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CAUSE NO. DC-18-08923

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' COMBINED RESPONSE AND OPPOSITION TO DEFENDANTS' MOTION TO QUASH NOTICE OF ORAL AND VIDEOTAPED DEPOSITION OF DR. JAY MABREY and MOTION TO STRIKE PLAINTIFFS' SUPPLEMENTAL DESIGNATION OF EXPERT WITNESS DR. JAY MABREY

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW, Plaintiffs, Tracy Fleming and Norma Egea, and files this their Combined Response and Opposition to Defendants' Motion to Quash Notice of Oral and Video Recorded Deposition of Dr. Jay Mabrey and Motion to Strike Plaintiffs' Supplemental Designation of Expert Witness Dr. Jay Mabrey, and in support thereof would show as follows:

I. INTRODUCTION/SUMMARY OF ARGUMENT

This products liability case has become all too familiar to the Court in the past eighteen months or so. Extensive written discovery has been exchanged in this case since it was filed almost two years ago. Numerous depositions have been taken. The latest discovery issue exists solely because the Defendants produced an important email from Dr. Jay Mabrey *after* Plaintiffs' Expert Designation date. Everything changed in this case on April 24, 2020, which is when the attached email marked **Exhibit A** was produced. Six Smith & Nephew witnesses are on this email along with Defendant Brian Childress. The very late production of this email is what justifies the decision to retain Dr. Mabrey as a testifying expert witness and to designate him as such on May 26, 2020.

This Response will demonstrate that the Defendants' Motion should be denied for many reasons, but the main reason is that Dr. Mabrey is a ***fact witness*** who is well-known to Defendants and he is being deposed as an expert and fact witness in a related case in Beaumont on Wednesday, June 17. Dr. Mabrey is a treating physician who was first listed as an expert and fact witness in this case on July 11, 2019. His initial Designation gave notice of numerous areas of testimony he would be offered to testify about. No one asked for his deposition or a report at that time. Dr. Mabrey was again designated as an expert and fact witness with additional information about him disclosed on February 14, 2020. No one asked for his deposition or a report at that time.

This case changed significantly when the attached Exhibit A was produced on April 24, 2020 among 10,000 other Smith & Nephew documents. ***Exhibit A is a game-changer***. It informs Smith & Nephew and Brian Childress that, according to Dr. Mabrey, their entire defense of this case is flawed. Dr. Mabrey was the Chief of Orthopedics at Baylor University Medical Center when he wrote that email to six Smith & Nephew employees and Brian Childress more than thirteen years ago. He had also just recently finished his tenure as the Chairman of the Food and Drug Administration Advisory Committee that conditionally approved one of Mr. Fleming's component parts for a completely different surgery than what it was used for in Mr. Fleming. This email makes it clear to everyone that "*you will still have to wait for final FDA approval*" for any future case involving the metal parts involved in this email. Mr. Fleming's surgery involved the same parts that are covered in this email, but no one bothered to "*wait for final FDA approval*" as Dr. Mabrey instructed. Smith & Nephew and Brian Childress completely ignored Dr. Mabrey's instructions. They sold the parts anyway. It is difficult to imagine how any piece of evidence could be more relevant or more important than this recently produced, thirteen-year-old email from the surgeon who referred Tracy Fleming to Dr. Schubert.

The Court should deny Defendants' Motion, allowing the deposition to proceed, and then deal with any issues of surprise or hardship after the deposition is completed.

II. FACTUAL AND PROCEDURAL BACKGROUND

Dr. Mabrey is a fact witness in all hip implant cases involving Smith & Nephew metal hips. He was the Chairman of the Food and Drug Administration Panel that conditionally approved a Smith & Nephew medical device known as the "Birmingham Hip Resurfacing System." One of the parts implanted in Mr. Fleming is called the "BHR Cup", and the FDA approved the BHR Cup as part of the Birmingham Hip Resurfacing System in early 2006. Dr. Mabrey, as FDA Chairman for these products, is a fact witness with special expertise and knowledge just like a state trooper who investigates a motor vehicle accident or a police officer at a crime scene. Dr. Mabrey's deposition as an expert witness and fact witness is being taken on June 17, 2020 in a related case in Beaumont, and he was designated as a retained expert in this case only after Smith & Nephew recently produced this thirteen-year-old email.

The first time Plaintiffs' counsel spoke with Dr. Mabrey was May 19, 2020, and his expert designation in this case was updated on May 26, 2020. His Designation was supplemented again on June 2, 2020 and again on June 8, 2020. Plaintiffs received, and produced to opposing counsel, Dr. Mabrey's Curriculum Vitae on May 19, 2020, and Plaintiff designated **Exhibit A** as his expert report. Plaintiffs have subsequently produced a handful of documents that have been provided to Dr. Mabrey in the last month. Importantly, *everything provided to Dr. Mabrey except for two photographs consists of Smith & Nephew documents produced in this and the Beaumont case or documents that have been previously marked at depositions related to this litigation*. There is no sandbagging or game playing here except to the extent that Smith & Nephew and Childress did

not produce Dr. Mabrey's 2006 email until more than two months after the expert deadline had passed in this case.

The combination of parts implanted in Mr. Fleming was NOT approved to be used in total hip replacement surgeries like the one that Dr. Schubert performed on Mr. Fleming. Dr. Schubert testified that he never would have implanted the parts in the Plaintiff if he knew they were not approved for that type of surgery. He testified that Smith & Nephew and the Sales Rep Defendants caused him to believe that the parts were "available" for surgeries like Mr. Fleming underwent. In other words, he would not have implanted these parts in Mr. Fleming if he knew the contents of Exhibit A.

Dr. Mabrey, as Chairman of the FDA Panel, is a fact witness who can testify about FDA Approval and how device parts get approved or rejected for use in America. He can testify about his extensive involvement with Smith & Nephew as a customer who used their products. He can testify about product literature, Power Points, slides, and data that Smith & Nephew provided to him over the years. He can also testify as a fact witness about the email that he wrote to Smith & Nephew in 2006 when he told them that: "***You will still have to wait for final FDA approval for any other case***" except the specific one involved in his 2006 email. All of that testimony is factual in nature, but Plaintiffs supplemented his designation as an expert so his Designation could reflect the full breadth of his anticipated testimony on the subject of FDA approval.

Dr. Mabrey can also testify factually about his extensive involvement as a consultant and expert witness for Smith & Nephew on roughly a dozen occasions over the past ten years. Smith & Nephew has presented him for deposition as an expert witness in their patent infringement cases many times. Smith & Nephew has paid him tens of thousands of dollars to testify and consult as *their expert*. The company knows when they paid him and what he was paid for. In addition, they

know the size, model, approval status, and date of implantation of every hip implant of theirs that he ever used. They have every email that Dr. Mabrey has ever sent to anyone at Smith & Nephew.

Plaintiffs' counsel recently asked Smith & Nephew to produce Dr. Mabrey as a witness in this case and the Beaumont case. That was just a few days after Smith & Nephew first produced the email that lead to all this activity. Both groups of attorneys began reaching out to Dr. Mabrey to schedule his deposition. Smith & Nephew, knowing how to reach him, contacted him first. Plaintiffs' counsel spoke with him for the first time the very next day. Dr. Mabrey provided his CV and his designation as an expert was supplemented just a few days later.

III. ARGUMENT

A. The "untimely" designation is curable under TRCP 193.6.

The Defendants' Motion conspicuously omits any references to the applicable case law because it knows that they are not applying the correct law to this issue. Texas Rule of Civil Procedure 193.6 unquestionably applies here. Smith & Nephew's motion to strike Dr. Mabrey as an expert witness fails if Plaintiff can show either: "(1) there was good cause for the failure to timely make, amend, or supplement the discovery response; or (2) the failure to timely make, amend, or supplement the discovery response will not unfairly surprise or unfairly prejudice the other parties." TEX. R. CIV. P. 193.6(a). Both standards are easily met here.

The cornerstone of a Motion like this one is whether the Movants can show surprise or hardship. Are Smith & Nephew and Brian Childress truly surprised that a recently produced email from Dr. Mabrey about FDA matters in 2006 would result in a request for his deposition? Of course not. The email was written when Dr. Mabrey was Chief of Orthopedics at Baylor University Medical Center in Dallas. He was arguably still Chairman of the FDA Panel at the time because the FDA approval of the subject device was "conditional." Dr. Mabrey's email is only a few

sentences long and it mentions the need for FDA approval in almost every sentence. He explicitly tells Smith & Nephew and Brian Childress that "*final FDA approval*" is required in "*any other case*" besides the specific one mentioned in his email. He had extensive dealings with Smith & Nephew about his email before it was written, and six Smith & Nephew people along with Childress were copied on the email.

It is anticipated that most of Dr. Mabrey's testimony will be factual in nature, answering questions like, "what does the FDA expect when it grants conditional approval of a device" or "what does Conditional Approval mean?" Factual testimony is anticipated about why he said, "*final FDA approval*" is required in "*any other case*." Plaintiffs' counsel asked for depositions of all of the Smith & Nephew people on the email and David O'Quinn, counsel for Smith & Nephew, insisted on presenting Dr. Mabrey first so he could put the email, "in context." Plaintiffs submit that the best approach in a unique situation like this is to allow the deposition to occur and worry later about whether any actual or surprising "expert testimony" is provided at the deposition. There will be plenty of opportunity after the deposition to limit or exclude his testimony if there is any reason for that type of relief.

B. <u>The cure for untimely designation is allowing discovery about the expert, not striking them.</u>

Striking Dr. Mabrey's testimony would only be proper if there was no opportunity for the Defendants to discover his opinions and the bases for those opinions. *See City of El Paso v. Parsons*, 353 S.W.3d 215, 228–230 (Tex. App.—El Paso 2011, no pet.) (Where designation of attorneys' fee expert *after trial* was untimely but allowed when the Court allowed six additional weeks of discovery to cure any alleged surprise.). Here, though, the parties have already scheduled Dr. Mabrey's deposition so that Defendants can learn Dr. Mabrey's opinions and bases underlying them. That is the proper remedy for an untimely designation where there is good cause for the late

designation and where there is no unfair surprise or unfair prejudice—not striking the expert and quashing a scheduled deposition. *See* TEX. R. CIV. P. 193.6(c) ("Continuance. Even if the party seeking to introduce the evidence or call the witness fails to carry the burden under paragraph (b), the court may grant a continuance or temporarily postpone the trial to allow a response to be made, amended, or supplemented, and to allow opposing parties to conduct discovery regarding any new information presented by that response.").

In fact, the remedy that Smith & Nephew seeks—both striking Dr. Mabrey and quashing his deposition—is improper and *contradicts* the applicable Texas Rules of Civil Procedure. That sort of drastic remedy is only proper in cases where there is no way to cure (for example, when an expert is disclosed a month before trial and designated two weeks before trial, like in *Jafar v. Mohamed*, No. 14-14-00512-CV, 2016 WL 1455978, at *2–4 (Tex. App.—Houston [14th Dist.] Apr. 12, 2016, no pet.) (mem. op.)), not in cases where trial is possibly set for four months in the future and discovery into the expert's opinions is both feasible and actively being encouraged by the offering party.

Smith & Nephew's complaints about improper designation (no production and no expert report) are equally misguided. All communications and materials provided to Dr. Mabrey were sent to opposing counsel by Dropbox link on May 26, 2020, well before any proposed deposition of Dr. Mabrey, and an expert report is not explicitly required by the Texas Rules of Civil Procedure. When a plaintiff does not serve an expert report when designating experts, the Texas Rules of Civil Procedure simply require that they make the expert available for a deposition "reasonably promptly after the expert is designated." TEX. R. CIV. P. 195.3(a)(1).Although the Court's Discovery Control Plan required expert reports, the discovery control plan can be modified

by the Court "at any time" and *must* be modified "when the interest of justice requires." TEX. R. CIV. P. 190.5.

Given the simple remedies described above and the significant amount of time until the trial of this case, Plaintiffs respectfully submit that the Court is permitted to modify its Discovery Control Order to allow Dr. Mabrey's designation with no "formal" expert report other than the documents previously served and his deposition "reasonably promptly" after his designation (in this case, on June 17, 2020, by agreement of the parties). *See also* TEX. R. CIV. P. 191.1 ("Except where specifically prohibited, the procedures and limitations set forth in the rules pertaining to discovery may be modified in any suit . . . by court order for good cause."). Defendants also fail to mention that they've been provided extensive information about what Dr. Mabrey is going to testify about—both in this case and in the Jefferson County case (which again, involves only the same lawyers that are filing these motions).The Jefferson County supplemental designation was served the day before this present motion was filed, and outlines every area of testimony that Plaintiffs anticipate Dr. Mabrey is going to testify about. A substantially similar designation was filed in this case as well. The latest designation of Dr. Mabrey is attached as **Exhibit B**. It is 13 pages long and covers more than two dozen different topics and opinions.

IV. TIME AND PLACE PROTECTION IS PROCEDURALLY DEFECTIVE

Another reason the Motion should be denied is because it is procedurally defective. Smith & Nephew sought "*protection"* from the deposition, even though Counsel for Plaintiffs attempted to confer about the deposition date via several emails in advance. It is not true to suggest that no effort was made to coordinate the date of this deposition. Numerous emails offering seven different deposition dates in three separate weeks were sent and ignored before it was Noticed. Counsel for Dr. Schubert agreed to this date and has not objected to anything about the deposition. More

importantly, the presiding Court in Jefferson County, who heard a nearly-identical motion from these same lawyers on both sides a week ago, has ordered Dr. Mabrey's deposition to proceed. That deposition has been Noticed in the Beaumont case and is scheduled by agreement for June 17, 2020.

When a party seeks protection "regarding the time or place of discovery," they must "state a reasonable time and place for discovery with which the person will comply." TEX. R. CIV. P. 192.6(a). Smith & Nephew refused to do this when Plaintiffs offered seven different dates for this remote deposition, but they have now agreed on one of the other dates that was proposed – June 17. Smith & Nephew's Motion for Protection regarding the date and place is therefore procedurally defective and should be denied.

V. CONCLUSION AND PRAYER

Granting this Motion would be premature and unnecessary. It would reward Smith & Nephew and Brian Childress for their gamesmanship and late production, and it would accomplish nothing that cannot be accomplished after the deposition is completed. The deposition will proceed as agreed in the Beaumont case irrespective of what the Court does with the subject Motion. Most of the testimony will be factual in nature. This premature Motion that fails to comply with the Texas Rules of Civil Procedure should be denied.

Respectfully submitted,

LAW OFFICE OF KIP PETROFF

/s/ Kip Petroff

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ATTORNEYS FOR PLAINTIFFS

Certificate of Service

I HEREBY CERTIFY that on **June 10, 2020**, a true and correct copy of the foregoing was served on the Defendants by email as follows:

Defendants **Smith & Nephew, Inc., Brian Childress and Neylu, Inc. to:** Mr. Brian P. Johnson, Ms. Leila D'Aquin, Mr. David O'Quinn, Ms. Sarah Segrest-Jay, Mr. Douglas Moore, and Ms. Kealy Sehic.

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

/s/

Caio Formenti

EXHIBIT A

Exhibit "A"

Message

From: [redacted]
Sent: 8/10/2006 10:14:35 PM
To: JayM@BaylorHealth.edu; Thomas, Marc (Memphis) [marc.thomas@smith-nephew.com]
CC: lucin@Baylorhealth.edu; Christensen, Carey [carey.christensen@smith-nephew.com]; [redacted]; Coplan, Mary [mary.coplan@smith-nephew.com]; Riley, Robert [robert.riley@smith-nephew.com]; Buckley, Mark [mark.buckley@smithnephew.com]; Austin, Brian [brian.austin@smith-nephew.com]; Childress, Brian [brian.childress@smith-nephew.com]; MartyF@BaylorHealth.edu; ScottP@BaylorHealth.edu; SherryTu@BaylorHealth.edu; fabianp@BaylorHealth.edu; LeeG@BaylorHealth.edu
Subject: Re: Birmingham Hip Resurfacing at Baylor

Thanks to all for making this backup happen. Hopefully BHR is all we need. Please keep [redacted] in your thoughts and prayers. [redacted]

Sent from my BlackBerry Wireless Handheld

-----Original Message-----
From: Mabrey, Jay <JayM@BaylorHealth.edu>
To: Marc.Thomas@smith-nephew.com <Marc.Thomas@smith-nephew.com>
CC: [redacted]; Neumann, Luci <LuciN@BaylorHealth.edu>; Carey.Christensen@smith-nephew.com <Carey.Christensen@smith-nephew.com>; [redacted]; Mary.Coplan@smith-nephew.com <Mary.Coplan@smith-nephew.com>; Robert.Riley@smith-nephew.com <Robert.Riley@smith-nephew.com>; Mark.Buckley@smith-nephew.com <Mark.Buckley@smith-nephew.com>; Brian.Austin@smith-nephew.com <Brian.Austin@smith-nephew.com>; Brian.Childress@smith-nephew.com <Brian.Childress@smith-nephew.com>; MartyF@BaylorHealth.edu <MartyF@BaylorHealth.edu>; Scott Patterson (Patterson, Scott) <ScottP@BaylorHealth.edu>; SherryTu@BaylorHealth.edu <SherryTu@BaylorHealth.edu>; Pollo, Fabian <fabianp@BaylorHealth.edu>; Gilleland, Lee <LeeG@BaylorHealth.edu>
Sent: Thu Aug 10 09:11:12 2006
Subject: Birmingham Hip Resurfacing at Baylor

Dear Dr. Thomas:

As Chief of Orthopaedics at Baylor University Medical Center, I fully support Smith & Nephew in releasing the total hip version of the Birmingham Hip Resurfacing for [redacted]s surgery this Monday. I can only speak for the Department of Orthopaedics and not for the FDA, although I have continued my efforts at FDA to ascertain the status of the total hip version. You will still have to wait for final FDA approval for any other case.

My decision is supported by the fact that three other companies, Biomet, DePuy, and Zimmer offer nearly identical, FDA-approved devices composed of large diameter heads with tapers to fit their total hip stems. I understand that it is Dr. [redacted]'s intent to proceed with the BHR as the primary procedure and only go to a total hip version if the femoral head is too involved with avascular necrosis. Thus, the device I am approving is essentially a backup for the primary procedure which utilizes the FDA approved BHR.

Thank you for your understanding and support. It is very important that we resolve this matter as quickly as possible as [redacted] has rearranged his entire schedule for the next several weeks to allow for this surgery. He can put this off no longer as the pain is simply too great.

Please feel free to call my office direct any time this morning should you wish to discuss this further.

Sincerely,

Jay D. Mabrey, MD, FAAOS

Chief, Department of Orthopaedics

George Truett James Orthopaedics Institute

Baylor University Medical Center

3500 Gaston Ave.; 6th Floor Hoblitzelle Bldg

Dallas, Texas 75246-9990

Voice: 214-820-3434

jaym@baylorhealth.edu

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EXHIBIT B

FILED
6/8/2020 6:53 PM
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DISTRICT CLERK
DALLAS CO., TEXAS
Terri Kilgore DEPUTY

CAUSE NO. DC-18-08923

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 TRACY FLEMING AND NORMA EGEA'S SUPPLEMENTAL DESIGNATION OF EXPERT WITNESS DR. JAY MABREY

COMES NOW, Plaintiffs Tracy Fleming and Norma Egea, and serve this their Supplemental Designation of Expert Witness Dr. Jay Mabrey, and for such would show the Court as follows:

I. DESIGNATION OF EXPERTS

Plaintiffs previously designated Dr. Jay Mabrey as a treating physician and non-retained expert witness. That was originally done when retained and non-retained experts were identified on July 11, 2019, and he was designated again when other experts were designated against Smith & Nephew on February 14, 2020. Things changed on April 24, 2020 when Smith & Nephew finally produced an email from Dr. Mabrey (Smith & Nephew_Fleming-0110251) that the company had possessed for almost fourteen years. This supplemental designation incorporates the opinions in Smith & Nephew_Fleming-0110251 and is the Plaintiffs' good faith attempt at providing the parties with an outline of Dr. Mabrey's anticipated testimony at his upcoming Zoom deposition scheduled by agreement for Wednesday, June 17, 2020. Plaintiffs retained Dr. Mabrey as an expert consultant on May 19, 2020, and this is the second supplement related to Dr. Mabrey in this case since then.

A. **Brief summary of opinions of retained and consulting experts and basis for opinions (TEX. R. CIV. P. 194.2(f)(2), 194.2(f)(3), 194.2(f)(4)(A), and 194.2(f)(4)(B)**.

The supplemental information required by TEX. R. CIV. P. 194.2(f)(2) and TEX. R. CIV. P. 194.2(f)(3) (subject matter, opinions, brief summary of basis for them, and documents reflecting such information) for Dr. Mabrey is as follows: he will base his opinions in part on his education and professional experience in the relevant fields as noted in his CV and a review of documents and litigation materials that Plaintiffs' counsel provided to him as noted below. Dr. Mabrey's expert report is Smith & Nephew_Fleming-0110251 and it identifies his opinions and provides specific information that he is basing his opinions on. His basic opinion is that Smith & Nephew was required to "**wait for final FDA approval for any other case**" besides the specific surgery identified for the specific patient on Smith & Nephew_Fleming-0110251. Dr Mabrey is also of the opinion that as far back as 2006, "**three other companies, Biomet, DePuy, and Zimmer offered nearly identical, FDA-approved devices composed of large diameter heads with tapers to fit their hip stems**."

Detailed information required by Tex. R. Civ. P. 194.2(f)(3) and the below discovery requests concerning the general substance of Dr. Mabrey's mental impressions and opinions is provided in his expert report identified above and also include the following topics: (a) the medical device industry and the relationship between orthopedic surgeons, hospitals, sales representatives, the manufacturers of the devices that are sold, and federal and state regulatory agencies; (b) the responsibilities and obligations of the entities and people involved in Tracy Fleming's implantation surgery in September 2009, including Smith & Nephew, Inc., Dr. Schubert, Brian Childress, and Neylu, Inc..; (c) safer alternative hip implant designs and products were available from Smith & Nephew and other manufacturers in September 2009, (d) the benefits to patients and surgeons of a device having received FDA approval or clearance; (e) the need for compliance with regulatory

processes; (f) the orthopedic biomechanics of hip implants; and (g) all other matters referred to in his expert report.

The information required by Tex. R. Civ. P. 194.2(f)(3) and the below discovery requests concerning the brief summary of the basis for his opinions is as follows:

Dr. Mabrey will base his opinions about Smith & Nephew, Inc. and the other Defendants' conduct on his review of documents provided to him as described herein. This is in addition to his background, training, and experience as noted in his CV and in his report. The information required by Tex. R. Civ. P. 194.2 (f)(4)(A) and Tex. R. Civ. P. 194.2 (f)(4)(B) concerning documents provided to him includes **FLEMING [MAB]-000001–000452**. These documents are more fully described in the Production Index that has previously been made available to counsel. Any additional information requested may be produced again if specifically requested. The documents produced as **FLEMING [MAB]-000001–000452** include both documents and communications. The information required by Tex. R. Civ. P. 194.2(f)(4)(A) (documents, things, reports, models, or data compilations) for information provided to or received from Dr. Mabrey has previously been described to opposing counsel and was made available to them via Dropbox link as recently as June 2, 2020. Only one additional document has been shown to Dr. Mabrey since that last supplement, a photograph of a Synergy Stem instrument kit that is stamped **FLEMING [MAB]-000452**. That document is now available on Dropbox as well, and Plaintiff's counsel has separately emailed that single photograph to defense counsel.

The information required by Tex. R. Civ. P. 194.2(f)(4)(A) (documents, things, reports, models, or data compilations) for information provided to or received from Dr. Mabrey is summarized as follows and has previously been made available to opposing counsel.

A. **Supplemental designation of Dr. Mabrey**

Dr. Jay Mabrey is an orthopedic surgeon who has been designated previously, and everything in that Designation is applicable here, and is incorporated herein by reference. Dr. Mabrey is retired, but his business office address is 343 Brightwaters Boulevard NE, Saint Petersburg, FL 33705. His email address is dallasbonedoc@me.com, and his telephone number is unknown.

Dr. Mabrey is a witness who is well known to all the parties in this case. He referred Tracy Fleming to Dr. Schubert. Brian Childress was Dr. Mabrey's sales rep for Smith & Nephew while Dr. Mabrey was still practicing medicine in Dallas. Smith & Nephew knows Dr. Mabrey from working with him for years in various capacities, including as a customer using Smith & Nephew medical devices and as an FDA representative when Dr. Mabrey was the Chairman of the FDA Panel that approved the BHR in America. Smith & Nephew worked extensively with Dr. Mabrey on the limited approval for a backup device as described in his expert report. His report mentions assistance he was providing to Smith & Nephew with the FDA on August 10, 2006 as follows: "I have continued my efforts at FDA to ascertain the status of the total hip version." Plaintiffs have requested information from Smith & Nephew about that activity, but none has been provided yet. Smith & Nephew knows more about that activity than Plaintiffs do.

In addition, it is believed that Smith & Nephew has presented Dr. Mabrey as an expert witness on at least a dozen occasions on its behalf in patent litigation. He also has consulted with Smith & Nephew about hip implants, and has used their written materials for speeches he has given to the orthopedic community about hip implants. He has visited Smith & Nephew's world headquarters. He has used Smith & Nephew's products in patients of his, including Smith & Nephew metal hip implants and the BHR Cup and femoral head involved in this case.

Dr. Mabrey first spoke with Plaintiff's counsel on May 19, 2020 and was designated as an expert in *Kemp v. Smith & Nephew* on that very day. Dr. Mabrey wrote the email marked SMITH&NEPHEW_FLEMING-0110251 in August of 2006. He is and was of the opinion that Smith & Nephew "*will have to wait for final FDA approval*" before it can sell the combination of parts that were implanted in the Plaintiff in this case. To the extent a written report is required, Plaintiff submits SMITH&NEPHEW_FLEMING-0110251 as Dr. Mabrey's written expert report. This expert report was produced by Smith & Nephew within the last couple of weeks, but the company has had it for almost fourteen years. All of the opinions and conclusions in SMITH&NEPHEW_FLEMING _0110251 are incorporated herein by reference.

Dr. Mabrey's background, training, and experience are referenced in his CV dated March 26, 2020 that was previously produced to counsel. Dr. Mabrey was Chairman of the FDA Advisory Committee that voted to approve the Premarket Approval application for the Birmingham Hip Resurfacing ("BHR") device in the United States. Dr. Mabrey will be called to testify about metal-on-metal total hip arthroplasty and resurfacing success rates, failure rates, failure modes, and the symptoms, side effects, and health impact of metal-on-metal failure, especially involving large diameter metal heads and adapter sleeves like the combination of parts used in this case. In addition, Dr. Mabrey may be asked questions about any emails that have his name on them out of the thousands of documents that Smith & Nephew has produced or will produce in hip implant litigation. Plaintiffs have formally requested such emails form Smith & Nephew, and Dr. Mabrey has signed an authorization permitting the production of such information. No responsive documents have been provided yet.

Dr. Mabrey may also testify about his observations of the numerous promises that Smith & Nephew made to the Food and Drug Administration when seeking approval to market the BHR

to surgeons in America. Dr. Mabrey may also testify about the lack of training that Smith & Nephew provided to surgeons wishing to perform hip resurfacing with the Birmingham Hip Resurfacing system as reflected in his testimony at the FDA Advisory Meeting pertaining to the medical device Menaflex on November 14, 2008. Dr. Mabrey stated the following and it is anticipated he will testify to these facts and opinions if permitted:

> *"I think from my own personal experience, having been on the Panel that approved the Birmingham Hip and having introduced the suggestion that there be extensive clinical training for surgeons attempting to implant the Birmingham Hip, that held for about six months or so after the implant was introduced. And 1 then, after that, literally every orthopedic surgeon in the city was putting in Birmingham hips whether correct or incorrect. So my concern would be if this device is offered that there be some type of training program offered and some evaluation of skills because it does appear to be somewhat technique-dependent."*

See FDA Transcript of FDA Orthopedic and Rehabilitation Panel Meeting Menaflex on November 14, 2008, at 236–237. Dr. Mabrey will also testify about his BHR training as provided to him by Smith & Nephew. Dr. Mabrey has signed this Court's Confidentiality Order and has been given access to some of the "Confidential" documents produced in this case, and he will be asked questions about those materials.

Dr. Mabrey may also testify about the Food and Drug Administration, the benefits to the patient and physician of FDA approval or clearance of a medical device, and the way the orthopedic business worked in America from 2005 until metal-on-metal implants were removed from the market in 2016 for safety reasons. He also may testify about surgeon use of unapproved medical devices and the responsibilities of Smith & Nephew and its sales reps when observing unapproved uses. He will also testify about a company's responsibility to inform surgeons if their medical devices were not FDA approved and to inform surgeons if the FDA had specifically rejected applications for FDA clearance to sell nearly identical products in America. Dr. Mabrey will also testify about the standard of care that applies to orthopedic surgeons when dealing with

medical device companies like Smith & Nephew. It is believed that Dr. Mabrey will testify that Brian Childress and Smith & Nephew were required to inform Dr. Schubert if the combination of parts implanted in Mr. Fleming was not FDA approved or had been rejected by the FDA. It is believed that Dr. Mabrey will testify that Brian Childress and Smith & Nephew were required to inform Dr. Schubert that the price list for the parts implanted in Mr. Fleming contained the following disclaimer of warranty:

> Customer agrees that Smith & Nephew products are approved by the United States Food and Drug Administration ("FDA") only for certain indications. Smith & Nephew 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."

In addition, it is anticipated that Dr. Mabrey will testify that Dr. Schubert was practicing medicine within the standard of care applicable to him on September 28, 2009 in Dallas, Texas if **(a)** Brian Childress told Dr. Schubert that the Smith & Nephew parts implanted in Mr. Fleming were "available" and if **(b)** Brian Childress and/or Smith & Nephew did not comply with "the right way" video (SN_Kemp-0356154) by explicitly making sure that Dr. Schubert understood that the parts were not FDA-approved for use in a total hip arthroplasty.

In addition, Dr. Mabrey's opinions include the following:

- Color Code. Dr. Mabrey holds the opinion that the color code system for the Modular Femoral Head and Birmingham Hip systems cause confusion. While the use of a color code system to prevent mismatches makes sense, color coding causes confusion if the components are not FDA cleared or approved for intraoperative use together. The addition of the colors to the labels and the boxes, in a surgeon's mind, would only serve to confirm to the surgeon that those products went together. Even if the color-coded components were never approved to go together, if the surgeon sees these labels and the nurse holds up the labels, and the colors are to confirm correct sizing, the average surgeon would not question whether the device had been approved or not because every device they use in the OR is approved by the FDA. It has to be. If something is used off-label, the products used off-label together should have different labels.

In this case, the labels tend to reinforce that the use of the BHR Cup/R3 Metal Liner with a Modular Femoral Head is an approved use.

- Sales representative's role in the OR. Dr. Mabrey is of the opinion that a sales representative should inform the doctor about the FDA status of the device. When a sales representative says that a part is "available" it says to the surgeon that the device is available because it's approved (because most hospitals do not allow unapproved parts into the OR).
- What surgeons see in the OR. It is anticipated that Dr. Mabrey will testify that, in many cases, the sales rep will remove the shrink wrap off the boxes of component devices before or during surgery. Dr. Mabrey's experience would be that he would not have seen the "HEMI-ARTHROPLASTY USE ONLY" disclaimer that is on the labeling of the Modular Femoral Head box, because most surgeons only looked at the device box to confirm sizing, which is on a different part of the box. Boxes with mixed messages (some sides saying "HEMI-ARTHROPLASTY USE ONLY" while others do not say that) are confusing and can mislead surgeons.
- On Labeling and the warning about no "commercially available device." Dr. Mabrey believes that, for an experienced surgeon who has done hundreds or thousands of total hips, there is no reason to go back and reread a surgical technique. Dr. Mabrey believes that many surgeons are not going to read the text of a surgical technique, and are more likely to look at the diagram. A disclosure about "commercially available" devices buried in the middle of text is not a warning at all—it's an easy out. Dr. Mabrey will testify that, if it is the first time he was going to use a particular device, he would probably read the surgical technique to familiarize himself with the parts. However, after a few cases, there's no need to do that. Unless the technique is so demanding that the surgeon wants to keep reviewing it, possibly. However, putting in a cup and stem is not a physically challenging task for an experienced total joint surgeon. An experienced surgeon would waste time reading company literature about a routine total hip arthroplasty when they really want to read the medical literature and learn what's going on.
- On trunnions and metallurgy. Dr. Mabrey will explain that the Garbuz, D. et al. article, "Metal on Metal Hip Resurfacing versus Large diameter Head Metal on Metal Total Hip Arthroplasty," is limited to the Durom cup. The Durom was a very similar system to the BHR, but it is not the same. He thinks a reasonable surgeon could continue using the BHR system despite that article because it is not the same system and it has different metallurgy. Dr. Mabrey remembers that S&N was very proud of the BHR metallurgy and touted the metallurgy as being "better" and "different from other products". Dr. Mabrey watched S&N make the BHR cup in England and remembers being impressed with how Mr. Derek McMinn had worked out the metallurgy issues. Dr. Mabrey believes the problem with large diameter MOM was the trunnion, and that surgeons were worrying about the trunnion in 2010 onwards. He does not remember S&N ever coming out to address trunnion issues with the Mod Head, and he thinks most surgeons skipped over the trunnion issues because of S&N's metallurgy claims.

- Marketing. Dr. Mabrey will also testify that, according to the CD called "Leveraging BHR to Maximize sales", (Hutchens(SN)-0023796), the company used the BHR as a "carrot" to get the "commitment" of surgeons for S&N products. Dr. Mabrey remembers that, when the BHR was launched, everybody wanted to use the BHR and that it was a huge draw. He also is of the opinion that the AAOS posters displayed at the AAOS national convention in 2009, (*see* Hutchens(SN)-0059108), made it look like Smith & Nephew had metal-on-metal total hips available. If he had received a sales pitch that was similar to the sales pitch depicted by "the right way" video stamped SN_Kemp_0356154, he would have moved to a different implant that had FDA clearance or approval for use as a metal-on-metal total hip arthroplasty. *See also* Bogk-0000167 (video where McMinn does not disclose off-label status). Dr. Mabrey is also of the opinion that most sales reps do not describe a product the way the R3 is described in "the right way" video, because very few surgeons would ever use such a product.
- On FDA. In addition to everything else contained in this Designation and in Dr. Mabrey's report, it is expected that Dr. Mabrey will testify that the FDA does "not clear or approve individual components but systems of components (e.g., stems, heads, cups, screws, etc.) that form joint replacement device systems." *See* FDA's deficiency letter dated September 1, 2006, SN_Kemp_0271504 at 00271508.

II. SUPPLEMENTAL RESPONSE TO REQUESTS FOR DISCLOSURE

Plaintiffs previously answered Requests for Disclosure from all Defendants asking about experts, and this Designation should also be considered a Supplemental Response to their previous responses to the Requests for Disclosure served by all three Defendants:

(f) Pursuant to TEX. R. CIV. P. 194.2(f), for any testifying expert:
- (1) the expert's name, address and telephone number;
- (2) the subject matter on which the expert will testify;
- (3) the general substance of the expert's mental impressions and opinions and a brief summary of the basis for them, or if the expert is not retained by, employed by, or otherwise subject to the control of the responding party, documents reflecting such information;
- (4) if the expert is retained by, employed by, or otherwise subject to the control of the responding party:
  - (A) all documents, tangible things, reports, models, or data compilations that have been provided to, reviewed by, or prepared by or for the expert in anticipation of the expert's testimony; and
  - (B) the expert's current resume and bibliography;

SUPPLEMENTAL RESPONSE: See the information provided above along with the previously-produced CV and written report for additional documents and information responsive to these

discovery requests about Dr. Jay Mabrey.

III. SUPPLEMENTAL RESPONSE TO REQUESTS FOR PRODUCTION

Plaintiffs previously answered all of Defendants' Requests for Production asking about experts, and this Designation should be considered a Supplemental Response to Plaintiffs' previous Responses to Requests for Production. Plaintiffs hereby supplement their previous responses to the following specific discovery requests.

A. Brian Childress and Neylu, Inc.'s Requests for Production.

55. A copy of the curriculum vitae and/or resume of all consulting experts whose opinions or impressions have been reviewed by a testifying expert with regard to the allegations in this lawsuit.

SUPPLEMENTAL RESPONSE: Dr. Jay Mabrey is an orthopedic surgeon and is a fact witness and a testifying expert in this case. Dr. Mabrey is retired, but his business office address is 343 Brightwaters Boulevard NE, Saint Petersburg, FL 33705. Dr. Mabrey's background, training, and experience are referenced in his CV dated March 26, 2020.

56. A copy of any and all documents, tangible things, and/or stored electronic information, including without limitation all tangible reports, physical models, compilations of data, and other material prepared by a consulting expert whose opinions have been reviewed by a testifying expert with regard to the allegations in this lawsuit.

SUPPLEMENTAL RESPONSE: Dr. Jay Mabrey is an orthopedic surgeon and is a testifying expert and fact witness in this case. Smith & Nephew has produced some communications to and from Dr. Mabrey in this and the related case of *Kemp v. Smith & Nephew*. Documents made available to Dr. Mabrey are produced in the Dropbox link that Plaintiffs previously provided to opposing counsel on June 2, 2020. *See* the Table of Contents that was previously produced.

57. A copy of the curriculum vitae and/or resume of all testifying experts with regard to the allegations in this lawsuit.

SUPPLEMENTAL RESPONSE: See the information provided above along with the CV and written report for additional documents and information responsive to these discovery requests about Dr. Jay Mabrey.

58. A copy of any and all documents, tangible things, and/or stored electronic information, including without limitation all tangible reports, physical models, medical literature, medical records, compilations of data, and any other material prepared by, prepared for, returned to, reviewed by, relied

upon in forming opinions, or shown to, in whole or in part, any person whom you anticipate will testify as an expert witness in this case.

SUPPLEMENTAL RESPONSE: Dr. Mabrey was provided the documents in the Table of Contents previously produced to opposing counsel as well as the materials produced at **FLEMING [MAB.]-000001–000452**. *See also* the above Designation for additional documents and information responsive to these discovery requests.

B. Dr. Schubert's Requests for Production to Tracy Fleming.

2. Any tangible reports, correspondence, writings, physical models, compilation of data, or other material prepared by any expert used for consultation but whose work product was reviewed by any expert who is to be called as a witness at the time of trial.

SUPPLEMENTAL RESPONSE: See the information provided above along with the CV and written report dated August 10, 2006 for additional documents and information responsive to these discovery requests about Dr. Jay Mabrey**.**

3. Every publication, article, periodical, pamphlet, book, treatise, or other authority you intend to utilize at the time of trial and/or which you intend to establish as an authoritative and reliable source.

SUPPLEMENTAL RESPONSE: See the information provided above along with the CV and written report for additional documents and information responsive to these discovery requests about Dr. Jay Mabrey.

5. Copies of all publications, articles, journals, or other documents you intend to use to establish standard of care in this matter.

SUPPLEMENTAL RESPONSE: See the information provided above along with the CV and written report for additional documents and information responsive to these discovery requests about Dr. Jay Mabrey.

9. Copies of each and every publication, article, pamphlet, treatise, book, periodical, or other written materials ever prepared by your designated expert witness(es) related to the subject matter of this Lawsuit.

SUPPLEMENTAL RESPONSE: See the information provided above along with the medical articles listed in Dr. Mabrey's CV and written report for additional documents and information responsive to these discovery requests about Dr. Jay Mabrey.

IV. SUPPLEMENTAL RESPONSE TO INTERROGATORY ANSWERS

Plaintiffs previously answered Defendants' Interrogatories asking about experts, and this Designation should be considered a supplemental response to Plaintiffs' previous Answers to

Written Interrogatories. Plaintiffs hereby supplement their previous responses to the following specific discovery requests.

A. Neylu, Inc.'s First Set of Written Interrogatories to Tracy Fleming.

1. If you contend that the S&N Product at issue in this lawsuit had a design defect and/or marketing defect, please state the basis and facts for your contention.

2. If you contend Defendants were negligent, made misrepresentations, breached warranties, conspired or acted in concert, committed fraud, violated the DTPA, or misrepresented to the FDA, please state your basis and facts for supporting your contention.

11. Please state in detail the factual basis for each and every way you contend that Defendants were responsible for or caused each of the physical and/or mental and/or emotional injuries listed in the answer to the preceding interrogatory.

15. Please state the name, address, and telephone number of any person who is expected to be called to testify at trial pursuant to TRCP 192.3(d).

SUPPLEMENTAL RESPONSE: Plaintiffs allege that design defects and/or marketing defects existed in the components implanted in Mr. Fleming and they also contend that Smith & Nephew, Neylu, Inc. and Brian Childress were negligent, made misrepresentations, breached warranties, conspired or acted in concert, committed fraud, and violated the DTPA. It is anticipated that Dr. Mabrey will testify about some of these issues when he is deposed on June 17, 2020 as noted in his expert report and above.

B. Dr. Schubert's First Set of Written Interrogatories to Tracy Fleming.

8. Please identify (by title, author, editor, edition, publisher, date of publication, section, portion and page) each published treatise, periodical, book, or pamphlet on a subject of history, medicine, or other science or art that you may offer or use in the trial of this case under Rule 803(18) of the Texas Rules of Evidence.

12. Pursuant to Tex. R. Civ. P. 192.3(d), please identify by name, address, and telephone number any person who is expected to be called by Plaintiffs to testify at trial.

16. Please list every article, pamphlet, treatise, book, periodical, or other written material prepared by your designated expert witness(es) which relates to the subject matter of this Lawsuit, or which provides any basis for your expert's/experts' opinions.

SUPPLEMENTAL RESPONSE: The name, address, and telephone number of any person who is expected to be called to testify at trial is listed in these Supplemental Answers and in the original

Answers to these Interrogatories, but Plaintiffs do not know Dr. Mabrey's telephone number. Plaintiffs will supplement as additional persons are identified.

In addition, Plaintiffs have previously produced Dr. Mabrey's report and his current CV.

Respectfully submitted,

LAW OFFICE OF KIP PETROFF

/s/ Kip Petroff

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ATTORNEYS FOR PLAINTIFFS

Certificate of Service

I hereby certify that on June 8, 2020, a true and correct copy of the foregoing has been served by email on the Defendants as follows:

Defendants **Smith & Nephew, Inc., Brian Childress** and **Neylu, Inc.**, to: Mr. Brian P. Johnson, Ms. Kealy C. Sehic, Mr. David W. O'Quinn, Mr. Douglas Moore, and Ms. Leila D'Aquin.

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

/s/

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