

CAUSE NO. DC-18-08923

**TRACY FLEMING and  
NORMA EGEA**

**Plaintiffs,**

**vs.**

**BRIAN CHILDRESS; NEYLU, INC.;  
RICHARD D. SCHUBERT, M.D., and;  
SMITH & NEPHEW, INC.**

**Defendants.**

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**IN THE DISTRICT COURT OF**

**DALLAS COUNTY, TEXAS**

**192<sup>nd</sup> JUDICIAL DISTRICT**

**PLAINTIFFS' AMENDED MOTION TO COMPEL DOCUMENTS FROM SMITH &  
NEPHEW, INC.**

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW, Plaintiffs TRACY FLEMING and NORMA EGEA, and file this Amended Motion to Compel Documents from Smith & Nephew, and would show as follows:

**I. INTRODUCTION**

Plaintiffs previously filed a Motion to Compel on some of this discovery on March 6, 2020. After filing that Motion, and after negotiations with Smith & Nephew, Plaintiffs have narrowed the disputed issues even further, and this Amended Motion replaces the original Motion.

The Court is familiar with this case. It is a products liability case involving three Defendants who worked together to sell and implant a certain type of metal hip implant that the FDA repeatedly ordered Smith & Nephew not to sell in America. The company tried at least four times to obtain FDA approval before Mr. Fleming's surgery, but the FDA refused each time for safety reasons. The company and Brian Childress sold the parts and Dr. Schubert implanted them in Mr. Fleming anyway.

Dr. Schubert claims he did not know the FDA had repeatedly rejected this combination of parts. He swears he would not have used the parts if he knew they were not FDA approved. Dr.

Schubert's decision to use orthopedic devices for unapproved uses is called, "off label" and he claims he would never knowingly do that. Plaintiffs are trying to find out how these unapproved parts got implanted in Tracy Fleming without him or his surgeon knowing these critical facts. All of the discovery requests discussed below are directly or indirectly related to Dr. Schubert's off label use of the four parts he implanted in Mr. Fleming. Plaintiffs keep hitting a stone wall with every discovery request they send.

## II. ARGUMENTS AND AUTHORITIES

Texas law is clear that discovery is broadly permitted and encouraged in cases like this one. In Texas, "Parties may seek discovery regarding any matter that is not privileged and is relevant to the subject matter of the pending action." TEX. R. CIV. P. 192.3(a). "Only in narrow circumstances is it appropriate to obstruct the search for truth by denying discovery. Very limited exceptions to the strongly preferred policy of openness are recognized in our state procedural rules and statutes." *Ford Motor Co. v. Castillo*, 279 S.W.3d 656, 663 (Tex. 2009) (internal quotations and citations omitted). The burden in discovery disputes is on the *producing party*. *State v. Lowry*, 802 S.W.2d, 669, 671 (Tex. 1991) (orig. proceeding). ("The burden is on the party seeking to avoid discovery to plead the basis for exemption or immunity and to produce evidence supporting that claim."); *In re Rogers*, 200 S.W.3d 318, 321–22 (Tex. App.—Dallas 2006, orig. proceeding) ("In the trial court, the party resisting discovery bears the burden of proving the request lies outside the guidelines described by the rules and the [Texas Supreme Court].").

## III. REQUESTS AT ISSUE

The documents discussed in this Section are important to Plaintiffs' case, and they are all discoverable. Plaintiffs will attempt to concisely show why the Court should order Smith & Nephew to provide appropriate answers and produce responsive documents.

**A. Plaintiff Tracy Fleming’s First RFPs to Smith & Nephew**

Plaintiff moves to compel proper responses and production of documents in response to the following requests:

*i. Schubert/Baylor-Related (Requests 118, 141, 253–255).*

This first group of discovery requests all relate to Dr. Schubert or one of the hospitals he was affiliated with before Tracy Fleming’s surgery. Not only that, but they all relate directly to specific documents that were previously produced in litigation with Smith & Nephew. Plaintiffs and Defendants know these documents exist and the underlying document is even identified after each Request, but the company simply refuses to look for them. These Requests all seek information about the following very specific topics which Smith & Nephew can easily produce.

Request 118 uses Smith & Nephew’s documents and asks them to produce other relevant documents. Smith & Nephew has information “on file” about its surgeons, including Dr. Schubert. Plaintiffs are entitled to that information.

**118. Any information that “Memphis [has] on file” about Dr. Schubert as referenced in KIRBY-000238.**

*RESPONSE: Smith & Nephew objects to this Request as not relevant to the parties’ claims and defenses, and not reasonably calculated to lead to the discovery of admissible evidence. See Tex. R. Civ. P. 192.3.*

Smith & Nephew’s objections are improper and should be overruled. Request # 118 seeks relevant information in a very narrowly worded Request that mentions the “Memphis file.”

Smith & Nephew and Baylor Health Systems—which runs or has an ownership interest in both surgical facilities that Dr. Schubert operated at—agreed that they would “*specifically measure*” Dr. Schubert’s use of the BHR Acetabular Cup that was implanted in Tracy Fleming three days after the Baylor agreement was signed. Justifiably, Plaintiffs sought to learn more about this arrangement, including the communications that preceded the final agreement discussed in an

email marked Hutchens(SN)-0015647. The email mentions Dr. Schubert's use of one specific product – the “BHR Cup”, which is the exact product implanted in Mr. Fleming. Smith & Nephew agreed to “specifically measure” Dr. Schubert's “BHR Cup usage pre July 2009 vs. post July 2009” and “units implanted.” Witnesses have been asked about this statement and no one can explain this agreement.

**141. Produce all follow-up emails or other written communications relating to the Baylor business meeting described in Hutchens(SN)-0015647.**

*RESPONSE: Smith & Nephew objects to this Request as overly broad and unduly burdensome insofar as it uses the phrases “all follow-up emails” or “other written communications.” Such a request would constitute an improper fishing expedition prohibited under Texas Law. See In re National Lloyds Insurance Company, 449 S.W.3d 486, 489 (Tex., 2014). Further, this Request is disproportionate to the needs of the litigation as the burden and expense of the proposed discovery outweighs any benefit. See Tex. R. Civ. P. 192.4(b). Smith & Nephew further objects to this Request as vague and ambiguous insofar as it uses the phrase “Baylor business meeting.” Finally, Smith & Nephew objects to the scope of this Request insofar as it seeks documents that are not relevant to the parties' claims and defenses, and not reasonably calculated to lead to the discovery of admissible evidence. See Tex. R. Civ. P. 192.3*

**253. All written communications relating to the “BHR cup usage pre July 2009 vs. post July 2009” as referenced in Hutchens(SN)-0015647.**

*RESPONSE: Smith & Nephew is conducting a diligent search for “BHR cup usage pre July 2009 vs. post July 2009” and will produce responsive documents identified, to the extent any such documents exist, following the entry of an order controlling the production of personal data related to European data subjects.*

**254. Any report discussing “BHR cup usage pre July 2009 vs. post July 2009” as referenced in Hutchens(SN)-0015647.**

*RESPONSE: Smith & Nephew objects to this Request as duplicative of Request 253 in violation of Texas Rule of Civil Procedure 192.4. Subject to this objection, and without waiver of the same, please see the Response to Request 253.*

**255. All documents discussing “BHR cup usage pre July 2009 vs. post July 2009” as referenced in Hutchens(SN)-0015647.**

*RESPONSE: Smith & Nephew objects to this Request as duplicative of Request 253 in violation of Texas Rule of Civil Procedure 192.4. Subject to this objection, and without waiver of the same, please see the Response to Request 253.*

Smith & Nephew objected to three of the requests with baseless objections and refused to

produce any documents. Notably, though, Smith & Nephew did not object to request 253. Instead, it decided to use an impossibly narrow phrase to “search” with. It is extremely unlikely that any documents besides the email chain that has already been produced uses this *exact* phrase. It is, however, extremely likely that other responsive documents exist that will not be identified by Smith & Nephew’s proposed search. Smith & Nephew’s objections should be overruled, and Smith & Nephew should be ordered to conduct an appropriate and diligent search instead of the impermissibly narrow one it will use if the Court provides no guidance.

ii. **CFR Part 99 (Requests 230, 236–238).**

The following Requests concern Code of Federal Regulation Part 99, which applies to record-keeping in connection with the intentional off-label promotion of medical devices to healthcare providers. A medical device manufacturer can lawfully promote a device off-label to a surgeon if the company diligently complies with CFR Part 99. The company literally has a First Amendment right to promote off label use as long as they comply with the requirements of CFR Part 99. Smith & Nephew’s decision not to comply (or to comply) with each of these federal regulations is relevant and discoverable. It is unlikely the company complied with this Federal law, but it is a critical event in this case and Plaintiffs are entitled to know. It is very likely that the Response to these Requests is “None”, but Plaintiffs have to ask.

**230. Any documents involving any of the Device Components that YOU maintain in compliance with 21 C.F.R. § 99.501.**

*RESPONSE: Smith & Nephew objects to this Request as overly broad and unduly burdensome insofar as it requests “any documents” involving “any Device Components.” Such a request would constitute an improper fishing expedition prohibited under Texas Law. See In re National Lloyds Insurance Company, 449 S.W.3d 486, 489 (Tex., 2014). Further, this Request is disproportionate to the needs of the litigation as the burden and expense of the proposed discovery outweighs any benefit. See Tex. R. Civ. P. 192.4(b). Finally, Smith & Nephew objects to the scope of this Request insofar as it seeks documents that are not relevant to the parties’ claims and defenses, and not reasonably calculated to lead to the discovery of admissible evidence. See Tex. R. Civ. P. 192.3.*

**236. Any written communication about the Device Components required by 21 C.F.R. § 99.201 which YOU sent to the FDA.**

*RESPONSE: Smith & Nephew objects to this Request as duplicative of Request 229 in violation of Texas Rule of Civil Procedure 192.4.*

**237. All written communication referring to or mentioning any of the Device Components that YOU maintain, in compliance with 21 C.F.R. § 99.501.**

*RESPONSE: Smith & Nephew objects to this Request as overly broad and unduly burdensome insofar as it requests “any written communication” referring to or mentioning “any of the Device Components.” Such a request would constitute an improper fishing expedition prohibited under Texas Law. See *In re National Lloyds Insurance Company*, 449 S.W.3d 486, 489 (Tex., 2014). Further, this Request is disproportionate to the needs of the litigation as the burden and expense of the proposed discovery outweighs any benefit. See *Tex. R. Civ. P. 192.4(b)*. Finally, Smith & Nephew objects to the scope of this Request insofar as it seeks documents that are not relevant to the parties’ claims and defenses, and not reasonably calculated to lead to the discovery of admissible evidence. See *Tex. R. Civ. P. 192.3*.*

**238. Any written communication which disseminates information about any of the Device Components pursuant to 21 C.F.R. Part 99.**

*RESPONSE: Smith & Nephew objects to this Request as overly broad and unduly burdensome insofar as it requests “any written communication” which disseminates information about “any of the Device Components.” Such a request would constitute an improper fishing expedition prohibited under Texas Law. See *In re National Lloyds Insurance Company*, 449 S.W.3d 486, 489 (Tex., 2014). Further, this Request is disproportionate to the needs of the litigation as the burden and expense of the proposed discovery outweighs any benefit. See *Tex. R. Civ. P. 192.4(b)*. Finally, Smith & Nephew objects to the scope of this Request insofar as it seeks documents that are not relevant to the parties’ claims and defenses, and not reasonably calculated to lead to the discovery of admissible evidence. See *Tex. R. Civ. P. 192.3*.*

Smith & Nephew’s objections concerning CFR Part 99 are improper and should be overruled.

**iii. “Four Strategic Pillars” (Requests 382).**

Another category of discoverable documents that Smith & Nephew refuses to produce are marketing documents related to a nationwide sales strategy called, “Four Strategic Pillars.” The “Four Strategic Pillars” (sometimes written out “4 Strategic Pillars”) was a consolidated monthly report that Smith & Nephew managers and executives produced relating to a broad range of topics, including things like device regulatory status, device promotion, sales rep training, surgeon

training, and compliance training. Plaintiffs have already seen multiple versions of these presentations, and they include updates about sales figures, high-sales customers, high selling sales districts, training updates, compliance updates, and individual product sales numbers. The “Four Strategic Pillars” slide show changes from time to time and Smith & Nephew likes to argue that the ones produced were just “drafts.” These slide shows are highly informative and relate to the time period and devices that are at issue in this case. However, Smith & Nephew has decided to object and refuse to search for anything else. Smith & Nephew should be ordered to produce responsive documents.

**382. All final versions of the “Four Strategic Pillars” documents created during 2007–2009.**

*RESPONSE: Smith & Nephew objects to this Request as vague and ambiguous insofar as it uses the undefined phrase “Four Strategic Pillars.” Smith & Nephew further objects to this Request as overly broad and unduly burdensome insofar as it requests “all final versions.” Such a request would constitute an improper fishing expedition prohibited under Texas Law. See In re National Lloyds Insurance Company, 449 S.W.3d 486, 489 (Tex., 2014). Finally, Smith & Nephew objects to this Request as duplicative of Request 381 in violation of Texas Rule of Civil Procedure 192.4.*

“Four Strategic Pillars”, as its name implies, is a centerpiece of Smith & Nephew’s training and education of sales reps. These presentations provide valuable insight into the fundamental practices and sales rep training that the company employed during the relevant time frames. Smith & Nephew has produced a few documents related to this strategy, but there are probably many more documents related to this program. Smith & Nephew is not excused from searching for responsive documents simply because the phrase “Four Strategic Pillars” is undefined, especially when Smith & Nephew produced one or two of these PowerPoint presentations with this exact name several years ago.

*iv. “Miscellaneous Requests” (Requests 160, 415).*

Plaintiff served two “Miscellaneous” requests that request specific information about

documents already produced. One is a video update and one is a website.

Request 160 seeks the production of a video update that featured Smith & Nephew's president speaking to its sales representatives. This video was being developed during the weeks around Plaintiff's surgery discussing device sales, product goals and product focuses (R3 and BHR), and surgeon training. The video is referred to in at least one document the company already produced. Smith & Nephew improperly responded to # 160 as shown below:

**160. Produce any documents relating to the video update referred to in Hutchens(SN)-0069601.**

*RESPONSE: Smith & Nephew objects to this Request as duplicative of Request 159 in violation of Texas Rule of Civil Procedure 192.4. Subject to this objection, and without waiver of the same, please see the Response to Request 159.*

Request 415 seeks the production of websites that the Department of Justice required Smith & Nephew to create so they could publicly disclose surgeon payments from 2007–2009. Plaintiffs are aware of some archived versions of this website, but do not know how many versions exist or what those other versions disclose. Plaintiffs are trying to determine how much money Smith & Nephew paid Dr. Schubert in the two years leading up to Mr. Fleming's surgery. After all this time, Smith & Nephew still refuses to say. The websites will disclose that information. It is likely that Smith & Nephew maintained this information since they were on probation during that time for overpaying surgeons nationwide.

**415. All versions of the website <http://www.smithnephewdpacompliance.com>.**

*RESPONSE: Smith & Nephew objects to this Request as overly broad and unduly burdensome insofar as it requests "all versions" of the obsolete website <http://www.smithnephewdpacompliance.com>.*

Each of these requests seeks documents or communications related to events, documents, or materials that are possibly probative of intent, marketing plans, defect, bias, off-label promotion, or improper surgeon payments. Smith & Nephew's boilerplate and conclusory objections are improper and should be overruled.

B. **Plaintiff Norma Egea's First RFPs to Smith & Nephew.**

Plaintiff served the following request, which seeks job evaluations of Brian Childress. This goes to the core of this case as such information could explain why and how Childress was able to facilitate Dr. Schubert's use of unapproved parts on such a massive scale. Childress is one of the central figures who facilitated and encouraged Dr. Schubert to implant a dangerous and untested device into Tracy Fleming. Smith & Nephew responded as follows:

**128. Please produce any documentation in YOUR possession describing Smith & Nephew's evaluation of Brian Childress or Neylu, Inc. at any time.**

*RESPONSE: Smith & Nephew objects to this Request as not appropriately limited in scope, insofar as it seeks information not relevant to the claims or defenses of the parties to this litigation nor reasonably calculated to lead to the discovery of admissible evidence. Such a request constitutes an improper fishing expedition as prohibited under Texas Law. See In re National Lloyds Insurance Company, 449 S.W.3d 486, 489 (Tex., 2014).*

Smith & Nephew claims that it takes "reasonable care in selecting them [sales reps/third party representatives] and do appropriate reviews from time to time." Smith & Nephew's boilerplate and conclusory objections are improper and should be overruled.

C. **Nonresponsive Searches.**

Smith & Nephew has realized that simply stonewalling and refusing to produce responsive documents is not a permissible litigation tactic in Texas, so it has created a new tactic for avoiding legitimate discovery efforts. The company has now turned to using narrowly crafted electronic "searches" in order to reduce the chance of finding any responsive documents. By doing this, Smith & Nephew has managed to create yet another way to avoid legitimate discovery efforts. There are at least two types of "search requests" that obstruct the discovery process in this case, and they will be discussed separately.

i. ***Different Searches.***

For the first, Smith & Nephew takes a narrow request and agrees to search for something

that is sort of related, but much broader. Not only does this tactic not meet the spirit of the request, it will probably create mountains of otherwise irrelevant production that Smith & Nephew is going to unceremoniously dump on Plaintiffs. Smith & Nephew's searches using different terms than the actual discovery request is improper and will not provide the requested information.

Request 229 from Plaintiff Tracy Fleming's First Requests for Production illustrates this first type of obstruction:

**229. Any information required by 21 C.F.R. § 99.201 that YOU sent to the FDA about any of the Device Components.**

*RESPONSE: Smith & Nephew is conducting a diligent search for FDA submissions and will produce responsive documents identified, to the extent any such documents exist, following the entry of an order controlling the production of personal data related to European data subjects.*

This section of the Code of Federal Regulations requires manufacturers of medical devices to send certain information to the FDA at least sixty days before they promote a medical device to an orthopedic surgeon for an off-label use. Smith & Nephew did not object. Instead, it agreed to search for something completely different, and *much, much broader*: "FDA Submissions." This is not what was requested, and it is not responsive. This search request will probably result in tens of thousands of pages of irrelevant documents that Smith & Nephew will give to Plaintiffs as purportedly responsive documents. The company will then add those thousands of documents to the list they brag about producing when they seek to avoid legitimate discovery efforts. Smith & Nephew should be ordered to search for what was requested.

On the other hand, Smith & Nephew sometimes takes a request (which often uses quotation marks around a phrase because it quotes a previously-produced document as a courtesy) and agrees to search for only the literal term or phrase that was directly quoted in the request. Plaintiffs have conferred with opposing counsel, and they have confirmed that if a response states that Smith & Nephew is conducting a diligent search for a quoted term, they are searching for literally that term

and nothing else. Smith & Nephew knows that this is improper, but their lawyers refuse to use proper searches to identify responsive documents. Appendix A has numerous other examples of Smith & Nephew unreasonably changing a Request and then agreeing to search for that instead of what was actually requested.

*ii. Unreasonably Narrow Search.*

The second type of unhelpful search is exemplified by their response to Request 405 from Plaintiff Tracy Fleming's First Requests for Production. This is another Request that Smith & Nephew did not object to, but they agreed to search for something different from what was requested.

**405. Any documents discussing the Leveraging BHR to Maximize Sales CD or its audio.**

*RESPONSE: Smith & Nephew is conducting a diligent search for documents discussing the "Leveraging BHR to Maximize Sales CD" and will produce responsive documents identified, to the extent any such documents exist, following the entry of an order controlling the production of personal data related to European data subjects.*

This sought the production of documents that discussed a CD that Smith & Nephew's marketing department created and distributed to all its sales representatives nationwide. This CD, which Plaintiffs have, teaches the sales reps how to use the FDA-approved BHR System to convince surgeons to use S&N's unapproved products. Smith & Nephew agreed to "conduct a diligent search", but only will produce documents that use the exact words in this exact order: "Leveraging BHR to Maximize Sales CD". Plaintiffs know this because they already have some documents that "discuss" this CD but do not use those exact words in that exact order. For example, there is a powerpoint about the BHR Pull-Through plan that discusses BHR "Launch Plan Assets." Smith & Nephew's stated plan was to "Protect and leverage BHR and it's [sic] clinical history to garner THA business from competitors, and specifically mentions a "Sales Pitch" for "Leveraging BHR." See Smith&Nephew\_Fleming-0034321 at 0034325. However, Smith & Nephew's search

would not uncover this document because they are only searching for the *entire phrase listed in quotation marks*. This is not a diligent search.

These are not isolated examples. In addition to the similar requests that were addressed in the original Motion, Plaintiffs challenge Smith & Nephew's responses and searches in response to the following specific Requests for Production that are listed verbatim in Exhibit A:<sup>1</sup>

- Nonresponsive Searches in Response to Plaintiff Tracy Fleming's First RFPs Nos. 68, 98, 128, 131, 148, 152, 153, 161, 229, 362, 405.
- Nonresponsive Searches in Response to Plaintiff Norma Egea's First RFPs Nos. 11–14, 33–35, 37–42, 62–64, 69–72, 77, 201, 202, and 233–237.

These “searches” have become a regular practice of Smith & Nephew's since they realized that they cannot simply object and continue to obstruct discovery in this case. This is impermissible and amounts to a failure to answer the request or diligently search for responsive documents. Smith & Nephew has an obligation to conduct a diligent search for responsive documents, but the company and its lawyers are trying to evade their obligations by using unreasonably specific and narrow search terms instead of searching for responsive documents. It should be relatively simple to confer and resolve these issues, but it is not: Plaintiffs sent all of these requests and a draft of this Motion to Smith & Nephew's counsel and Plaintiffs were simply told that Smith & Nephew was “standing” on their previous objections.

Plaintiffs are reluctant to take up the Court's time with these disputes, but it is necessary. Plaintiffs cannot take a “wait and see” approach to this discovery for multiple reasons. First, Smith & Nephew may not finish searching for responsive documents for months and its lawyers refuse to provide any timeline for its document production schedule. Second, even if Smith & Nephew finished responding to specific discovery, they refuse to identify what documents were produced in response to specific discovery requests. Plaintiffs are forced to ask the Court to intervene now

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<sup>1</sup> Excerpted for the Court in **Exhibit A**.

or they will risk never receiving responsive documents. Plaintiffs respectfully request the Court to find that Smith & Nephew's searches are insufficient and order diligent searches that search for the discoverable information in the Request for Production. An appropriate Order has been filed with this Motion.

#### **IV. CONCLUSION AND PRAYER**

Plaintiffs request the Court to set this Motion for a Zoom hearing and order Smith & Nephew to respond to the Requests for Production listed above, and to order Smith & Nephew to produce the requested documents promptly.

Respectfully Submitted,

#### **LAW OFFICE OF KIP PETROFF**

\_\_\_\_\_  
/s/ Kip Petroff

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#### **ATTORNEYS FOR PLAINTIFFS**

#### **Certificate of Conference**

I hereby certify that Plaintiffs attempted to confer about the discovery requests above and Smith & Nephew confirmed that they were opposed. A draft of this Motion was sent to David O'Quinn and Brian Johnson the day before it was filed and no agreement was reached. Therefore, this Motion is submitted to the Court as an OPPOSED Motion.

**SIGNED April 23, 2020.**

\_\_\_\_\_  
/s/

Kip A. Petroff

**Certificate of Service**

The undersigned certifies that on **April 23, 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, Ms. Sarah Segrest-Jay, and Ms. Kealy C. Sehic.

Defendant **Richard D. Schubert, M.D.** by email: Mr. David Criss and Ms. Alexandra Sallade.

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/s/

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## **EXHIBIT A—List of Nonresponsive Searches**

### **I. Nonresponsive Searches in Response to Plaintiff Tracy Fleming’s First RFPs.**

**68. Produce the attachment related to “Specials Department failure to deliver a reliable working product” described in Hutchens(SN)-0044782 at Hutchens(SN)- 0044795.**

*RESPONSE: Smith & Nephew is conducting a diligent search for “Specials Department failure to deliver a reliable working product” and will produce responsive documents identified, to the extent any such documents exist, following the entry of an order controlling the production of personal data related to European data subjects.*

**98. Please produce the “Mike Frazzette & John Soto comms” mentioned on Kirby-0029964.**

*RESPONSE: Smith & Nephew is conducting a diligent search for “Mike Frazzette & John Soto comms” and will produce responsive documents identified, to the extent any such documents exist, following the entry of an order controlling the production of personal data related to European data subjects.*

**128. Documents regarding IRB Approval for Dr. Schubert for BHR Safety Survey. See Kirby-000196.**

*RESPONSE: Smith & Nephew is conducting a diligent search for “IRB Approval” related to Dr. Schubert and “BHR Safety Survey” and will produce responsive documents identified, to the extent any such documents exist, following the entry of an order controlling the production of personal data related to European data subjects.*

**131. “Detailed Surgeon Scorecard for tracking surgeon training” referenced in Hutchens(SN)-0063360.**

*RESPONSE: Smith & Nephew is conducting a diligent search for “Detailed Surgeon Scorecard for tracking surgeon training” and will produce responsive documents identified, to the extent any such documents exist, following the entry of an order controlling the production of personal data related to European data subjects.*

**148. Produce all documents related to the September 2009 meeting described in Hutchens(SN)-0068747.**

*RESPONSE: Smith & Nephew is conducting a diligent search for documents related to a September 2009 meeting and will produce responsive documents identified, to the extent any such documents exist, following the entry of an order controlling the production of personal data related to European data subjects.*

**152. Produce all written communications related to the McMinn video referred to in Kirby-0040314.**

*RESPONSE: Smith & Nephew is conducting a diligent search for written communications related to a McMinn video and will produce responsive documents identified, to the extent any such documents exist, following the entry of an order controlling the production of personal data related to European data subjects.*

**153. Produce all documents related to the McMinn video referred to in Kirby-0040314.**

*RESPONSE: Smith & Nephew objects to this Request as duplicative of Request 152 in violation of Texas Rule of Civil Procedure 192.4. Subject to this objection, and without waiver of the same, please see the Response to Request 152.*

**161. Produce the video update referred to in Hutchens(SN)-0069601.**

*RESPONSE: Smith & Nephew objects to this Request as vague and ambiguous insofar as it requests a “video update.” Subject to this objection, and without waiver of the same, Smith & Nephew is conducting a diligent search for documents related to the referenced video update and will produce responsive documents identified, to the extent any such documents exist, following the entry of an order controlling the production of personal data related to European data subjects.*

**229. Any information required by 21 C.F.R. § 99.201 that YOU sent to the FDA about any of the Device Components.**

*RESPONSE: Smith & Nephew is conducting a diligent search for FDA submissions and will produce responsive documents identified, to the extent any such documents exist, following the entry of an order controlling the production of personal data related to European data subjects.*

**362. Please produce any written correspondence involving the “Southwest Region, Hip Task Force” from 2006–2010 which mentions Richard D. Schubert, M.D.**

*RESPONSE: Smith & Nephew objects to this Request as duplicative of Request 360 in violation of Texas Rule of Civil Procedure 192.4. Smith & Nephew also objects to this Request as overly broad, unduly burdensome, and disproportionate to the needs of the litigation as the burden and expense of the proposed discovery outweighs any benefit. See Tex. R. Civ. P. 192.4(b). Such a request would constitute an improper fishing expedition prohibited under Texas Law. See *In re National Lloyds Insurance Company*, 449 S.W.3d 486, 489 (Tex., 2014). Smith & Nephew further objects to this Request as not relevant to the parties’ claims and defenses, and not reasonably calculated to lead to the discovery of admissible evidence. See Tex. R. Civ. P. 192.3. Subject to these objections, and without waiver of the same, Smith & Nephew is conducting a diligent search for written correspondence involving “Southwest Region, Hip Task Force” from 2006–2010 mentioning Dr. Richard Schubert, to the extent any such documents exist, following the entry of an order controlling the production of personal data related to European data subjects.*

**405. Any documents discussing the Leveraging BHR to Maximize Sales CD or its audio.**

*RESPONSE: Smith & Nephew is conducting a diligent search for documents discussing the “Leveraging BHR to Maximize Sales CD” and will produce responsive documents identified, to the extent any such documents exist, following the entry of an order controlling the production of personal data related to European data subjects.*

II. Nonresponsive Searches in Response to Plaintiff Norma Egea’s First RFPs.

**11. Any order confirmation forms for any of the Device Components used in Plaintiff’s surgery.**

*RESPONSE: Smith & Nephew objects to this Request as vague and ambiguous in its use of the undefined phrase “order confirmation.” Smith & Nephew further objects to this Request as not appropriately limited in scope, insofar as it seeks information not relevant to the claims or defenses of the parties to this litigation nor reasonably calculated to lead to the discovery of admissible evidence. Such a request constitutes an improper fishing expedition as prohibited under Texas Law. See *In re National Lloyds Insurance Company*, 449 S.W.3d 486, 489 (Tex., 2014). Subject to this objection, and without waiver of the same, Smith & Nephew is conducting a diligent search for “order confirmation forms” pertaining to the specific components used in Plaintiff’s surgery and will produce any responsive documents identified following the entry of an order governing the production of personal data related to European data subjects.*

**12. Any Distribution Records in YOUR actual or constructive possession relating in any way to any of the Device Components used in Plaintiff’s surgery.**

*RESPONSE: Smith & Nephew objects to this Request as vague and ambiguous in its use of the undefined phrase “distribution records.” Smith & Nephew further objects to this Request as not appropriately limited in scope, insofar as it seeks information not relevant to the claims or defenses of the parties to this litigation nor reasonably calculated to lead to the discovery of admissible evidence. Such a request constitutes an improper fishing expedition as prohibited under Texas Law. See *In re National Lloyds Insurance Company*, 449 S.W.3d 486, 489 (Tex., 2014). Subject to this objection, and without waiver of the same, Smith & Nephew is conducting a diligent search for any documents referencing “Distribution Records” pertaining to the specific components used in Plaintiff’s surgery and will produce any responsive documents identified following the entry of an order governing the production of personal data related to European data subjects.*

**13. Any bill of lading in YOUR actual or constructive possession relating in any way to any of the Device Components used in Plaintiff’s surgery.**

*RESPONSE: Smith & Nephew objects to this Request as vague and ambiguous in its use of the undefined phrase “bill of lading.” Smith & Nephew further objects to this Request as vague and ambiguous insofar as it uses the phrase “constructive possession.” Smith & Nephew further objects to this Request as not appropriately*

*limited in scope, insofar as it seeks information not relevant to the claims or defenses of the parties to this litigation nor reasonably calculated to lead to the discovery of admissible evidence. Such a request constitutes an improper fishing expedition as prohibited under Texas Law. See In re National Lloyds Insurance Company, 449 S.W.3d 486, 489 (Tex., 2014). Subject to this objection, and without waiver of the same, Smith & Nephew is conducting a diligent search for any documents referencing “bill of lading” pertaining to the specific components used in Plaintiff’s surgery and will produce any responsive documents identified following the entry of an order governing the production of personal data related to European data subjects.*

**14. Any consignment record in YOUR actual or constructive possession relating in any way to any of the Device Components used in Plaintiff’s surgery.**

*RESPONSE: Smith & Nephew objects to this Request as vague and ambiguous in its use of the undefined phrase “consignment record.” Smith & Nephew further objects to this Request as vague and ambiguous insofar as it uses the phrase “constructive possession.” Smith & Nephew further objects to this Request as not appropriately limited in scope, insofar as it seeks information not relevant to the claims or defenses of the parties to this litigation nor reasonably calculated to lead to the discovery of admissible evidence. Such a request constitutes an improper fishing expedition as prohibited under Texas Law. See In re National Lloyds Insurance Company, 449 S.W.3d 486, 489 (Tex., 2014). Subject to this objection, and without waiver of the same, Smith & Nephew is conducting a diligent search for any documents referencing “consignment record” pertaining to the specific components used in Plaintiff’s surgery and will produce any responsive documents identified following the entry of an order governing the production of personal data related to European data subjects.*

**33. Any written communications relating to Dr. Schubert’s “smoldering problem” email dated June 12, 2011.**

*RESPONSE: Smith & Nephew objects to this Request as vague, ambiguous, overbroad, and unduly burdensome insofar as it requests “any written communications.” Smith & Nephew is conducting a diligent search for any written communications referencing “smoldering problem” and that relate to the Device Components and will produce any responsive documents identified following the entry of an order governing the production of personal data related to European data subjects.*

**34. Any documents relating to Dr. Schubert’s “smoldering problem” email dated June 12, 2011.**

*RESPONSE: Smith & Nephew objects to this Request as vague, ambiguous, overbroad, and unduly burdensome insofar as it requests “any documents.” Smith & Nephew is conducting a diligent search for any documents referencing “smoldering problem” and that relate to the Device Components and will produce*

*any responsive documents identified following the entry of an order governing the production of personal data related to European data subjects.*

**35. Any email from YOU relating to Dr. Schubert’s “smoldering problem” email dated June 12, 2011.**

*RESPONSE: Smith & Nephew objects to this Request as vague, ambiguous, overbroad, and unduly burdensome insofar as it requests “any email from you.” Defendant refers Plaintiff to its Response to Request No. 33 and incorporates same here.*

**37. Please produce any documents related to Smith & Nephew metal on metal hip implants that YOU or anyone associated with YOU ever provided to or received from North Central Surgical Center, including emails, letters, product brochures, Surgical Techniques, Surgical Technique Addendums, package inserts, patient package inserts, or cards of any kind.**

*RESPONSE: Smith & Nephew objects to this Request as vague and ambiguous insofar as it uses the phrase “anyone associated with you.” Smith & Nephew further objects to this Request as vague, ambiguous, overbroad, and unduly burdensome insofar as it requests “any documents related to Smith & Nephew metal on metal hip implants.” Smith & Nephew further objects to this Request as not appropriately limited in scope, insofar as it seeks information not relevant to the claims or defenses of the parties to this litigation nor reasonably calculated to lead to the discovery of admissible evidence. Such a request constitutes an improper fishing expedition as prohibited under Texas Law. See *In re National Lloyds Insurance Company*, 449 S.W.3d 486, 489 (Tex., 2014). Subject to this objection, and without waiver of the same, Smith & Nephew is conducting a diligent search for documents and communications related to the Device Components and that Smith & Nephew provided to or received from Dr. Schubert or North Central Surgical Center, and will produce any responsive documents identified following the entry of an order governing the production of personal data related to European data subjects.*

**38. Please produce any documents related to Smith & Nephew metal on metal hip implants that YOU or anyone associated with YOU ever provided to or received from Dr. Schubert, including emails, letters, product brochures, Surgical Techniques, Surgical Technique Addendums, package inserts, patient package inserts, or cards of any kind.**

*RESPONSE: Defendant refers Plaintiff to its Response to Request No. 37 and incorporates same here.*

**39. Any document of any kind, including emails, which would show, refer to, or identify any sales calls that YOU or anyone associated with YOU made to Dr. Schubert at any time during the years 2003–2006.**

*RESPONSE: Smith & Nephew objects to this Request as overbroad. Subject to this objection, and without waiver of the same, Smith & Nephew is conducting a diligent search for documents referencing “sales calls” related to Dr. Schubert and the*

*Device Components and will produce any responsive documents identified following the entry of an order governing the production of personal data related to European data subjects.*

**40. Any document of any kind, including emails, which would show, refer to, or identify any sales calls that YOU or anyone associated with YOU made to Dr. Schubert at any time during the years 2007–2009.**

*RESPONSE: Smith & Nephew objects to this Request as overbroad. Subject to this objection, and without waiver of the same, Smith & Nephew is conducting a diligent search for documents referencing “sales calls” related to Dr. Schubert and the Device Components and will produce any responsive documents identified following the entry of an order governing the production of personal data related to European data subjects.*

**41. Any document of any kind, including emails, which would show, refer to, or identify any sales calls that YOU or anyone associated with YOU made to Dr. Schubert at any time during the years 2010–2015.**

*RESPONSE: Smith & Nephew objects to this Request as overbroad. Subject to this objection, and without waiver of the same, Smith & Nephew is conducting a diligent search for documents referencing “sales calls” related to Dr. Schubert and the Device Components and will produce any responsive documents identified following the entry of an order governing the production of personal data related to European data subjects.*

**42. Any document of any kind, including emails, which would show, refer to, or identify any sales calls that YOU or anyone associated with YOU made to Dr. Schubert at any time during the years 2016–present.**

*RESPONSE: Smith & Nephew objects to this Request as overbroad. Subject to this objection, and without waiver of the same, Smith & Nephew is conducting a diligent search for documents referencing “sales calls” related to Dr. Schubert and the Device Components and will produce any responsive documents identified following the entry of an order governing the production of personal data related to European data subjects.*

**62. Any “call notes” or written or electronic report of any kind that exists with respect to any sales calls concerning the Device Components that anyone associated with YOU made to Dr. Schubert during the period from January 1, 2004 to November 30, 2009.**

*RESPONSE: Smith & Nephew objects to this Request as overbroad. Subject to this objection, and without waiver of the same, Smith & Nephew is conducting a diligent search for documents referencing “call notes” related to Dr. Schubert and the Device Components and will produce any responsive documents identified following the entry of an order governing the production of personal data related to European data subjects.*

**63. Any “call notes” or written or electronic report of any kind that exists with respect to any sales calls concerning the Device Components that anyone associated with YOU made to Dr. Schubert during the period from December 1, 2009 to December 31, 2016.**

*RESPONSE: Smith & Nephew objects to this Request as overbroad. Subject to this objection, and without waiver of the same, Smith & Nephew is conducting a diligent search for documents referencing “call notes” related to Dr. Schubert and the Device Components and will produce any responsive documents identified following the entry of an order governing the production of personal data related to European data subjects.*

**64. Produce any written communications or documents showing that YOU informed Dr. Schubert before the Plaintiff’s surgery that any of the Device Components were considered to be used “off-label” when they were used as part of a conventional total hip arthroplasty.**

*RESPONSE: Smith & Nephew objects to this Request as vague and ambiguous in its use of the undefined phrase “off-label.” Smith & Nephew further objects to this Request as vague, ambiguous, and misleading to the extent it suggests that Smith & Nephew promoted any component for any indication in the United States other than as approved by the Food and Drug Administration. Smith & Nephew further objects to this Request as vague, ambiguous, and misleading to the extent it suggests the existence of or seeks to impose any affirmative duty on Smith & Nephew other than those mandated by the Food and Drug Administration and the Code of Federal Regulations. Subject to that objection and without waiver of the same, Defendant refers Plaintiff to its Response to Request No. 7 and incorporates same here.*

**69. Please produce any documents or written communications of any kind that YOU or anyone associated with YOU provided to or received from anyone associated with North Central Surgical Center in connection with the Birmingham Hip Resurfacing System or BHR Acetabular Cup at any time from 2003–2006.**

*RESPONSE: Smith & Nephew objects to this Request as vague, ambiguous, overbroad, and unduly burdensome insofar as it requests “any documents or written communications.” Smith & Nephew further objects to this Request as vague and ambiguous insofar as it uses the phrase “anyone associated with you.” Subject to that objection and without waiver of the same, Defendant refers Plaintiff to its Response to Request No. 7<sup>1</sup> and incorporates same here.*

**70. Please produce any documents or written communications of any kind that YOU or anyone associated with YOU provided to or received from anyone associated with North Central Surgical Center in connection with the Birmingham Hip Resurfacing System or**

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<sup>1</sup> Smith & Nephew’s response to Request No. 7 is, in relevant part, “Smith & Nephew is conducting a diligent search for any documents or correspondence relating to Plaintiff’s surgery or the Device Components, which was sent to Smith & Nephew by the identified entities and individuals or that the identified entities and individuals received from Smith & Nephew.”

**BHR Acetabular Cup at any time from 2007–2009.**

*RESPONSE: Defendant refers Plaintiff to its Response to Request No. 69 and incorporates same here.*

**71. Please produce any documents or written communications of any kind that YOU or anyone associated with YOU provided to or received from anyone associated with North Central Surgical Center in connection with the Birmingham Hip Resurfacing System or BHR Acetabular Cup at any time from 2010–2015.**

*RESPONSE: Defendant refers Plaintiff to its Response to Request No. 69 and incorporates same here.*

**72. Please produce any documents or written communications of any kind that YOU or anyone associated with YOU provided to or received from anyone associated with North Central Surgical Center in connection with the Birmingham Hip Resurfacing System or BHR Acetabular Cup at any time from 2016–present.**

*RESPONSE: Defendant refers Plaintiff to its Response to Request No. 69 and incorporates same here.*

**77. Please produce any documents or correspondence, including emails, that YOU ever sent to or received from North Central Surgical Center in connection with Smith & Nephew large diameter metal on metal hip implants.**

*RESPONSE: Smith & Nephew objects to this Request as not appropriately limited in scope, insofar as it seeks information not relevant to the claims or defenses of the parties to this litigation nor reasonably calculated to lead to the discovery of admissible evidence. Such a request constitutes an improper fishing expedition as prohibited under Texas Law. See *In re National Lloyds Insurance Company*, 449 S.W.3d 486, 489 (Tex., 2014). Smith & Nephew further objects to this Request as vague, ambiguous, overbroad, and unduly burdensome insofar as it requests “produce any documents or correspondence.” Subject to these objections, and without waiver of the same, Smith & Nephew is conducting a diligent search for correspondence with North Central Surgical Center referencing “large diameter metal on metal hip implants” and will produce any responsive documents identified following the entry of an order governing the production of personal data related to European data subjects.*

**201. Produce any documentation or written communication, including emails, which informed Brian Childress or Neylu, Inc. of the indications for use of the Device Components.**

*RESPONSE: Smith & Nephew is conducting a diligent search for documents and written communication referencing “indications” and “Brian Childress” or “Neylu, Inc.” as pertaining to the device components used in Plaintiff’s surgery and will produce any responsive documents identified following the entry of an order governing the production of personal data related to European data subjects.*

**202. Produce any documentation or written communication, including emails, which informed Brian Childress or Neylu, Inc. of the intended use of the Device Components.**

*RESPONSE: Smith & Nephew objects to this Request as vague and ambiguous in its use of the undefined phrase “intended use.” Subject to this objection, and without waiver of the same, Smith & Nephew is conducting a diligent search for documents and written communication referencing “intended use” and “Brian Childress” or “Neylu, Inc.” as pertaining to the device components used in Plaintiff’s surgery and will produce any responsive documents identified following the entry of an order governing the production of personal data related to European data subjects.*

**233. Produce all versions of any Net Sales Reports for Dr. Schubert from 2005–2006 (see the redacted Smith & Nephew document produced as Hutchens (SN)-00150021 for an example of a Net Sales Report, attached as Exhibit D).**

*RESPONSE: Smith & Nephew is conducting a diligent search for documents referencing “Net Sales Reports” in relation to Dr. Schubert from 2005-2015 and will produce any responsive documents identified following the entry of an order governing the production of personal data related to European data subjects.*

**234. Produce all versions of any Net Sales Reports for Dr. Schubert from 2007–2008 (see the redacted Smith & Nephew document produced as Hutchens (SN)-00150021 for an example of a Net Sales Report, attached as Exhibit D).**

*RESPONSE: Smith & Nephew is conducting a diligent search for documents referencing “Net Sales Reports” in relation to Dr. Schubert from 2005-2015 and will produce any responsive documents identified following the entry of an order governing the production of personal data related to European data subjects.*

**235. Produce all versions of any Net Sales Reports for Dr. Schubert from January 1, 2009–September 28, 2009 (see the redacted Smith & Nephew document produced as Hutchens (SN)-00150021 for an example of a Net Sales Report, attached as Exhibit D).**

*RESPONSE: Smith & Nephew is conducting a diligent search for documents referencing “Net Sales Reports” in relation to Dr. Schubert from 2005-2015 and will produce any responsive documents identified following the entry of an order governing the production of personal data related to European data subjects.*

**236. Produce all versions of any Net Sales Reports for Dr. Schubert from September 29, 2009–2015 (see the redacted Smith & Nephew document produced as Hutchens (SN)-00150021 for an example of a Net Sales Report, attached as Exhibit D).**

*RESPONSE: Smith & Nephew is conducting a diligent search for documents referencing “Net Sales Reports” in relation to Dr. Schubert from 2005-2015 and will produce any responsive documents identified following the entry of an order governing the production of personal data related to European data subjects.*

**237. Produce all versions of any Net Sales Reports for Dr. Schubert from 2016–present (see the redacted Smith & Nephew document produced as Hutchens (SN)-00150021 for an example of a Net Sales Report, attached as Exhibit D).**

*RESPONSE: Smith & Nephew is conducting a diligent search for documents referencing “Net Sales Reports” in relation to Dr. Schubert from 2005-2015 and will produce any responsive documents identified following the entry of an order governing the production of personal data related to European data subjects.*