the intended use for the implanted products. You also cannot sue the careless surgeon in this MDL even though he or she failed to inform you that the implanted parts were not FDA-approved.

The idea of not suing a careless surgeon in an implantable device case has always presented a logical problem for me, and that is why the

¹ The term, “MDL” means, “Multi District Litigation.” Three types of Smith & Nephew cases in Federal Court have all been sent to one “MDL” Judge in Baltimore, Maryland.

² The comments below only apply to the total hip replacement (“THR”) cases and do not apply to any of the “Birmingham Hip Resurfacing (“BHR”) cases.

³ A THR is a hip replacement procedure where both the hip socket and the human femur are replaced with prosthetics, including a metal femoral stem, metal or ceramic femoral head, and metal or ceramic acetabular cup. Often, the THR also includes a liner—metal or polyethylene—between the femoral head and acetabular cup.

cases I file involving Smith & Nephew THR cases almost always include the surgeon, the Smith & Nephew sales reps, and Smith & Nephew.

There are three types of Smith & Nephew hip implant cases pending in front of Federal Judge Catherine C. Blake in Baltimore, Maryland. The largest group of cases involve a type of hip resurfacing device known as the “Birmingham Hip Resurfacing System” (BHR). There are also two types of THR devices that don’t have product names because they were never approved for sale in this country. As of yesterday’s weekly update to Judge Blake, there are currently 371 BHR cases pending against Smith & Nephew in the consolidated Federal Court proceedings known as MDL-2775. There are also 147 cases involving the no-name THR cases.

The BHR cases involve an FDA-Approved device system, and those cases present all the usual legal issues that face any Court trying to decide if there’s a possible products liability case despite FDA Approval. A manufacturer of an FDA-Approved device enjoys numerous protections from products liability cases, and the legal hurdles that must be overcome to make a valid case against a manufacturer of an approved device are well-known and familiar to medical device lawyers.

Judge Blake has already outlined the contours of the BHR cases in her Order granting in part and denying in part Smith & Nephew’s Motion to Dismiss issued on March 26, 2018. She dismissed many of the Plaintiffs’ claims due to Federal Preemption,⁴ and the manufacturing defect claims were dismissed for failure to state a claim,

⁴ “Federal Preemption” is a legal doctrine that exempts manufacturers of FDA approved products from most products liability lawsuits.

but most of the other claims survived the Motion to Dismiss and will proceed to the discovery phase, involving the production of documents and depositions of company witnesses. There is a tentative trial scheduled for March of 2020 involving some of the BHR cases. Again, the comments in this blog only apply to the THR cases targeted for dismissal at the upcoming January 30 hearing.

II. Why Are the No-Name THR Cases So Unique?

The THR cases, on the other hand, are a more recent addition to the MDL, and are just beginning to get the Judge's full attention. This month, the Court will hear arguments on Smith & Nephew's Motion to Dismiss the THR cases.⁵ Smith & Nephew is asking the Judge to dismiss *all* the THR cases based on Federal Preemption, and it is likely the Court will trim some of the Plaintiffs' claims just like she did with the BHR cases.

What strikes me about this round of Motions, Briefs, and arguments is the fact that *all* of the THR cases involve surgeries where the surgeon absolutely had to know that the metal parts he or she was implanting in the patient were not FDA-Approved or FDA-Cleared for a THR surgery at all. Unlike the other MDLs against other metal hip implant manufacturers, the Smith & Nephew MDL is unique because it involves cases that would not even exist if the surgeons had simply used the parts as they were intended. The two types of THR cases targeted for dismissal this month both involve combinations of metal parts that are clearly sold for different surgeries than the 147 Plaintiffs in MDL-2775 underwent. This fact cannot be ignored, but nearly 150

⁵ Smith & Nephew's Motion, like all legal documents discussed in this Blog, are available on my website at <https://www.kippetroff.com/smith-and-nephew-hip-implant-legal-information/>.

people nationwide have already filed THR cases in the MDL without suing the surgeon who was in the O.R. when the unapproved parts were implanted. In many cases, the Smith & Nephew sales rep was right there helping with the surgery.⁶ In my opinion, a products liability lawsuit filed against the surgeon, sales rep, and Smith & Nephew is much stronger and more difficult to defeat than one where the only party sued is the manufacturer.

PREDICTION. I predict a vigorous courtroom debate in Baltimore on January 30, but I think the Judge will probably trim some of the Plaintiffs' claims against Smith & Nephew. I also predict there will be fewer THR cases filed in Federal Court after the MDL Court rules on the Motion to Dismiss a few months from now. That's because more people will see the importance of suing the commission-based sales rep and careless surgeon who used unapproved parts without informing the patient.

Every person with a THR case in the MDL will eventually have to accept the fact that their surgeon ignored the obvious fact that the parts used were not approved or intended for the very surgery they are suing the company for. It will be part of Smith & Nephew's defense, and it will present a problem in all cases where the surgeon is not sued. This is especially true when the company told the surgeon the product was not FDA-approved, and many surgeons were directly told that—in writing.

The Smith & Nephew THR cases were part of a medical experiment that failed when many of their unapproved parts had to be

⁶ The sales rep in the cases I have filed were commission-based salesmen who knew the parts were not approved, but the sales rep looked the other way rather than reminding the surgeon that a THR surgery was an unintended use of the parts.

surgically revised and partly replaced a few years after implantation. Their products liability cases are now part of a legal experiment where the injured patients are trying to hold a company liable for parts that failed to work when they were used in ways that are inconsistent with the manufacturer's clearly stated intended use.⁷ Smith & Nephew has raised many defenses already, and refusing to sue the implanting surgeon and sales reps just makes it easier for them to continue defending these cases.

Kip A. Petroff

Dallas, Texas

(972) 294-7530

kpetroff@petroffassociates.com

www.KipPetroff.com

⁷ You can read more about my analysis of the risky approach of suing only one of the liable entities in a products liability case by reading the following articles in the "Hip Implant Publications" section of my website: "*Don't Shoot from the Hip: Navigating Medical Device Mass Torts in Multidistrict Litigation*" and "*What's So Special About Smith & Nephew Metal Hip Implant Cases?*"