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

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

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

COME NOW, Smith & Nephew, Inc. ("S&N"); Brian Childress; and Neylu, Inc. (collectively, "Defendants"), and file this Reply in support of their Motion to Quash Plaintiffs' Notice of Oral and Video Recorded Deposition of Dr. Jay Mabrey (the "Notice") and Motion to Strike Plaintiffs' Supplemental Designation of Expert Witness Dr. Jay Mabrey, and for cause would show the following:

**ARGUMENT SUMMARY**

Plaintiffs have known about Dr. Mabrey, his connection to this case as a treating physician and head of department, and his involvement with an FDA Advisory Panel, since the beginning of this litigation, but they chose not to retain him as an expert witness and pay him a retainer until May 19, 2020. Now,in an attempt to come up with some reason as a pretext for their late designation of Dr. Mabrey as a retained expert, Plaintiffs have seized upon a 14-year old email dealing with another patient and unrelated circumstances giving rise to an off label use of S&N components. S&N's motion to strike and motion to quash address two aspects of the same issue – Plaintiffs' attempt to designate a retained expert outside the agreed scheduling order

deadline (February 14, 2020) and to require S&N to take an expert deposition without a report, without an adequate designation, without feedback from its own experts, and at a time of Plaintiffs' choosing.[1]

Simply put, Plaintiffs (1) missed the expert designation deadline and did not seek leave from court; (2) failed to comply with the scheduling order by providing a report and an adequate designation; and (3) improperly seek to prejudice Defendants by rushing to depose Dr. Mabrey despite these and other deficiencies in the designation. Granting leave would prejudice S&N because the expert deadline has closed and allowing this deposition to occur will prevent S&N from adequately discovering Dr. Mabrey's opinions.

**REPLY TO FACTUAL AND PROCEDURAL BACKGROUND**

Let it be clear. Dr. Mabrey is not being designated as a retained expert in this case because of his factual knowledge. Dr. Mabrey's only factual connection with Plaintiffs occurred when he referred Mr. Fleming to Dr. Schubert for surgery. Plaintiffs are only now designating Dr. Mabrey as a retained expert because they neglected to so much as interview him (despite identifying him long ago) until May 19, 2020, and only then discovered that he might have opinions helpful to them.

Plaintiffs tout Exhibit A as a "game changer," but a closer look explodes that characterization. The background is apparent from the context of the email. A surgeon at Baylor University Medical Center wanted the option to use a S&N component in an off-label application as a backup to a planned hip resurfacing procedure. The surgeon contacted the Chief of the

[1] Significantly, Plaintiffs and Co-Defendants have had the benefit of coordination between their experts as Dr. Mabrey prepares for his deposition. *See* Ex. 1 (Email from Jay Mabrey to Kip Petroff dated June 2, 2020). The only people without access to Dr. Mabrey's opinions in order to prepare for the deposition are those associated with S&N.

Department of Orhopaedics (Dr. Mabrey) for approval, and he gave that approval. Indeed, Dr. Mabrey expressed his support for FDA approval of the "total hip version of the Birmingham Hip Resurfacing." He noted that three other companies already had FDA approved systems using "nearly identical" components, which justified his decision. However, he did make it clear that he was not authorizing blanket off label use in his department at Baylor. Dr. Mabrey was speaking in the context of a single patient and only for his department at Baylor. He emphasized that he did not speak for the FDA, and did not purport to instruct S&N or surgeons in other departments.

Finally, S&N's discussions with Plaintiffs about deposing Dr. Mabrey as a fact witness concerning his 2006 email have nothing to do with taking the deposition of a retained expert. These are birds of a different color, and Plaintiffs cannot leverage S&N's willingness to do one with permission to do the other.

## ARGUMENT IN REPLY

### I. DR. MABREY'S EXPERT DEPOSITION CANNOT OCCUR AS A LATE-DESIGNATED RETAINED EXPERT WITH NO REPORT AND AN INADEQUATE DESIGNATION.

Plaintiffs cannot both designate a retained expert out of time and dictate to S&N when and on what basis that expert's deposition may be taken. When a court has set a deadline for designation of experts and ordered that all experts produce a report (as this Court has done), the parties are bound to comply. Failure to timely or adequately respond bars the admission of the undisclosed or inadequately disclosed evidence.

> A party who fails to make, amend, or supplement a discovery response in a timely manner **may not introduce in evidence** the material or information that was not timely disclosed, or offer the testimony of a witness (other than a named party) who was not timely identified.

TEX. R. CIV. P. 193.6(a) (emphasis added). In this case, it is Plaintiffs' burden to establish an exception to this rule by proving that there was good cause for its failure or by establishing the lack of unfair surprise or unfair prejudice. TEX. R. CIV. P. 193.6(a)(1)&(2); 193.6(b). The proper remedy is not simply to allow additional discovery. The proper remedy is to strike that testimony, a nondiscretionary mandate unless Plaintiffs carries their burden of proof, which they have not done.

Plaintiffs still have not filed a motion for leave, but even treating their response and opposition as such a motion under Rule 71, they have not shown that they are entitled to such leave. Despite Plaintiffs' suggestions otherwise, this Court cannot arbitrarily disregard its own orders but may alter deadlines when justified by the requesting party. *Mercedes-Benz Credit Corp. v. Rhyne*, 925 S.W.2d 664, 666 (Tex. 1996). The rules of discovery are not a system of ratchets to be tightened by the court for one party and loosened for the other. Plaintiffs claim that they have good cause for their delay because they did not receive Dr. Mabrey's 2006 email concerning another patient (an email that endorsed an off label use of S&N products) until April 24, 2020. But this rationalization is nothing but a fig leaf that does little to camouflage Plaintiffs' naked arguments.

Plaintiffs' attorney certainly knew who Dr. Mabrey was as he designated Dr. Mabrey as an expert treating physician:

> **Dr. Jay Mabrey** is an orthopedic surgeon who also was the doctor who referred Tracy Fleming to Dr. Schubert for resurfacing. Upon information and belief, Dr. Mabrey is retired, but his last known business office address was 3600 Gaston Avenue, Suite 1101, Dallas, TX 75246. Dr. Mabrey was also the deciding vote 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. In addition, Dr. Mabrey may testify about his recommendations, opinions and conclusions for Mr. Fleming as referenced in his medical records.

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 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 Dallas in and before September 2009. **He also may testify about surgeon use of unapproved medical devices** in September 2009 along with his personal knowledge of the meaning and importance of the American Academy of Orthopaedic Surgeon's Position Statement on off label use that was issued in 2009 before Mr. Fleming's surgery.

Ex. 1 (Designation) (bold added to text) As reflected in Plaintiffs' designation of Dr. Mabrey , Plaintiffs' counsel was already well-aware of Dr. Mabrey's work with the FDA with regard to metal-on metal hip implant devices, and represented in the designation that Dr. Mabrey had knowledge about total metal-on-metal hip arthoplasty, off label use of medical devices, and the American Academy of Orthopedic Surgeon's Position Statement on off label use. Furthermore,

Plaintiffs intended to solicit Dr. Mabrey's expertise concerning off label use as demonstrated by the bolded language. There is nothing in the 2006 email concerning Dr. Mabrey's expertise that Plaintiffs were not already aware of in February 2020 when they designated Dr. Mabery as a non-retained expert.

Dr. Mabrey's email revealed the truth in orthopedic surgery that (1) yes, surgeons can and do use medical devices in off label configurations when medically appropriate and (2) yes, each off label use is a one-time decision that does not endorse off label use in every case for all patients. There is nothing earth-shattering or new about this reality. Plaintiffs feigned shock at discovering that doctors (including Dr. Mabrey) approve off label use on a case-by-case basis is not credible and is contradicted by his own counsel's representations in other litigation.

Plaintiffs claim that S&N should not be surprised that Dr. Mabrey may be called as a witness regarding his factual knowledge about FDA approval and the decision process for off label use. But the motion to strike is not about whether Dr. Mabrey may be called **as a fact witness**. Indeed, the examples of proposed questions given by Plaintiffs are not factual at all but inquire about Dr. Mabrey's expertise as an M.D. and surgeon sitting on a policy-making FDA committee and about the medical judgment exercised in approving an off-label use of a surgical device. But such disputes aside, this motion is about whether Dr. Mabrey may be untimely designated and called to be deposed **as a retained testifying expert** (he cannot) and about whether Plaintiffs can designate a retained expert without providing a report and without producing the materials **that the expert relied upon** in reaching the opinions that have been

disclosed (he cannot).[2] Plaintiffs offer no evidence that supports a finding that S&N has not been unfairly surprised or prejudiced by his untimely, inadequate designation of Dr. Mabrey four months after the expert designation deadline.

The "simple remedies" suggested by Plaintiffs fly in the face of the purpose of a scheduling order, which is to provide a plan for preparing a case for trial. It is certainly simple to discard the plan and allow a free-for-all, but it is not efficient of fair. Plaintiffs have a responsibility to identify witnesses and investigate their claim. Plaintiffs knew the identity of Dr. Mabrey long ago, knew that he was a treating physician, and knew that he served on the FDA committee. Just because they neglected to interview him until May 19, 2020, and only then discovered that he had information they might be interested in is not a reason to allow Plaintiffs to supersede the plan to the prejudice of Defendants.

Plaintiffs claim that the remedy when the producing party has not met his discovery obligations and "cannot show good cause, no unfair surprise, and no unfair prejudice" is to allow more discovery, citing TEX. R. CIV. P. 193.6(c). But that is not what Rule 193.6(c) says. It allows the responding party to request "a continuance or temporarily postpone trial." *Id.* Plaintiffs have not moved for nor contacted S&N to request a continuance or postponement of

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[2] The option to conduct an immediate deposition in lieu of a report only applies when the trial court has not ordered that a report be provided by all retained testifying experts. *See Dennis v. Haden*, 867 S.W.2d 48, 51-52 (Tex. App.—Texarkana 1993, writ denied). A court may not simply disregard its own requirement that experts produce a report.

Furthermore, disclosing a list of materials that Plaintiffs have provided to Dr. Mabrey does not satisfy the rule requirement. Rule 194.2(f)(4)(A) requires disclosure of materials "provided to, **reviewed by**, or **prepared by** or for the expert." Nothing Plaintiffs have provided includes the materials Dr. Mabrey **reviewed** or **prepared** in drafting the 2006 email or in providing his comments or conclusions to the FDA. Instead, Plaintiffs have provided some general materials that he indicated that he would provide to Dr. Mabrey.

the trial date. If that is what they are asking for, S&N urges Plaintiffs to make that request explicitly so that it can be responded to and considered.

## II. PLAINTIFFS MISSTATE THE LAW BY CLAIMING A PROCEDURAL DEFECT IN DEFENDANTS' MOTIONS.

Plaintiffs' discussion of procedural defect is simply wrong. It is wrong because Rule 199.4 does not require S&N to offer an alternative date in its motion to quash, and (Plaintiffs' representations notwithstanding) S&N did not move for protection under Rule 192.6(a). Dr. Mabrey's deposition is now set for June 17, 2020, but the issue remains in question as to whether Plaintiffs can notice the deposition of a purported retained expert who has not been timely designated, who has not been adequately designated, and who has not produced a report as required by this Court's order.

## PRAYER

WHEREFORE, PREMISES CONSIDERED, Defendants Smith & Nephew, Inc.; Brian Childress, and Neylu, Inc. respectfully request that the designation of Dr. Jay Mabrey as a retained testifying expert be stricken, that Dr. Mabrey be excluded from testifying as a retained expert in this matter, and that his deposition be quashed. Further, Defendants request such other and further relief, both at law and in equity, to which they may be justly entitled.

Respectfully submitted,

By: */s/ Brian P. Johnson*

Brian P. Johnson
TX Bar No. 10685700
Kealy C. Sehic
TX Bar No. 24040688
JOHNSON, TRENT & TAYLOR, LLP
919 Milam, Suite 1500
Houston, Texas 77002
(713) 222-2323 (Telephone)
(713) 222-2226 (Facsimile)
bjohnson@johnsonsontrent.com
ksehic@johnsontrent.com

Kim E. Moore (La. Bar No. 18653)
David W. O'Quinn (La. Bar No. 18366)
Leila A. D'Aquin (TX Bar No. 00789882)
Sarah Segrest-Jay (La. Bar No. 32476)
Kelly Brilleaux (La. Bar No. 33030)
IRWIN FRITCHIE URQUHART & MOORE, LLC
400 Poydras Street, 27th Floor
New Orleans, Louisiana 70130
(504) 310-2100 (Telephone)
(504) 310-2101 (Facsimile)
kmoore@irwinllc.com
doquinn@irwinllc.com
ldaquin@irwinllc.com
ssegrestjay@irwinllc.com
kbrilleaux@irwinllc.com

**ATTORNEYS FOR DEFENDANTS**

## CERTIFICATE OF SERVICE

I certify that, in accordance with the Texas Rules of Civil Procedure, a true and correct copy of the foregoing document was served upon the following counsel of record on the 12th day of June 2020:

Kip Petroff
Caio Formenti
LAW OFFICE OF KIP PETROFF
8150 North Central Expressway
Suite 500
Dallas, Texas 75231
kpetroff@petroffassociates.com
caio@kippetroff.com

David Criss
Alexandra Sallade
CRISS LAW GROUP, PLLC
12222 Merit Drive, Suite 1350
Dallas, Texas 75251
dcriss@criss-law.com
alexandra@criss-law.com

Kristopher A. Bonham
K. Bonham, PLLC
307 Pine Circle
Boca Raton, FL 33432

*/s/ Brian P. Johnson*
Brian P. Johnson

# EXHIBIT 1

## Kip Petroff

**From:** Jay Mabrey <dallasbonedoc@me.com>
**Sent:** Tuesday, June 2, 2020 10:33 AM
**To:** Kip Petroff
**Subject:** Re: One more update re: Dr. Mabrey's Dropbox for Smith & Nephew cases

David Criss contacted me via email today and asked to speak with me prior to my deposition. If it's ok with you, I'll agree to talk to him after our discussion on Thursday, or would you rather hear what he has to say before then?

On Jun 1, 2020, at 6:23 PM, Kip Petroff <kpetroff@petroffassociates.com> wrote:

Hi Dr. Mabrey. Attached is the next and hopefully last update to Dropbox in connection with our Zoom call scheduled for this Thursday afternoon. This lists everything in Dropbox, including the documents added Friday at 5:43 p.m. (see email below) as well as a few more added today.

I also wanted to let you know that you will be receiving a FedEx package tomorrow that contains a small notebook of ***some*** of the materials in Dropbox. Nothing is new in the notebook; everything is already in Dropbox.

Included in the FedEx package are four color-coded trial heads that we will want to discuss with you on Thursday. Please make sure you have those handy when we talk on Thursday.

Thanks again, and let me know if you have any questions. Sincerely,

Kip Petroff
Dallas, Texas
www.kippetroff.com
email= kpetroff@petroffassociates.com

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**From:** Kip Petroff
**Sent:** Friday, May 29, 2020 5:43 PM
**To:** Jay Mabrey <dallasbonedoc@me.com>
**Cc:** Kip Petroff (kpetroff@petroffassociates.com) <kpetroff@petroffassociates.com>; Caio Formenti <caio@kippetroff.com>; Kris Bonham <kris@kippetroff.com>
**Subject:** Update re: Dr. Mabrey's Dropbox for Smith & Nephew cases

Dr. Mabrey, Thanks again for talking with us Wednesday morning. As we discussed, we have added a new folder to your dropbox titled "**Additional Materials (added on 05.29.2020)**." This folder contains 6 subfolders: **(1)** Taper Wear Documents; **(2)** Color Code Documents; **(3)** Warnings and Warranties Documents; **(4)** Knowledge of Off Label Use Documents; **(5)** Dr. Mabrey Smith & Nephew Documents, and **(6)** Miscellaneous.

Attached is a revised Table of Contents with an item by item list of the entire dropbox. Please let me know if you have any other questions or documents you may want to see and we will provide them for you. Thank you again for your help with these cases. I look forward to talking with you June 4.

Sincerely,

Kip Petroff
Dallas, Texas
www.kippetroff.com
email= kpetroff@petroffassociates.com

<Dr. Mabrey Expert Dropbox TOC (06.01.2020).pdf>