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**CAUSE NO. DC-18-08923**

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| **TRACY FLEMING and NORMA EGEA** | § | **IN THE DISTRICT COURT OF** |
| **Plaintiffs,** | § | |
| **vs.** | § | **DALLAS COUNTY, TEXAS** |
| **BRIAN CHILDRESS; NEYLU, INC.; RICHARD D. SCHUBERT, M.D., and SMITH & NEPHEW, INC.** | § | |
| **Defendants.** | § | **192nd JUDICIAL DISTRICT** |

**PLAINTIFFS' RESPONSE TO SMITH & NEPHEW'S MOTION FOR PROTECTIVE ORDER RE: 5TH REQUESTS FOR PRODUCTION**

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW, Plaintiffs TRACY FLEMING and NORMA EGEA, and file this Response to Smith & Nephew's Motion for Protective Order, and respectfully show as follows:

## I. INTRODUCTION/SUMMARY OF KEY FACTS

There is no fishing expedition here. Plaintiffs are diligently trying to learn some details about what really happened between the three Defendants before Tracy Fleming's surgery. The facts known so far reveal a longstanding business relationship between the three Defendants and a set of mysterious facts that would cause concern for any patient. Those facts will be briefly explained at the outset so the Court can see how Smith & Nephew is intentionally evading its discovery obligations. Plaintiffs simply want to make this trial against these three business partners a fair one, and that requires, as Defendant says, "*a fair contest with the basic issues and facts disclosed to the fullest practicable extent*." See Motion, page 4. This brief Response will demonstrate that the "*basic facts and issues*" in this case have not been "*disclosed to the fullest practicable extent.*" The Motion for Protection never once quotes an actual Request for Production, choosing instead to paraphrase them and mislead the Court, and the Motion should be denied.

A court cannot determine if the facts of a case have been "disclosed to the fullest practicable extent" without knowing what the "basic facts and issues" really are. Smith & Nephew's Motion mischaracterizes the Plaintiff's allegations so the company can say that "full disclosure" is occurring, but a review of the actual allegations and the documents produced so far will show otherwise. Smith & Nephew still does not understand or simply will not face the facts and allegations in this case—No wonder they refuse to cooperate in discovery.

Smith & Nephew made the hip implant parts in question, and Brian Childress and his company Neylu, Inc. convinced Dr. Schubert to use them despite the lack of FDA approval. Dr. Schubert implanted the parts in Mr. Fleming on September 28, 2009 without knowing the FDA had rejected this exact combination of parts several times before then. Dr. Schubert has unequivocally testified that he would not have implanted these parts in Mr. Fleming if he knew just some of the regulatory facts that Smith & Nephew argues are legally irrelevant here.

Smith & Nephew's attempt to pigeonhole Plaintiff's lawsuit into a narrow medical malpractice claim against Dr. Schubert is inaccurate. For example, Smith & Nephew's Motion characterizes this case as one involving ***only*** "*what Dr. Schubert knew or should have known*" (page 4) and the company even argues that, "***all*** *that is relevant here is whether Dr. Schubert was properly made aware of the uses and potential risks of using the device components*." (page 6, emphasis added). Why Dr. Schubert was ignorant of certain critical facts is certainly an important question in this case, but this case involves much more than just Dr. Schubert's admitted lack of information.

Plaintiff's Petition—and the evidence—shows that Smith & Nephew and the Sales Rep Defendants had a concerted plan to "convert" orthopedic surgeons from using an FDA-approved hip implant to their unapproved metal-on-metal products. The company did not want to do this –

they tried repeatedly to obtain FDA approval so they could openly sell these devices. The FDA rejected every one of the company's attempts.

A. The "Conversion" of Dr. Schubert.

Dr. Schubert was using a competitor's product in 2005 when Smith & Nephew offered him an all-expense paid trip to Europe to meet with Smith & Nephew executives, play golf, and learn about a new type of implant called the Birmingham Hip Resurfacing System (the "BHR"). While in Europe, he also learned about the exact combination of Smith & Nephew parts that was implanted in Tracy Fleming. Smith & Nephew received FDA approval for the BHR hip system shortly after Dr. Schubert returned from Europe, but the company never received approval for the combination of parts that was implanted in Mr. Fleming. Dr. Schubert was a member of the "BHR Team" after that trip, *see* Hutchens(SN)-0014156, but the "BHR Team" was involved in using FDA-*approved* devices. Smith & Nephew wanted Dr. Schubert to also use their *unapproved* devices. The process of trying to "convert" him to using their unapproved metal devices was just beginning. The trip to Europe was the start of their attempted "conversion" (their word) of Dr. Schubert to using their unapproved products.

In early 2006, the three Defendants started an informal business enterprise that involved all three of them engaging in promotional activities that helped them all make money off of a combination of implants that the FDA had repeatedly ordered Smith & Nephew not to sell in this country. Dr. Schubert helped train sales reps, including "role playing" to make it even more effective. He spoke highly of Smith & Nephew products from the podium at professional meetings where he was an invited speaker. He used slides from Smith & Nephew when he made those presentations. He provided quotes and allowed his name to be used in a Baylor Hospital press release just days after the BHR received FDA approval. He also accepted money from Smith &

Nephew for allowing foreign surgeons to watch him perform surgeries using Smith & Nephew's unapproved parts.

Dr. Schubert's "conversion" to unapproved metal-on-metal took years and was not fully accomplished until mid-2009 when Childress' boss gave Brian Childress a District-wide shout out. The email praising "Team Childress" for a "great job" at his "***ongoing/recent conversion***" of Dr. Schubert emphasized, "*new patients, new cases, new location, new $$$*." See Hutchens(SN)-0015676. The company considered him a "BHR Champion" of theirs by the time of Mr. Fleming's surgery. See Hutchens(SN)-0041661. An email showing nationwide usage of this unapproved combination of parts lists Schubert in the top ten nationwide and Brian Childress was in the top five of all sales reps in the entire country. *See* SN_Kemp_0015612 (Ozyp Exhibit 345). The conversion was working!

Backdated "honorarium agreements," large fees, huge commissions, hundreds of emails, postdated "invitations", and probably financial rebates or "kickbacks" were exchanged between the Defendants. All three of them had *all expenses paid* meetings, dinners, and trips together before Mr. Fleming's surgery. The company even paid Dr. Schubert to help make their sales reps better salesmen, thereby helping the company make even more money. As part of one of Dr. Schubert's backdated consulting payment requests, he agreed in writing that he would never "***promote or recommend the use of any S & N product in any manner inconsistent with the product's FDA approved labeling,***" but he did exactly that with Mr. Fleming. *See* Exhibit 18 to Dr. Schubert's deposition, Hutchens(SN)-0014812. A tactic Dr. Schubert employed around this time was to use Smith & Nephew slides at speeches where he encouraged the audience to use Smith & Nephew unapproved products or, better yet, send him their patients so he and Smith & Nephew would both benefit financially.

There are still substantial undisclosed details about these dubious arrangements after all this time and all this discovery. Smith & Nephew was aware of the potential for litigation ever since the company decided to sell these devices against FDA Orders, and the company is not claiming that detailed information about these activities is unavailable. They are just saying they should not have to search for it.

The contours of Dr. Schubert's two-plus year conversion are still hazy because of Smith & Nephew's refusal to cooperate in discovery and because Schubert and Childress have deleted their old emails. However, a renewed interest in these transactions occurred when a "**surgeon target**" spreadsheet was recently produced in a Beaumont case. That spreadsheet has a "***next steps to conversion***" column with information about Childress and Schubert that was previously unavailable. This has opened the door to a whole new insight into how sophisticated and carefully watched this "conversion" process was.

It is becoming clearer every day that this two-year conversion scheme is important because it involved convincing Dr. Schubert to transition from using FDA-approved parts to using FDA-rejected, unapproved parts. It was a complicated, multi-party scheme and it will probably require circumstantial evidence to prove, but it is also a clearly relevant topic. Information about tracking of the "*next steps to conversion*" with an actual "*surgeon target*" spreadsheet was only provided recently when it was produced in Beaumont.

B. <u>The hospital contracts.</u>

A good example of Smith & Nephew's unacceptable discovery tactics involves its contract with North Central Surgical Center, the hospital where Mr. Fleming's surgery occurred. The relevance of that contract has not been seriously challenged, because Dr. Schubert was part owner of North Central Surgical Center when he operated on Mr. Fleming there. The problem is that the contract with Schubert's hospital still has not been produced, but no one suggests there was not a

written contract. Smith & Nephew has produced a contract with Baylor Hospital[1] in Dallas that was signed three days before Mr. Fleming's surgery. There are attachments omitted, but another contract with Baylor in Dallas was produced in Beaumont, and it reveals that the company falsely told Baylor in Dallas that "the Products" all "*conform to all applicable federal, state and local laws, regulations and ordinances, including Federal Drug Administration rules, regulations, guidelines and required approvals*. . . ." See SN_Kemp_ SN_Kemp_0356764 at 0356772. Smith & Nephew's Motion admits that is not true on page 3. That contract clearly shows that Smith & Nephew simply lied to Baylor about its lack of FDA approval for the exact same parts used in Mr. Fleming. It is likely that the Baylor contract applied to this particular surgery because of Baylor's part ownership in the hospital, but Smith & Nephew has not produced any emails that would explain that. They all admit a contract probably exists and they don't deny that Smith & Nephew pays huge amounts of money to its consultants and pays large rebates to high volume hospitals who use their unapproved parts, but they still have not produced any information about these arrangements.

The Baylor contract itself says there were nine weeks of negotiations about it before it was signed right before Mr. Fleming's surgery, but not one document related to those negotiations has been produced. An email after the contract was signed specifically mentions Dr. Schubert's use of the exact combination of products he implanted in Tracy Fleming. The email suggests the Baylor contract probably applies to Dr. Schubert's hospital. Brian Childress was the local "POD Manager for BHCS" for this contract and probably for the one with Schubert's hospital, but he has not produced anything related to his activities in forming either of those contracts. *See* SN_Kemp_0356751. The Baylor contract shows that Smith & Nephew gave deep discounts for its

[1] Baylor is a part owner of North Central Surgical Center along with Dr. Schubert.

unapproved, difficult to sell parts and the company even offered rebates to the hospital if enough of the unapproved parts were used. Similar rebates or kickbacks involving Dr. Schubert's hospital almost certainly exist, and any form of rebate to Schubert's hospital for using FDA-rejected combinations of parts in uninformed patients would create significant legal and ethical issues for all three Defendants.

C. Dr. Schubert, Brian Childress, and a DOJ Federal Monitor go to Las Vegas.

There were also Smith & Nephew meetings with Dr. Schubert and Dallas sales reps in several different states and at least two countries, and all three Defendants have still not produced any specific information about a three-day meeting they had together in Las Vegas at Smith & Nephew's expense before Mr. Fleming's surgery. Dr. Schubert was not a fully committed Smith & Nephew customer before the Vegas trip, but Childress was given credit for "converting" him (their word) after that trip.

In 2008, S&N was deep into the conversion process and Dr. Schubert was hoping for two sources of direct revenue from Smith & Nephew at that time, but both involved him "consulting" with them. There was a budgetary commitment to pay Schubert at least twenty thousand dollars a year for unspecified "consulting" in 2008, but he was never paid any of it after questions were raised. He was also already owed $2,500 for a day he allegedly spent with some sales reps in Dallas before he went to Vegas with Brian Childress. It took him almost two years to get paid the $2,500, and that only occurred after he backdated a payment request form and "accepted" an invitation to speak that was sent to him two full months *after* the speech allegedly took place. He apparently never got the $20,000. The only reason Plaintiffs know about the $20,000 side deal is because an agenda and spreadsheet of attendees containing Schubert and Childress's names was recently produced in another case pending in Beaumont, Texas. Years of depositions and hundreds of requests in Dallas cases never uncovered information about that Las Vegas trip.

Despite numerous requests, Smith & Nephew has just recently produced an eight-page public announcement about the meeting. That announcement shows that Dr. Schubert probably spent an entire day learning about Smith & Nephew's unapproved metal on metal hip implants, probably including the unapproved combination involved here, but Smith & Nephew has not produced anything else about that three-day meeting. Dr. Schubert and Brian Childress have not produced anything at all about the Vegas trip.

The back-dated payment arrangements with Dr. Schubert occurred during a time when Smith & Nephew was under indictment in the United States District Court for the Southern District of New York for criminally over-paying orthopedic hip implant surgeons throughout this country. A "Federal Monitor" was appointed to oversee the company's payment arrangements with its surgeons, including Dr. Schubert. The Federal Monitor attended the meeting in Las Vegas and was concerned about what he learned there. His concern extended beyond just "the events in May", as he called them. The Federal Monitor questioned the mysterious Smith & Nephew practice of paying surgeons large sums of money without having written agreements or proof of what was done to earn the money. That 2007 charge was not allowed or was delayed after further review. The circumstances surrounding the Federal Monitor's concern about untracked, backdated payments to Dr. Schubert raise questions about any other "honorarium" payments related to Dr. Schubert. In the same vein, while Smith & Nephew has tried to explain the vanishing $20,000 "budget" item for Dr. Schubert, nothing has been produced about that agreement or why it was disallowed. None of the three Defendants have produced even one document or email about the dubious $20,000 arrangement or the backdated payments from 2007.

D. <u>After years of litigation, Plaintiffs have only scratched the surface of this conspiracy because of Smith & Nephew's discovery tactics.</u>

Smith & Nephew does not deserve protection from these discovery requests. It deserves

sanctions. Plaintiffs want to make this trial against these three business partners[2] a fair one, which requires, as Defendant says, "*a fair contest with the basic issues and facts disclosed to the fullest practicable extent*," see Motion, page 4, but that is impossible when Smith & Nephew continues to withhold important evidence and obstruct discovery. Smith & Nephew's delay and obstruction tactics so far include (a) threatening an improper removal to federal court if it is made a party, (b) producing documents only after years of delay and repeated requests, (c) using boilerplate objections to good discovery requests, (d) producing as many as five or six duplicate copies of most emails and documents (and then patting itself on the back for its two-million pages of production), and (e) allowing its sales representatives to delete possibly relevant information. Smith & Nephew has taken every opportunity possible to delay discovery, avoid producing relevant documents, and prohibit the just resolution of this case on the merits. Granting any part of the Motion for Protective Order would just encourage more discovery obstruction.

Despite what Smith & Nephew says in its Motion, there are still other very significant documents that have not been produced. Plaintiffs had no way of knowing that the Las Vegas "training" ever happened until a group of documents was recently produced in an unrelated case involving a different surgeon in Jefferson County. No witness had ever mentioned it even though Childress and Schubert were deposed, and a corporate rep was deposed about "sales rep training." Dozens of Requests for Production have asked about surgeon and sales rep training.[3]

At a minimum, Plaintiffs are aware of the following relevant topics, but Smith & Nephew has produced almost no communications to or from Dr Richard Schubert or Brian Childress regarding these events:

1. In 2007, Smith & Nephew paid for flights for Dr. Schubert that were

[2] Dr. Schubert's hospital administrator calls Smith & Nephew its "partner" in writing.
[3] Plaintiffs even served Smith & Nephew with a subpoena before the company was a party and a hearing was held on a Motion to Quash.

reported to the DOJ-appointed Federal Monitor and were disclosed on an online Deferred Prosecution Agreement list.

2. In 2007, Dr. Schubert's knee consulting payments were delayed.
3. In 2008, the company "budgeted" $20,000 for Dr. Schubert, but the work was never done, and he was never paid.
4. The previously mentioned 2008 Henderson/Las Vegas Trip.
5. Dr. Schubert attended a dinner with high-level Smith & Nephew executives in 2011.
6. A 2011 Consulting Deal where Smith & Nephew paid Dr. Schubert to teach a Chilean surgeon how to use metal products in unapproved ways.
7. Dr. Schubert went to Memphis to discuss hip implants after Smith & Nephew started recalling its metal parts from the market. He took a list with him of what he called "smoldering problems" that included Mr. Fleming's name.

Smith & Nephew has produced a total of three communications related to these seven events and not a single one is an email from Dr. Schubert.[4] Smith & Nephew has produced emails from Dr. Schubert concerning other events, but nothing from him about these seven critical events. These communications are the best evidence Plaintiffs have for Dr. Schubert's conduct because he kept no emails, and Smith & Nephew and the Sales Rep Defendants have still refused to produce dozens of emails that probably exist. Based on previous document productions involving other events, it is extremely unlikely that Dr. Schubert's trip to Las Vegas, at Smith & Nephew's expense, was scheduled and completed without a *single email* passing between the three Defendants. This isn't "fishing" for *hoped for* communications—coordinating these events had to include at least one email and probably included dozens to and from Dr. Schubert or his wife (who has emailed on Dr. Schubert's behalf to set up other trips). However, Plaintiffs do not know of any related communications that have been produced. All three Defendants are refusing to produce relevant documents, but this Response will be limited to Smith & Nephew's discovery tactics.

[4] Plaintiffs do not expect to receive anything about these events from Dr. Schubert. He has simply allowed his emails to vanish despite his lawyer being requested in writing on October 13, 2015 to "please ensure the doctor keeps all his files and computer communication relative to Smith & Nephew (hips or anything else). . . ."

## II. RESPONSE TO MOTION FOR PROTECTIVE ORDER

The following analysis of Plaintiffs' Fifth Requests for Production and Smith & Nephew's Motion (and mischaracterizations) will hopefully be easier to follow with the above background in mind. A case like this requires extensive discovery because the Defendants have a long-standing business relationship and they are unwilling to produce relevant documents that would shed light on the business details. This Response will analyze the Motion and will respond to each of the complaints about specific discovery requests in the Fifth Request for Production.

Dr. Schubert has admitted he was ignorant of decision-changing facts about the FDA status of the parts he implanted in Mr. Fleming. He has unequivocally testified that he simply would not use the parts if he knew they were not FDA approved. Smith & Nephew tries to downplay the significance of lack of FDA approval, but it is a critical fact at this stage of the case for several reasons. The company knew that selling their unapproved parts "poses a potential liability risk to the customer" Hutchens(SN)-0093328. Some hospitals would not even discuss Smith & Nephew's unapproved hip implants, and numerous emails show that "not having an FDA approved" hip implant was "crippling sales efforts". See Hutchens(SN)-0050190. Another reason Dr. Schubert would not use the unapproved parts is because the company stipulated in writing in its price list that its warranties were "void" if a surgeon did what he did to Mr. Fleming. The price list stated:

> Customer agrees that Smith & Nephew products are approved by the United States Food and Drug Administration ("FDA") only for certain indications. Smith & Nephew's products should only be used for FDA-approved indications. Smith & Nephew will not be responsible for damages or losses of any kind arising out of uses that are other than, or contrary to, those indications (commonly called "off-label" uses). Smith & Nephew's warranties, representations, and obligations pursuant to these Terms and Conditions are void as to any such off-label uses.

PurePlay_Kemp-0002140 at 0002141. No reasonable surgeon or patient would use these unapproved parts if the above facts were known. Smith & Nephew and Childress knew that no one would knowingly use unapproved parts that voided the customer's warranty, and the Plaintiffs

want to learn how this could have happened. They keep running into a stone wall when they attempt to find out.

A. Arguments and Authorities.

Limitations on the scope of discovery are the exception, not the rule. *See* TEX. R. CIV. P. 192.3. Restrictions should be applied "only to prevent unwarranted delay and expense." TEX. R. CIV. P. 192.7, cmt. 7 (1999) ("A court abuses its discretion in unreasonably restricting a party's access to information through discovery."). A defining principle is that "[p]arties are 'entitled to full, fair discovery' and to have their cases decided on the merits." *Ford Motor Co. v. Castillo*, 279 S.W.3d 656, 663 (Tex. 2009) (internal quotations and citations omitted). The Texas Supreme Court has "vigorously sought to ensure that lawsuits are 'decided by what the facts reveal, not by what facts are concealed,'" noting that "[d]iscovery is the linchpin of the search for truth." *Id.* This Court should "balance[] the parties' competing interests" in determining whether a protective order is appropriate by looking at whether "the burden or expense of the proposed discovery outweighs its likely benefit, taking into account the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the litigation, and the importance of the proposed discovery in resolving the issues." *Eurecat US, Inc. v. Marklund*, 527 S.W.3d 367, 376 (Tex. App.—Houston [14th Dist.] 2007, no pet.); TEX. R. CIV. P. 192.4(b). Granting Smith & Nephew's Motion for Protective Order would unfairly eliminate items from discovery that have still not been fully disclosed.

"To the extent that a discovery request is burdensome because of the responding party's own conscious, discretionary decisions, that burdensomeness is not properly laid at the feet of the requesting party, and cannot be said to be 'undue.'" *ISK Biotech Corp. v. Lindsay*, 933 S.W.2d 565, 569 (Tex. App.—Houston [1st Dist.] 1996, orig. proceeding). Such is the case here. Smith &

Nephew's noncompliance with the Texas Rules of Civil Procedure in previous litigation is largely why Plaintiff is forced to ask additional Requests that Smith & Nephew rightfully should have "closed the door on" long ago. The vast majority of the document production to date has not been compelled. Smith & Nephew has agreed to the discovery, mostly by Rule 11 agreements negotiated right before scheduled hearings. They should not be allowed to weaponize those good-faith agreements now without trying to confer on the individual discovery Requests mentioned below.[5] The affidavit that Smith & Nephew filed as "Exhibit BB" in a supplemental motion on April 17, 2020 exemplifies the challenges raised by addressing this Motion as it stands. The Affidavit asserts a final, conclusory dollar amount for 18,000 hours of work without explaining whether any individual Requests were disproportionately burdensome. Smith & Nephew goes to great lengths to explain that it would need to create a "list of *every orthopedic surgeon* who practiced in the United States for the years 2006 through 2015 – in untold thousands – and a search of each of those names across all S&N documents and emails." Motion, at page 9. How many work hours in the Affidavit are dedicated to that unnecessary task? There is no way to tell. Smith & Nephew seeks protection due to undue burden and asks this Court to throw out all the discovery Requests without actually quoting a single one. The Affidavit should have delineated how much it would cost to search for each group of Requests, because that would enable this Court to make an informed judgment about the burden of the narrow, appropriately-tailored responses that Plaintiff served. However, an "omnibus" affidavit is inaccurate and, in essence, misrepresents the burden of each individual Request.

Smith & Nephew has decided to mischaracterize the Requests for Production it wants

[5] Plaintiffs have not discussed with opposing counsel the substance of any of the discovery Requests in this Motion because Smith & Nephew has not attempted to confer on the specific discovery requests before filing its Motion. The extent of the "conferral" was an email asking if Plaintiffs' counsel was opposed to a Motion for Protection.

protection from by grouping them into broad categories and then omitting crucial details about each group and specific Request. In each instance, they are asking for "protection" from Requests that don't actually exist. That is why they never actually quote a specific Request. *They* have made these Requests as broad as possible and then hid the actual wording of the Requests in mountains of pages of exhibits amid an unpaginated Motion. However, a clearheaded analysis of the real Requests shows that they are narrow and very appropriately tailored.

*i. S&N mischaracterizes the substance, relevance, and scope of RFPs 1, 4, 7, 10, 13, 16, 19, 22, 25 (**S&N Section A, Page 7**), RFPs 55–199, 265–272 (**S&N Section D, Page 11**), RFPs 277–326 (**S&N Section E, Page 13**), RFPs 327, 337, 338, 340–343 (**S&N Section F, Page 14**), 344–380 (**S&N Section G, Page 14**), RFPs 477–488 (**S&N Section I, Page 16**), RFPs 489–525 (**S&N Section J, Page 16**), and RFPs 537–544 (**S&N Section K, Page 17**.*

Smith & Nephew has spent almost nine pages characterizing two or three hundred Requests with a sweeping brush, omitting key information in the process. All of the Requests from section A are, in fact, limited by time period, specific device, and type of arthroplasty that is discussed. Had Smith & Nephew attempted to confer about their Motion, Plaintiffs would have noted that Smith & Nephew recently produced a spreadsheet in another case that lists *every single modular femoral head* ever sold in the U.S., including surgeon and sales representative information. The list includes hundreds of surgeons and it seems to include every surgeon who ever implanted this combination of parts. This is what Plaintiffs wanted. Had Smith & Nephew bothered to ask, Plaintiffs would have gladly considered a search using only those names sufficient. Instead, Smith & Nephew filed an Affidavit that includes searching for "untold thousands[6]" of surgeons' names even though a relevant and comprehensive spreadsheet was produced in another case after the Fifth Request for Production was served in this case. The Affidavit is useless, because it includes extensive time needed to search for untold thousands of surgeons' names even though a sufficient

[6] See Motion, page 9.

spreadsheet was produced in another case. A quick overview of the other Requests in Section A will show that all of them are valid attempts at obtaining relevant information.

Requests 55–84 are not overly broad. The Requests are limited to specific sales representatives related to this case and a specific handful of high-level marketing employees, and are further limited to very specific dates and types of training. Requests 85–146 are limited to specific training of surgeons (for 103–126 and 137–146, Dr. Schubert specifically) that should never happen in the U.S. because it would be training them on an unapproved use of Smith & Nephew's metal-on-metal products. The answer to Requests 85–146 should be a simple "None" unless Smith & Nephew admits it engaged in illegal promotion of unapproved uses of their products. Requests 147–153 (for 152, Dr. Schubert specifically) seek documents that explain what surgeons in the U.S. were supposed to be trained on relating to relevant devices to this case. Requests 154–168 are narrow Requests relating to a document previously produced in other litigation that describes surgeon training, BOGK-000171, and request 169 seeks information about a Canadian surgeon that Smith & Nephew paid to train U.S. surgeons. Requests 170–174 seek communications that were intended to be used with surgeons (including specifically Dr. Schubert at Requests 172–174) and Requests 175–198 seek communications with the FDA about the FDA-mandated training for devices Plaintiff received or related devices. Request 199 seeks documents related to any "VIP" visits Dr. Schubert took to Memphis to meet with Smith & Nephew. Plaintiffs have agendas and schedules for other "VIP" visits with other surgeons and Smith & Nephew can easily determine if that kind of special treatment was provided to Dr. Schubert. The "VIP" forms from other visits show that the company spent hours explaining their products, and such information would be very helpful in this case. Request 265 also seeks documents that relate directly to Dr. Schubert's training.

Requests 266–272 seek training materials for sales representatives limited to discrete topics and specific devices that are relevant to this case. Requests 277–326 involve healthcare contracts that Plaintiff discussed above, where very little has been produced despite weeks of negotiations. Unlike a fishing expedition, the Requests provide specific bates references and limit the documents sought to specific dates, individuals, devices, and topics relating to a previously produced contract. Requests 327, 337, 338, 340–343 are all narrowly-tailored and directly related to documents that have been previously produced. They usually even include bates references to a specific document that has been produced. Despite Smith & Nephew's assertion that the "R3 Metal Liner" is unrelated, Dr. Schubert regularly used the R3 Metal Liner and there is circumstantial evidence that the R3 Metal Liner was what finally "converted" Dr. Schubert to Smith & Nephew metal-on-metal in 2009. There are also training videos about the R3 Metal Liner that make detailed statements that apply to informing surgeons about *any* unapproved Smith & Nephew hip implant device.

Requests 344–380 seek proof of any training event that Brian Childress, Chris Baker, Scott Scheel, James Thompson, or Dr. Schubert attended. All of these individuals have been deposed and they all interacted with one another before Mr. Fleming's surgery and with Smith & Nephew. Sales representatives and surgeons needed to sign in on a sign-in sheet when they attended training sessions. Plaintiffs are entitled to those slips for these individuals. Answering these Requests would have revealed information about the Las Vegas trip that was disclosed in Beaumont, but Smith & Nephew objected to all of the Requests in this case.

The "celebrity endorsements" Requests (Requests 477–488) are relevant because they involve off-label MOM procedures—one performed by Dr. Schubert—that were proudly announced to U.S. sales representatives nationwide as early as 2007. Smith & Nephew was breaking the law when it sent information about that "celebrity" surgery involving unapproved

metal parts.

Requests 489–525 are not an attempt to "audit" the Federal Monitor. Those Requests are an attempt to get unredacted copies of documents that Plaintiffs have some knowledge about, since many of these records were produced in redacted form by the Department of Justice pursuant to a Freedom of Information Request several years ago. Based on what Plaintiffs know already, Dr. Schubert and Brian Childress attended a training event held in Henderson, Nevada in 2008 where violations of the Deferred Prosecution Agreement occurred while some surgeons and rep attendees were partying in nearby Las Vegas. After this event, Smith & Nephew stopped hosting similar events in Henderson or anywhere near Las Vegas. The Requests that plaintiffs served here are narrow and related to the Federal Monitor whose supervision affected every aspect of Brian Childress's work and regulated Smith & Nephew's relationship with Dr. Schubert in the two or three years before Plaintiff's September 2009 surgery. These records are relevant and discoverable and should have been produced in this case many months ago. They are very easily located in permanent files related to the Federal Monitor.

Finally, the last group of requests (RFPs 537–544) seek the production of any videos of S&N Metal-on-Metal revisions. These videos are some of the best evidence available to aid Plaintiffs in explaining to a jury what metal-on-metal failure is, what it looks like, and what happens when MOM implants need to be revised. The requests are narrowly tailored, relevant, and discoverable. It would take almost no effort to locate these videos if they exist.

*ii. Communications with Dr. Schubert, RFPs 2, 3, 5, 6, 8–9, 11–12, 14–15,1 17–18, 20–21, 23–24, 26–27 (**S&N Section B, Page 9**), Schubert's wife, RFPs 525–536 (**S&N Section K, Page 17**), and payments related to Dr. Schubert, RFPs 381–476 (**S&N Section H, Page 15**), are narrowly tailored and discoverable.*

The Requests listed in **Section B** of the Motion seek information about communications with Dr. Schubert. They are all relevant—even the ones about emails to and from Dr. Schubert's

wife. Even the allegedly "totally irrelevant, overbroad, and disproportionate" requests about communications with Dr. Schubert's wife that have "no limitation on them whatsoever," Motion at page 17, are limited by time, sender, and recipient. The main reason Plaintiffs seek emails to and from Dr. Schubert's wife is because her personal email is listed as the contact email for Dr. Schubert in a spreadsheet that Smith & Nephew produced (*See* Smith&Nephew_Fleming-0007836, listing "L. Schubert" as the contact email). Smith & Nephew has also previously produced business emails that were sent to her, *see* Hutchens(SN)-0014167, including one where she was busily coordinating Dr. Schubert's all-expense paid trip to Europe for his initial meeting and golf outing with Smith & Nephew at their world headquarters. *See* Kirby-000271. A Dallas sales rep accompanied him on that trip. In addition, one of Childress' helper reps was previously Linda Schubert's tennis instructor. Plaintiffs are not interested in her tennis lessons, but emails that Smith & Nephew has to or from her are relevant no matter what the subject is. This kind of relationship could explain why Dr. Schubert is so strongly biased in favor of his co-Defendants and against his former patient.

RFPs 381–476 focus on a Smith &Nephew training program that Dr. Schubert allegedly hosted for sales reps in 2007. Everything about this event is suspicious. Schubert was not paid for that event until 2009. Payment to Dr. Schubert was delayed while the Federal Monitor audited his extensive dealings with Smith & Nephew. That was around the time that Dr. Schubert's scheduled $20,000 payment was cancelled – probably at the insistence of the Federal Monitor. Plaintiffs seek evidence that can prove whether this training actually happened, since the small cluster of documents about this event have obviously been backdated during the 18 months while Dr. Schubert sought payment.[7] It would be easy to produce the requested information if the training

[7] Even the invitation to speak at the meeting is bogus – the "invitation" to conduct the training for pay is inexplicably dated two months *after* the event had already occurred!

actually happened and if Dr. Schubert really was there.[8]

*iii. Communications with experts are discoverable, RFPs 28–54 (**S&N Section C, Page 10**).*

The last group of discovery consists of documents related to the experts designated in this case. All three Defendants have designated multiple experts but have produced very little documentation about what has been sent to or received from those experts. Two of these experts are practicing orthopedic surgeons with extensive Smith & Nephew business relationships. These experts are relying on their decades of successful experience as orthopedic surgeons who implanted Smith & Nephew devices. Documents relating to all of these experts are relevant and discoverable. Otherwise, Plaintiffs have no real way of knowing what they have been told about the Device Components, metal-on-metal, or what their bias for or against Smith & Nephew is, even if they are deposed. Evidence from depositions already taken in this case reveals that the information requested about these experts is readily and easily available. It would be unfair for Smith & Nephew to conceal this relevant and easily obtainable information about their decades-long relationship with the Defendants' retained testifying experts.

## CONCLUSION AND PRAYER

The Court has heard the expression, "you are judged by the company you keep." Dr. Schubert and Brian Childress chose to do business with a foreign company that was under Federal indictment at the time for bribing and overpaying orthopedic surgeons. The hospital that Dr. Schubert partly owned chose to make a contract with Smith & Nephew and accept discounts and probably rebates for the same products Dr. Schubert implanted in Tracy Fleming. Dr. Schubert's individual use of these unapproved devices was a measuring stick for the success of their joint

[8] The suspicion about this alleged training event is heightened because Dr. Schubert emphatically denied it ever happened until he was confronted at his deposition with his backdated contract, postdated invitation, and eighteen months of payment efforts involving it.

venture and probably was the basis for the hoped-for financial rebates. Smith & Nephew tracked it all and has easy access to this information.

The three Defendants were involved in all these financial arrangements and Plaintiffs are interested in learning more about all of this. Smith & Nephew has not even scratched the surface on producing documents related to the aforementioned events and transactions. Smith & Nephew's vague Motion lumps together and misquotes Requests, and never really asks for anything specific to be ordered. An appropriate Order in light of the foregoing has been filed with this Motion.

Respectfully Submitted,

**LAW OFFICE OF KIP PETROFF**

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**ATTORNEYS FOR PLAINTIFFS**

**Certificate of Service**

The undersigned certifies that on **April 20, 2020**, a true and correct copy of the foregoing was served on the Defendants as follows:

Defendants **Smith & Nephew, Inc., Brian Childress, and Neylu, Inc.,** by email: Mr. Brian Johnson, Ms. Leila D'Aquin, Mr. David O'Quinn, Mr. Douglas Moore, Ms. Sarah Segrest-Jay, and Ms. Kealy C. Sehic. Defendant **Richard D. Schubert, M.D.** by email: Mr. David Criss and Ms. Alexandra Sallade.

/s/
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