The Mass Tort Litigation Landscape—A Critical Analysis MDL Conference + Don't Shoot from the Hip: Navigating Medical Device Mass Torts in Multidistrict Litigation

The Law Office of Kip Petroff announced today that Kip Petroff will be speaking at an upcoming "MDL Mass Torts" seminar in Napa, California. The seminar, entitled, "MDL Conference: The Mass Tort Litigation Landscape—A Critical Analysis" is held the day before the MDL Court hearing in Napa this week. Kip Petroff was quoted saying, "As I predicted in May when I spoke at the Chicago MDL [multidistrict litigation] conference, Smith & Nephew metal-on-metal total hip arthroplasties involving the R3 Metal Liner or Modular Femoral Head have been added to the Birmingham Hip Resurfacing ("BHR") MDL. This makes the BHR MDL a unique litigation because of the many challenges it presents to plaintiff's lawyers. I touch on these issues this week at the HarrisMartin's MDL Conference in Napa, California.

I am hopeful that the considerations I raise in this paper and in my presentation are going to be helpful in ensuring that the many victims of the Smith & Nephew metal-on-metal experiment can get justice. My paper for this seminar is on my website at

https://www.kippetroff.com/defective-products/the-mass-tort-litigation-landscape-a-critical-analysis-mdl-conference/ ."

Don't Shoot from the Hip: Navigating Medical Device Mass Torts in Multidistrict Litigation

By Kip Petroff and Caio Formenti[1]

This paper and my brief presentation at the HarrisMartin MDL Conference seminar on September 26, 2018 will discuss an unusual type of products liability personal injury mass tort because, unlike most of the cases discussed here, new hip implant cases and new hip implant MDLs just keep on coming. The physical materials and surgical procedures used in hip arthroplasties are constantly changing, and new shapes, styles, instruments, pegs, sheaths, finishes, adapters, guides, and accessories are still appearing on hospital shelves at a dizzying pace. But one thing remains unchanged: the "mass tort landscape" has included hip implant cases in one form or another for several years, and there's no end in sight.

This paper will provide a broad historical overview of recent hip litigation in courts throughout the country. I'll discuss what many of you already know, such as where the hip implant MDLs are and what products are involved. I'll also provide some practical suggestions based on having personally (1) tried a Zimmer hip case to a jury last year, (2) argued a federal court appeal involving Smith & Nephew hips, (3) watched an entire ten-week Team Lanier hip implant trial against J & J, (4) read hundreds of thousands of "confidential" hip implant documents, and (5) taken almost twenty Zimmer and Smith & Nephew hip implant depositions—so far. For those who are future-oriented but don't have a crystal ball, I'll even tell you how to predict where the next hip implant mass torts might be in the future.

I. FDA MoM Regulation

It is not surprising that there is, and will continue to be, hip implant litigation in this country. The hip replacement procedure has been successfully performed on millions of Americans since the earliest procedures were performed using metal-on-metal Charnley Hips in the early 1970s—before metal debris concerns led to a transition to metal-on-plastic in the mid-1970s.[2] The procedure is considered one of the most successful and life-changing procedures in America today, and its usage nationwide will continue to increase as we all live longer due to other medical advances. But the ceaseless competitive desire of medical device companies to rush to market with "the latest and greatest" products and procedures for this ever-growing

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[1] *Kip Petroff of Law Office of Kip Petroff in Dallas, TX is a plaintiff's lawyer who has focused his litigation on Smith & Nephew metal-on-metal hip implants. Caio Formenti is a recent law graduate of SMU Dedman School of Law in Dallas, TX awaiting results from the 2018 July Texas Bar Examination.*

[2] Witness Seminar held by the Wellcome Trust Centre for the History of Medicine at UCL London (ed. L.A. Reynolds and E.M. Tansey), *Early Development of Total Hip Replacement*, at xxvii (2006).

population ensures that mistakes will be made, and hip implant litigation will undoubtedly continue. This paper focuses on so-called "metal-on-metal" cases, because that's where the cases are today. But the discussion below and the "three-legged stool" analogy applies to almost any implantable medical device products liability case.

Metal-on-metal total hip arthroplasties have been around since before the Medical Device Amendments of 1976 to the Food Drug and Cosmetics Act. They were classified as "Class III" medical devices in 1987.[3] Unless there is a substantially equivalent predicate device (making clearance through 510(k) possible), a Class III device must be cleared through the slower, more expensive Premarket Approval ("PMA") process. Interest in the metal-on-metal total hip replacement procedure waned and then resurged in the late twentieth century, leading to a device classification panel meeting in mid-2001.[4] That's when the FDA Orthopaedic and Rehabilitation Devices Panel held a public meeting on the possible reclassification of metal-on-metal hip devices to Class II. At this meeting, the Orthopaedic Surgical Manufacturers Association (the representative for the medical device manufacturers) asserted that "sufficient information now exists to support the conclusion that the risks from metal-on-metal hips are no greater than those for metal-polyethylene hip prostheses."[5] However, the panel members had many concerns[6] and

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3 Glenn Steigman (speaking on behalf of the FDA Orthopaedic Devices Branch), FDA, Orthopaedic and Rehabilitation Devices Panel transcript. August 8, 2001. Available at http://www.fda.gov/ohrms/dockets/ac/01/transcripts/3780t1.rtf (accessible via Wayback Machine).

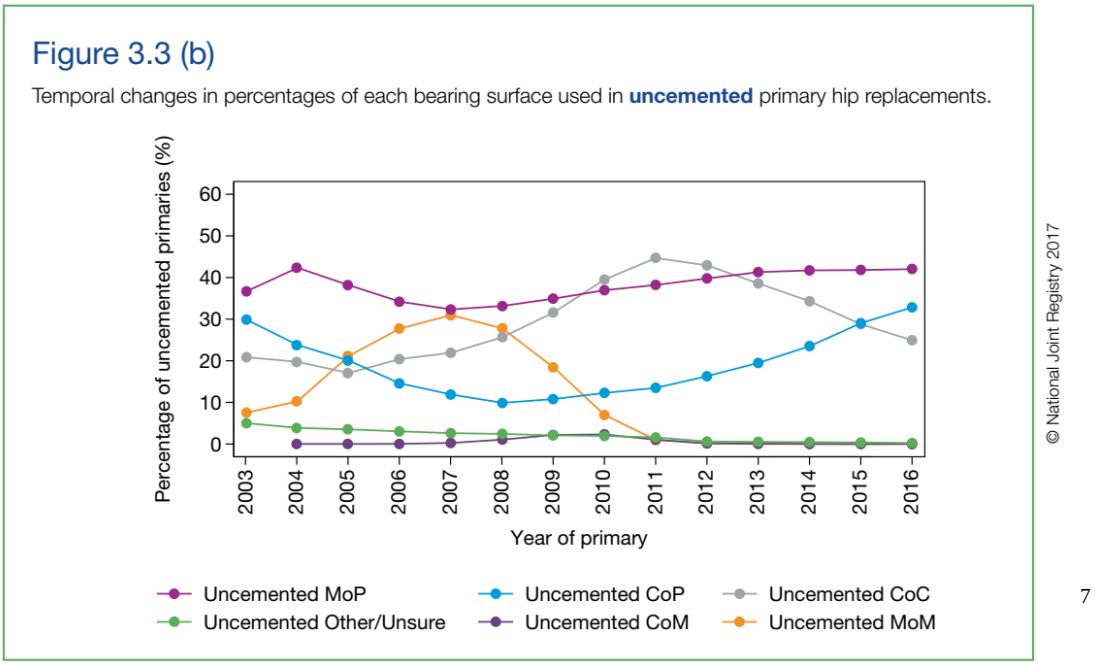
4 Effective Date of Requirement for Premarket Approval for Total Metal-on-Metal Semi-Constrained Hip Joint Systems, 81 Fed. Reg. 8,146-49, 8,147 (Feb. 18, 2016).

5 Tom Craig (speaking on behalf of the Orthopaedic Surgical Manufacturers Association), FDA, Orthopaedic and Rehabilitation Devices Panel transcript.

6 *See e.g., id.* for Stephen Li, Ph.D. lead panel member comments ("So the question for the design parameters is how were these actually arrived at, although it appears they just picked a range describing previous results," "I have projected four histories just to demonstrate that

ultimately voted 5-2 to keep metal-on-metal devices in Class III, which meant that any new metal-on-metal devices must first clear the 510(k) clearance (if a substantially equivalent, cleared predicate device already exists) or PMA process.

Undeterred by this regulatory setback, manufacturers continued promoting this new technology and metal-on-metal hip implant use skyrocketed in the 2000s (without any company actually proving they were safe), at one point comprising almost a third of the total hip market:



[7]

Pushed on by manufacturer promotions and manufacturer-sponsored papers praising the potential longevity of these devices, surgeons and device manufacturers developed extremely close relationships. In the absence of concrete ethical guidelines on surgeon-company relationships,

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although hip simulation is important and a necessary test to pass, it does not guarantee clinical success.").

[7] National Joint Registry for England, Wales, Northern Ireland and the Isle of Man, *14th Annual Report* at 45 (2017) ("NJR 2017").

four of the major manufacturers were the subject of criminal complaints in federal court in New Jersey, and they all entered into Deferred Prosecution Agreements with U.S. prosecutors in September 2007 for bribing surgeons.[8]

As use increased, so did reported failures. These reports prompted the FDA to take an active interest in evaluating the safety and efficacy of metal-on-metal hip implants. In early 2009, the FDA released a 515(i) "Call for Safety and Effectiveness Information," which five manufacturers responded to.[9] A year later, the FDA met with "professional societies to better understand current clinical practices"[10] and by early 2011 had created a website with patient and physician recommendations.[11] Section 522 postmarket surveillance orders—requiring manufacturers of metal-on-metal devices to provide information to the FDA about adverse events and metal ion levels in the metal-on-metal hips they invariably collected data on—were issued in May 2011.[12]

In mid-2012, the Orthopaedic and Rehabilitation Devices Panel held a two-day meeting to review metal-on-metal hips.[13] By this time, hundreds of 510(k) premarket notifications for metal-on-metal total hip systems had been filed, and 188 of them had been cleared by the FDA (although many of these 510(k)s were for the same "systems").[14] The Orthopaedic and

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8 These criminal proceedings were widely publicized, but a press release from Christopher J. Christie, U.S. Attorney, can be found at http://www.usdoj.gov/press/index.html. The September 27, 2007 press release is also on my website's Legal Page under "Criminal Proceedings." *See* www.KipPetroff.com.

9 FDA, Orthopaedic and Rehabilitation Devices Panel Transcript, at 26. June 27-28, 2012.

10 *Id.* at 27.

11 *Id.*

12 *Id.*

13 *See generally id.*

14 *Id.* at 21.

Rehabilitation Devices Panel's goals included reviewing data on metal-on-metal hip systems, describing "potential and real safety risks," and generating recommendations on how to "best communicate and mitigate risks."[15] The Panel ultimately noted that there were still "questions about the interpretation of imaging and ion testing results, questions about the performance of [metal-on-metal] devices relative to therapeutic alternatives, and . . . the need for some prospective longitudinal, randomized controlled studies to fill in some of these gaps."[16] By this time, the medical community had given up on metal-on-metal hip implants, and almost no one in America was still using them for total hip replacements. The metal-on-metal technology that received great fanfare in the mid-2000s was abandoned before the FDA finally got around to issuing new regulations less than a decade later.

This regulatory scrutiny over a then-abandoned technology culminated in a proposed FDA rule in 2013[17] requiring PMAs for all metal-on-metal hips and calling a meeting of a device classification panel for that same purpose. This rule was finalized and adopted in 2016 and required "a PMA . . . to be filed on or before May 18, 2016, for any of these preamendment class III devices that were in commercial distribution before May 28, 1976, or that has been found by FDA to be substantially equivalent to such a device."[18] This meant that every metal-on-metal system in America would need medical proof of safety and effectiveness after May 18, 2016. More importantly, should a device's PMA application be denied, the device is immediately considered "adulterated."[19] Adulterated devices cannot be placed into the stream of commerce,

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15 *Id.* at 28.
16 FDA, *24-Hour Summary: Orthopaedic and Rehabilitation Devices Panel, Day 2*, at 2. June 28, 2012.
17 81 Fed. Reg. at 8,147.
18 *Id*. at 8,148.
19 *Id.*

and doing so exposes both the distributor and seller to serious financial and criminal sanctions both at the state and federal level. These regulatory proceedings were the beginning of the end for metal-on-metal total hip replacements in America.

II. Hip Implant Litigation Today

Manufacturers stopped selling the devices and surgeons stopped prescribing them, but hundreds of thousands of people were implanted with this dubious combination of metal parts before the authorities could catch up with them. Given both metal-on-metal's high failure rate and the fact that over a million Americans received such an implant, metal-on-metal revisions are likely still being performed daily.[20] A firestorm of litigation began long before the FDA finally placed stringent regulations on metal-on-metal hip implants. This paper will briefly discuss that litigation. My main emphasis will be on **Smith & Nephew metal-on-metal hip implant litigation** because I can't cover everything and because the Smith & Nephew MDL is one of the most active and rapidly-growing hip implant MDLs in America today. It is also one of the more problematic of the MDLs for the reasons discussed below.

There are three "tracks" in the Smith & Nephew MDL: (1) the Birmingham Hip Resurfacing, a single device system entirely approved through PMA-approval; (2) the R3 track, which is a "traditional" total hip that includes the R3 Metal Liner (which was, confusingly, approved as a supplement to the Birmingham Hip Resurfacing PMA only for use in total hip *resurfacings* and *not* in "traditional" total hip arthroplasties), and; (3) the Modular Femoral Head hips, which involve the 510(k)-cleared Modular Femoral Head (cleared for use in hemiarthroplasties, where the femoral head articulates against the *natural* hip socket) and either

[20] Deborah Cohen, "Hip Implants: How Safe is Metal on Metal?" 344 BMJ 18, 18 (2012).

an R3 Acetabular Shell or BHR Acetabular Shell (Tracks 2 and 3 will be collectively referred to as "S&N THAs"). Smith & Nephew THAs are metal-on-metal and unquestionably "off-label," unapproved uses.

Because of this, S&N THA litigation is one of the most interesting and risky litigations because you usually cannot have a Smith & Nephew total hip case in the MDL unless your case involves these two critical factors:

1. Your client's surgeon used at least two metal parts that were very obviously not approved or intended for use together.
2. Your client's surgeon was ***not sued*** for using at least two metal parts that were very obviously not approved or intended for use together.

A plaintiff with a S&N THA case is ***always*** a plaintiff whose surgeon ignored explicit statements from the manufacturer about how and where to use the parts that were implanted. There are, of course, exceptions to these requirements, but they are very rare.

It looks like all the 100+ total hip replacement cases currently in the Smith & Nephew MDL meet the above two criteria. Some of the cases in the Smith & Nephew MDL even involve situations where the above two factors are met ***and*** the implanting surgeon was told ***in writing before the surgery*** that the metal parts used were not FDA-approved for use together. Some lawyers would agree that filing a case in an MDL under such circumstances is just too risky. The strategy of not suing a surgeon who carelessly disregarded obvious lack of FDA approval for a medical device is, in my opinion, too risky. Products liability cases are expensive and time-consuming to prove under the best of circumstances, but the risk of not suing negligent doctors and uncaring, dishonest sales representatives is simply too high for me.

III. <u>Proving Your Case</u>

It is not surprising that litigation has surrounded metal-on-metal total hip prosthetics in recent years. Whether it's Wright Medical, Biomet, DePuy, Smith & Nephew, or Stryker, the plaintiff's bar has eagerly tried to hold these manufacturers accountable. Many of these lawsuits have been consolidated into federal multi-district litigations. As of August 15, 2018, the following hip implant MDLs are still pending: Wright Medical Technology, Inc. Conserve Hip Implant (MDL-2329, 203 still-pending cases out of 641 total cases filed); Biomet M2a Magnum Hip Implant (MDL-2391, 402 out of 2,824); Stryker LFIT V40 Femoral Head (MDL-2768, 365 out of 373); Smith & Nephew Birmingham Hip Resurfacing (MDL-2528, 418 out of 437); Stryker Rejuvenated and ABG II Hip Implant (MDL-2441, 1,248 out of 3,498); Zimmer Durom Hip Cup (MDL-2158, 131 out of 732); DePuy Orthopaedics, Inc. ASR Hip Implant (MDL-2197, 1,715 out of 10,153), and; DePuy Orthopaedics, Inc. Pinnacle Hip Implant (MDL-2244, 9,644 out of 9,836).[21]

An individual lawyer's ability to fight for his or her client with products involved in the older MDLs is limited because discovery about the company's conduct is already completed in most of them. However, there are still opportunities to undertake discovery in cases outside the MDLs. Just last year, I tried a Zimmer case that was not in an MDL and the appeal I argued against Smith & Nephew in the Eleventh Circuit involved a case that had been dismissed before the Smith & Nephew MDL even existed. For the reasons discussed below, lawyers involved in these cases should consider alternatives to the MDLs when possible.

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[21] Judicial Panel on Multidistrict Litigation, "Pending MDLs by District as of August 15, 2018" (2018). Accessible at http://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDL_Dockets_By_District-August-15-2018.pdf.

The remainder of this paper will discuss some considerations that might help you decide whether to accept a hip implant case and where to file it if you end up getting that far. I will use the Smith & Nephew MDL as an example of the ways in which I am developing cases outside the MDL and why I am doing that in the Smith & Nephew cases. The analysis I am using for the Smith & Nephew hip implant cases applies to, and is useful in, any case involving injuries from implantable medical devices.

IV. The Non-MDL Option

I believe that too many cases are filed in MDLs without seriously considering alternative venues and litigation options. Filing in an MDL that involves devices that were granted FDA clearance for marketing and used that way is one thing, but do you really want to file your case in an MDL if the product was used in an off-label or unapproved way? What about the sales representative who mislead the surgeon and what about the surgeon who used the product in ways that were inconsistent with the manufacturer's written instructions for use and package inserts? You may eventually have to prove your allegations against the manufacturer you sued in an MDL, and failing to include the sales representatives and surgeons who disregarded instructions for use can be very troubling when it comes time for proof of defect.

Many lawyers sign up a client with a metal-on-metal claim and immediately join the MDL. Many lawyers won't even take a "one-off" case if there is no MDL involving that device. However, other lawyers will take a case if the product was recalled for safety reasons—even in the absence of an MDL. I tried such a case in federal court against Zimmer last year, but it involved an FDA-cleared device and there were no issues about the surgeon's unapproved, off-label use. On the other hand, I took depositions and obtained documents in several Smith & Nephew cases in state and federal court for almost two years before the MDL was formed. I have

seen documents that clearly show what the surgeons were told about Smith & Nephew products, and this information makes me very hesitant to file Smith & Nephew cases without including the surgeon and sales representative as defendants. A brief description of the Smith & Nephew BHR MDL[22] will explain why I believe in this approach.

The Smith & Nephew MDL, first established in April 2017, is one of the newest, quickest-moving, and smallest hip implant MDLs. Since then, Judge Catherine C. Blake has already denied (in part) the defendant's motion to dismiss in the hip resurfacing cases, and the parties are now proceeding towards discovery. In contrast, the larger DePuy Pinnacle MDL, filed in mid-2011, is still ongoing.[23] Part of why avoiding these MDLs is useful is because it allows you to explore who knew what, and when, on your own terms. More likely than not, if a device subject to an MDL was widely-used, it will follow similar timelines to these two litigations. When that happens, everything slows down: trial settings are later, discovery takes longer, and your motions might not even be "your" motions anymore.

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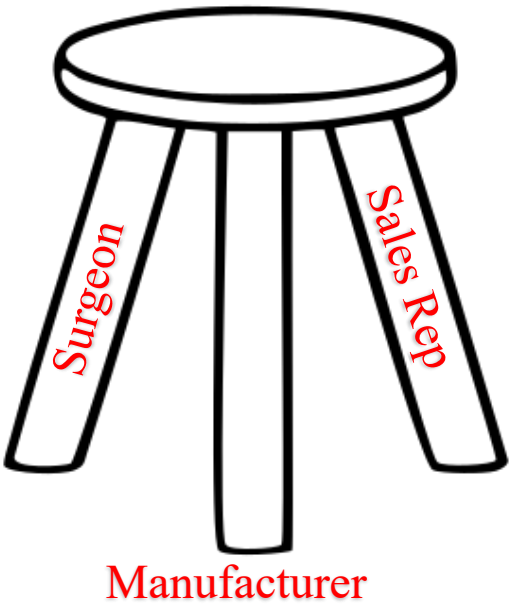
[22] *In re: Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Products Liability Litigation*, 1:17-cv-00943-CCB (MDL No. 2775) (D. Md. 2017).

[23] *See In re: DePuy Orthopaedics, Inc., Pinnacle Hip Implant Products Liability Litigation*, 3:11-md-02244-K (N.D. Tex. 2011).

The BHR MDL is unique because it illustrates the biggest challenge of MDLs: they forcibly create and exacerbate the "empty chair" problem. When litigating medical device products liability cases, the empty chair is a three-legged stool. One leg is the manufacturer, the second the sales representative, and the third is the doctor. If any one leg of the stool is absent, the empty chair becomes unstable. If two are gone, it will almost certainly topple.



The BHR MDL is a fascinating case study in the empty chair problem because, to be a total hip plaintiff in that MDL, the doctor had to have played a much larger role in the underlying claim than for most other devices. In fact, one cannot even have a total hip replacement case in the Smith & Nephew MDL case unless the surgeon used the components in ways that are drastically inconsistent with the written instructions both ***on*** and ***in*** the boxes containing them.

By definition, surgeons and local sales representatives are not part of the MDL, but their role in choosing and implanting these dangerous, U.K-sold but U.S.-uncleared devices makes them the *perfect* scapegoat. Holding the manufacturer liable is a challenge when the manufacturer can prove that the doctor and sales representative had to both look at, and then ignore, instructions like the ones on the packaging below.

These instructions on the boxes themselves make it clear that the modular heads were for "HEMI-ARTHROPLASTY ONLY" and that the metal liner was intended for resurfacing only. The package inserts inside the boxes say essentially the same thing. Your plaintiff never would have received a total hip replacement using these metal parts if the surgeon had simply followed these basic instructions. *It is impossible to have a metal-on-metal hip case if the surgery performed is a hemiarthroplasty*. These instructions are not in the fine print hidden somewhere inside the boxes. They are in ALL CAPITAL LETTERS on the first line of the box, and they make the surgeon and sales rep an easy scapegoat for the manufacturer when the surgeon is an "empty chair" because the company can disclaim their ability to prevent this: "We can't tell surgeons what to read or how to do their jobs!"

However, by bringing the surgeon in to the case, you both fill the empty chair and create a new avenue through which you can solidify the other two legs of the stool: the manufacturer and the sales representative. Plaintiffs in other MDLs have avoided dismissal because of what sales representatives told the patient's doctor, but that will usually not work in Smith & Nephew

cases because the sales representatives are "independent" and have a contract with Smith & Nephew that makes off-label promotion explicitly improper.

For example, in the DePuy Pinnacle Hip litigation, the bellwether plaintiffs defeated a motion for summary judgment on failure to warn, misrepresentation, and omission claims, in part because of what the doctors were told (or not told): one doctor "obtained information from—and relied on—the scientific and medical information the sales representative provided to him"; doctors were paid to "market and present DePuy products through what appeared to be neutral, even peer-reviewed sources"; the doctor might have read the literature that accompanied the products.[24] There was specific testimony in the DePuy case that at least one of the surgeons "would have wanted to know that [the device]'s predecessor was taken off the market in Europe," and that "[had he] been informed of such problems he would not have used the [device] or would have at least discussed these warnings with his patient."[25]

These statements are from an MDL that did not involve surgeons, but the products were FDA-cleared and widely promoted. Not so with the S&N THAs. In fact, the FDA specifically ***rejected*** multiple Smith & Nephew 510(k) submissions seeking to promote these parts for total hip replacements.[26] The only written statements that accompanied the parts used in S&N THA cases noted that the products were not intended for use in such procedures.

Without the surgeon in an off-label use case, only two legs remain. Although coexistent, the manufacturer and the sales representative cannot be combined, and the sales representative is

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[24] *In re: DePuy Orthopaedics, Inc. Pinnacle Hip Implant Products Liability Litigation*, No. 3:11-MD-2244-K, 2016 WL 6268090, at *5 (N.D. Tex. Jan. 5, 2016).

[25] *Id.*

[26] Chicago "Bet the Company" MDL Seminar, "What's So Special About Smith & Nephew Metal Hip Implant Cases?" May 23, 2018. Available on my website at https://www.kippetroff.com/pdf/smith-and-nephew/reg/chicago-mdl-paper.pdf.

often overlooked (and excluded) in litigation like this. With the BHR MDL, the sales representatives were typically "independent contractors" with shell companies and lengthy sales representative agreements. On paper, they were beyond the control of the manufacturer. In reality, they regularly conferred with their superiors and company executives, strategizing what products they plan to talk up to which surgeons. The surgeons and sales representatives are integral to proving liability in the context of the BHR MDL, and leaving them out of the case is an unnecessary gamble, in my opinion.

Without a doubt, the most important leg of our three-legged stool analogy is still usually the manufacturer themselves.[27] Their significance doesn't need explanation, but an understated benefit they bring is that they can help show you exactly what third parties knew about their devices. What the FDA knew about a device, gleaned from the publicly-available 510(k) or PMA records, can go a long way towards constructing both a timeline and liability list for a device. Although "Fraud on the FDA" is not actionable under federal law, the regulatory history of a device is a powerful tool in highlighting differences in how the manufacturer portrayed the intended uses, indications for use, and safety of the device to the FDA and to doctors, patients, and the public. The bad news? There is extensive evidence that Smith & Nephew explicitly informed many surgeons in writing and informed all their sales representatives that none of the Smith & Nephew metal parts were approved or intended for use in a metal-on-metal hip construct. That evidence is too strong for me to take a case without doing everything I can to

[27] I've also talked about some creative ways to investigate a device and its manufacturer before even filing suit, using things like pre-suit depositions. *See* Kip Petroff and Caio Formenti, "Preempting Preemption: Device Cases After *Shuker*—Part 1," LAW360 (Apr. 12, 2018).

include the surgeons and sales representatives who totally ignored the clear evidence that confronted them before they used these parts together in surgery.

The source of most of your discovery will be the doctor and the manufacturer, who is totally content to let these cases slowly develop in an MDL without surgeons or sales representatives. However, if you can stay in state court, you have access to *much, much* more discovery. Although the DePuy Pinnacle plaintiffs eventually acquired their surgeon information through depositions, the motion for summary judgment was ruled on in early 2016—nearly five years after the litigation had commenced. Again, the Pinnacle was FDA-cleared, so the empty chair is not nearly as obvious in those cases. But if the doctor is included in the initial state-court lawsuit, then this information could come much sooner. I have obtained hundreds of thousands of pages of Smith & Nephew documents in my state court cases, whereas the year-old MDL is just now beginning formal discovery. State court or non-MDL federal court litigation in these cases involves a lot more work in a shorter period of time, often without the support of other good attorneys like you'd have in an MDL, but you get to the good information a lot quicker.

V. Foreign Registries and the "Human Laboratory"

Mass torts aren't going away anytime soon, and one reason for that is the "human laboratory." This term was used by a surgeon I deposed in one of my metal-on-metal cases to describe how we learn about the safety of many implantable devices. Regrettably, laboratory, mechanical, and animal testing are not enough to give us a long-term insight into how safe or unsafe medical devices are. Often, the only way to truly discover the safety of a device is to track it in humans. What this means is that, as new medical technology is developed, we'll only find out that the "latest and greatest" medical device is actually the next mass tort after people have gotten seriously injured—just like we saw with metal-on-metal hips.

To better identify problematic implants earlier, a handful of nations have developed "joint registries"[28] which track, in excruciating detail, the survival rates of different joint replacements. Registries can be a valuable tool in taking on both the surgeon, who might have trusted a sales representative a little too much, and the device manufacturer, who might deny that its device was bad at all. You need to learn about these registries because they will always be used against you if they don't help prove your case.

If you know what you're looking at and how to use them, the annual reports that registries publish are great sources of information for both seeing what is showing high rates of early failure and looking at older annual reports to see what the surgeon or manufacturer knew or should have known when your client received an implant.

Newer reports are not as useful for showing what a doctor did—or did not—know when the device was used. For that, you need the data that was available when the device was implanted. We know that metal-on-metal hip implantations peaked in 2009. If we pull up a publicly-available foreign registry—for example, the 2009 Australian Orthopaedic Association National Joint Replacement Registry ("AOANJRR") Annual Report—and look for the

[28] Including the UK, Australia, and New Zealand. An American joint registry is in its infancy but will be an invaluable tool as its database grows.

component combination that the total hip plaintiffs from the BHR MDL received, we find these two tables:

Table HT31: Revision Rates of Primary Conventional Total Hip Replacement with Cementless Fixation

Femoral Component	Acetabular Component	N Revised	N Total	Obs. Years	Revisions per 100 Obs. Yrs	Exact 95% CI
Synergy	BHR	10	625	1320	0.8	(0.36, 1.39)
Synergy	R3	5	565	245	2.0	(0.66, 4.75)
Synergy	Reflection	167	6773	25781	0.6	(0.55, 0.75)
Taperloc	M2a	16	438	1449	1.1	(0.63, 1.79)
Taperloc	Mallory-Head	20	790	3127	0.6	(0.39, 0.99)
Taperloc	Recap	9	410	684	1.3	(0.60, 2.50)
VerSys	Trilogy	110	3659	14646	0.8	(0.62, 0.91)
Other (679)		632	16765	54448	1.2	(1.07, 1.25)

Table HT32: Yearly Cumulative Percent Revision of Primary Conventional Total Hip Replacement with Cementless Fixation

Femoral Component	Acetabular Component	1 Yr	3 Yrs	5 Yrs	7 Yrs	8 Yrs
Synergy	BHR	1.3 (0.6, 2.6)	1.8 (1.0, 3.3)			
Synergy	R3					
Synergy	Reflection	1.4 (1.2, 1.8)	2.3 (2.0, 2.7)	2.7 (2.3, 3.2)	3.5 (2.9, 4.4)	3.8 (3.0, 4.9)
Taperloc	M2a	1.7 (0.8, 3.5)	3.5 (2.0, 6.0)	5.0 (3.0, 8.2)		
Taperloc	Mallory-Head	1.7 (1.0, 2.9)	2.5 (1.6, 3.9)	2.8 (1.8, 4.5)	3.2 (2.0, 5.1)	
Taperloc	Recap	2.2 (1.1, 4.4)	3.0 (1.5, 6.1)			
VerSys	Trilogy	2.1 (1.7, 2.6)	2.8 (2.3, 3.4)	3.3 (2.7, 4.0)	3.7 (3.0, 4.6)	3.7 (3.0, 4.6)
Other (679)		2.1 (1.9, 2.4)	3.8 (3.5, 4.2)	5.0 (4.6, 5.5)	6.1 (5.6, 6.7)	6.8 (6.0, 7.7)

[29]

There's a good chance that the S&N THA plaintiffs received either an R3 Acetabular Shell with an R3 Metal Liner or a Modular Femoral Head paired with a BHR cup, and a strong likelihood that they received it sometime in or around 2009. Looking at this data, the first two entries might be what we're looking for. Place yourself in a reasonable surgeon's shoes: with what they had, would it be reasonable to use these devices? The revision rate in year one for the Synergy-BHR is alarmingly high, and the R3 doesn't have enough data to develop a revision rate. The revision rate for both is very high because the sample sizes are so small: the possible

[29] Australian Orthopaedic Association National Joint Replacement Registry, *Annual Report 2009* at 76, 77 (2009).

revision rate for the Synergy-BHR could be anywhere from .36% to 1.39% per year, and the Synergy-R3 ranges from 0.66% to 4.75% per year! What that means is that these devices could just as easily be one of the best hip implants or one of the worst.

Just like most of its metal-on-metal competitors, we now know that these devices fall squarely into the latter group. Any surgeon who bothered to look at these publicly available registries would know that this early data was not reassuring at all. That same surgeon would have to know that their use together is off-label. Is a surgeon being careful enough if he or she still used that combination of parts in or around 2009? Let's see.

The American Academy of Orthopaedic Surgeons *Guide to the Ethical Practice of Orthopaedic Surgery* defines off-label use as "any use that is not included in the cleared 'indications for use.'"[30] Although ethical, off-label use requires that the surgeon "be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain awareness of the product's use and effects."[31] Surgeons should also

> be aware of company sales and marketing tactics that may undermine the free and credible exchange of scientific information on new products . . . including inappropriate product comparisons between FDA approved and cleared products, misleading claims regarding product safety, efficacy, . . . and the omission of adverse clinical data.[32]

Imagine confronting a surgeon with this standard and the registry data above. Should a surgeon be comfortable implanting a device that could pose such a great risk in patient, when safer alternatives were readily available? Would the patient consent if all this was explained to him or her? The answer is almost certainly "no." As their insurer and attorney look over their

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30 American Academy of Orthopaedic Surgeons, *Guide to the Ethical Practice of Orthopaedic Surgery*, "Position Statement: Off-Label Use of Medical Products," at 125 (2013).

31 *Id.*

32 *Id.* at 127.

shoulder, the probable response (and the truth) is: "the manufacturer/sales representative told me different!" And suddenly, two of the three legs get much sturdier.

The above analysis is a quick example of the value of these published registries, but the wealth of information in each year means that a resourceful and creative attorney can enhance their advocacy through the careful use of these documents.

VI. Mirror, Mirror, On the Wall: What's the Worst Device of Them All?

Nobody I know has a crystal ball that can identify the next mass tort. However, registries can help you identify some devices that are problematic and might warrant some closer investigation. How would that work?

This first table is taken directly from the U.K. National Joint Registry Annual Report:

Stem/cup brand	Bearing surface	n	Median (IQR) age at primary	Percentage (%) males	Cumulative percentage probability of revision (95% CI) at: 1 year	3 years	5 years	7 years	10 years	13 years
Uncemented										
Accolade / Trident	MoP	11,698	71 (65-76)	41%	0.99 (0.82-1.19)	2.01 (1.77-2.30)	2.76 (2.46-3.11)	3.50 (3.10-3.94)	*5.76 (4.21-7.86)*	
	CoP	5,647	62 (56-68)	45%	0.72 (0.53-0.98)	1.52 (1.20-1.91)	1.95 (1.55-2.44)	2.20 (1.69-2.85)	*3.33 (2.28-4.85)*	
	CoC	7,335	62 (55-68)	46%	0.97 (0.77-1.22)	2.03 (1.73-2.38)	2.83 (2.46-3.25)	3.31 (2.89-3.78)	4.38 (3.73-5.14)	*5.48 (3.62-8.24)*
Corail / Pinnacle	MoP	48,744	71 (65-77)	41%	0.82 (0.74-0.91)	1.37 (1.26-1.48)	1.70 (1.57-1.84)	2.17 (1.99-2.36)	3.05 (2.71-3.43)	
	MoM	11,938	67 (60-74)	47%	0.87 (0.72-1.05)	2.44 (2.17-2.73)	5.17 (4.77-5.59)	8.78 (8.26-9.32)	13.98 (13.18-14.83)	
	CoP	21,533	64 (57-70)	45%	0.72 (0.61-0.85)	1.21 (1.05-1.39)	1.74 (1.50-2.00)	2.16 (1.83-2.55)	*2.78 (2.25-3.44)*	
	CoC	37,846	60 (53-66)	48%	0.83 (0.74-0.93)	1.79 (1.65-1.93)	2.40 (2.24-2.58)	2.93 (2.73-3.15)	3.90 (3.48-4.37)	
	CoM	1,784	63 (57-70)	41%	0.45 (0.23-0.90)	2.67 (2.02-3.54)	4.39 (3.52-5.47)	5.76 (4.72-7.03)		
Furlong HAC / Stem CSF	MoP	7,873	73 (67-78)	39%	1.29 (1.06-1.56)	2.07 (1.77-2.42)	2.43 (2.10-2.81)	3.06 (2.67-3.50)	4.41 (3.86-5.04)	*5.04 (4.31-5.89)*
	CoP	7,097	67 (61-73)	41%	0.71 (0.54-0.94)	1.26 (1.02-1.55)	1.65 (1.37-1.98)	2.07 (1.74-2.45)	2.65 (2.25-3.12)	3.62 (2.98-4.39)
	CoC	1,646	59 (53-66)	44%	1.28 (0.84-1.95)	2.08 (1.49-2.90)	2.59 (1.92-3.49)	3.19 (2.43-4.18)	4.36 (3.42-5.55)	*5.97 (4.47-7.94)*
Furlong HAC Stem / Furlong HAC CSF Plus	MoP	5,054	74 (70-79)	39%	1.55 (1.24-1.93)	2.24 (1.85-2.72)	2.91 (2.42-3.50)	3.34 (2.76-4.05)		
	CoP	2,496	67 (62-71)	47%	1.00 (0.67-1.49)	1.84 (1.35-2.51)	2.02 (1.48-2.75)	2.46 (1.77-3.40)		
	CoC	13,042	63 (56-69)	46%	0.93 (0.78-1.12)	1.59 (1.38-1.83)	1.84 (1.60-2.11)	2.15 (1.87-2.48)		
Taperloc Cementless Stem Exceed ABT	MoP	6,489	72 (66-77)	41%	1.23 (0.99-1.54)	1.75 (1.44-2.12)	2.07 (1.71-2.52)	2.52 (2.01-3.15)		
	CoP	3,795	65 (58-70)	45%	0.91 (0.65-1.27)	1.07 (0.78-1.48)	1.43 (1.01-2.02)	*2.14 (1.40-3.25)*		
	CoC	10,227	61 (54-67)	46%	1.08 (0.90-1.31)	1.52 (1.29-1.79)	1.83 (1.56-2.14)	2.02 (1.71-2.39)	*2.02 (1.71-2.39)*	

[33]

[33] NJR 2017 at 71.

If we were going to try and pick out the "next metal-on-metal," most of the total hip revision rates in this chart would not raise any red flags. None of these entries—save for the one metal-on-metal device, discussed below—are alarming and most of the devices have at least 7 years of data with revision rates that are well within the NICE standards (typically, a cumulative one percent per each year). These charts show that there aren't really any other hip implants that are failing at rates as high as metal-on-metal, so as of now, this data alone probably does not allow for prediction of a viable mass-tort here. You might need to follow the FDA recall announcements to find another way to identify the next types of cases.

Notably, one entry is still being litigated today. The MoM—Metal on Metal—data for the Corail/Pinnacle implant shows revision rates that far exceed NICE standards five years on, ballooning to almost fourteen percent by year ten. That means that, for this data set, fourteen percent of these hips have been revised within a decade of implantation. Not exactly "safe or effective," a pattern that has held true for *most* if not *all* metal-on-metal hip implants:

> Metal-on-metal stemmed and resurfacing implants continue to fail at higher than expected rates and their use is now extremely rare. The best performing brands of resurfacing have failure rates greater than 8% at ten years. It is striking to note the high rates of revision for adverse soft tissue reaction to particulate debris in patients who have received metal-on-metal bearings. Analysis of stemmed metal-on-metal bearings by head size shows that 28mm heads have the best survivorship, but this is still poor compared to alternatives.[34]

[34] *Id.* at 83.

That device likely showed similar issues in earlier annual reports, and someone reviewing the data might have been able to pick up on that. This can be illustrated by looking at a different section of the report:

Table 3.30 Kaplan-Meier estimates of the cumulative percentage probability of first revision (95% CI) of a primary unicompartmental knee replacement by main type of implant brand at the indicated number of years after primary operation[1].

Brand[2]	Number of knee joints	Median (IQR) age at primary	Percentage (%) males	Cumulative percentage probability of first revision (95% CI) if time elapsed since primary operation is:					
				1 year	3 years	5 years	7 years	10 years	13 years
All unicompartmental knee replacements	97,503	63 (56-70)	49%	1.09 (1.03-1.16)	4.34 (4.20-4.49)	6.64 (6.46-6.83)	8.78 (8.55-9.01)	12.25 (11.92-12.60)	16.99 (16.18-17.85)
Unicondylar									
AMC/Uniglide	2,848	64 (57-72)	50%	2.12 (1.65-2.73)	5.80 (4.97-6.76)	7.36 (6.41-8.44)	9.58 (8.42-10.88)	11.65 (10.20-13.28)	*14.63 (11.84-18.02)*
†MG Uni	2,381	62 (56-70)	54%	0.93 (0.61-1.40)	3.94 (3.22-4.80)	5.94 (5.05-6.97)	7.56 (6.55-8.71)	10.09 (8.84-11.50)	*12.22 (10.16-14.67)*
Oxford Partial Knee	55,447	64 (57-71)	52%	1.14 (1.05-1.24)	4.06 (3.88-4.24)	6.10 (5.87-6.33)	8.06 (7.78-8.34)	11.53 (11.11-11.96)	15.73 (14.76-16.77)
*Physica ZUK	10,246	63 (55-69)	55%	0.37 (0.26-0.51)	2.48 (2.13-2.88)	3.95 (3.45-4.52)	5.29 (4.60-6.07)	*6.66 (5.54-8.01)*	
†Preservation	1,515	62 (56-69)	55%	2.32 (1.67-3.21)	7.73 (6.49-9.20)	11.34 (9.83-13.06)	14.24 (12.55-16.13)	17.09 (15.19-19.19)	*26.23 (22.38-30.59)*
Sigma HP	7,587	62 (55-69)	57%	0.80 (0.61-1.04)	3.57 (3.10-4.10)	5.01 (4.38-5.74)	*5.68 (4.88-6.61)*		
Patellofemoral									
Avon	5,277	59 (50-68)	22%	0.77 (0.56-1.05)	4.24 (3.69-4.87)	7.47 (6.71-8.32)	10.08 (9.14-11.10)	14.43 (13.12-15.87)	*20.22 (17.47-23.33)*
FPV	1,587	59 (51-68)	23%	0.90 (0.53-1.51)	6.74 (5.56-8.15)	9.61 (8.15-11.31)	12.47 (10.65-14.57)		
Journey PFJ Oxinium	1,572	58 (50-67)	23%	2.08 (1.47-2.94)	7.39 (6.11-8.91)	12.63 (10.87-14.64)	17.84 (15.55-20.43)	*22.37 (19.35-25.77)*	
Sigma HP	1,164	58 (51-66)	22%	2.46 (1.69-3.57)	8.74 (7.09-10.75)	12.85 (10.64-15.48)	*16.90 (13.60-20.90)*		
Zimmer PFJ	1,774	57 (50-65)	22%	0.64 (0.35-1.19)	4.41 (3.39-5.75)	6.98 (5.43-8.95)	*9.54 (7.09-12.78)*		

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These are the results for some knee replacements. Knees probably have a higher NICE benchmark than hips, given how high the revision rates are for all of them; regardless, you can immediately pick out some implants that are still far and away worse. In particular, the Preservation, the Journey PFJ Oxinium, and (if the projection holds) the patellofemoral Sigma HP merit a closer look. The legend, which explains that the Preservation has been "discontinued/withdrawn/not implanted in last three years,"[36] confirms this. This is a quick example, but it shows you how to put certain devices on your radar. It doesn't guarantee that

35 *Id.* at 137.
36 *Id.*

these products are going to be the "next big thing," but they might help you narrow the field next time you are surveying the mass tort landscape.

VII. Conclusion

An MDL might be great at helping stop the already-overwhelmed court system from becoming even more weighed down by mass torts. However, its usefulness comes at a cost, especially for plaintiff's lawyers and their clients. Between the "empty chair" problem and the longer amount of time it usually takes for justice to be served in an MDL, any advantage is useful. Seminars like this might allow us to share ideas about these cases and learn that some people are independently litigating the very cases that are in the MDLs. Hopefully, by pointing out how to avoid the "empty chair" and using joint implant registries to your advantage, I have provided some new arrows for your quiver. Good luck!

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