

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

192nd JUDICIAL DISTRICT

**SMITH & NEPHEW, INC.’S REPLY TO
OPPOSITION TO MOTION FOR PROTECTION**

NOW COMES, Defendant, Smith & Nephew, Inc. (“S&N”), who respectfully files its Reply to Opposition to Motion for Protection:

I. PLAINTIFFS’ OPPOSITION CONFIRMS THE OVERBREADTH AND REDUDANCY OF THE 5TH REQUESTS FOR PRODUCTION (“RFPs”)

Plaintiffs’ theory is that S&N subverted Dr. Schubert’s independent medical judgment by improper financial inducements and misled him into using S&N’s hip implant products off-label. While the Opposition is pervaded with inaccuracy and distortion, it nonetheless demonstrates that the relevant inquiry is Dr. Schubert’s interaction with S&N and Brian Childress, and the information upon which Dr. Schubert based his treatment decisions – not communications sent to every orthopedic surgeon in the U.S., every contract entered into with any health care provider in Dallas, Texas, or information on irrelevant “celebrity endorsements.”

The inaccuracies in the Opposition, moreover, are pervasive. Plaintiffs characterize S&N’s consultant relationship with Dr. Schubert as nefarious and improper, but Dr. Schubert actually received consulting fees totaling \$31,600 over a seven year period from 2007 to 2014.

Almost all of these fees were for services rendered in connection with S&N's knee products, not its hip implants. Dr. Schubert's consulting contracts, the payments made to him, and documents describing the services he rendered were produced years ago in the *Kirby* case.

Plaintiffs assert that the brochure for the Henderson, Nevada seminar Dr. Schubert attended shows he was trained on off-label uses of hip implant components. The brochure shows no such thing. *See* Ex. 1. It refers only to FDA-cleared or approved products.

Plaintiffs say a price list is evidence of an intent to conceal the lack of a warranty for devices used off-label, but the price list does not apply to Baylor, which had a separate contract. Plaintiffs also allege that Baylor's contract demonstrates that S&N "lied to Baylor" by falsely representing that the devices sold had FDA-clearance or approval. Again, the truth is that the devices did have such clearance or approval: each device was FDA-approved or cleared for its labeled use.

Plaintiffs also repeatedly suggest that if a document has not been produced, it must necessarily exist and is being "deliberately withheld." Opposition p. 10. There is no support for this assertion. S&N is conducting diligent searches to respond to the 4,000+ RFPs Plaintiffs' counsel has served in this case and *Kemp*. Documents have been produced on a rolling basis and continue to be produced.

No matter how many documents S&N produces, Plaintiffs' counsel continues to serve additional RFPs -- more than 1000 since the COVID-19 national emergency was declared. The 5th RFPs are disproportionate, redundant, overly broad, and seek irrelevant information. S&N has agreed to produce the additional relevant information related to Dr. Schubert's attendance at educational programs (and Dr. Talbert's, the surgeon in the *Kemp* case.) This Court should quash the remaining RFPs and send a clear signal that this discovery onslaught must stop.

II. ARGUMENT

A. S&N's Motion Tracks Plaintiffs' Categories.

Plaintiffs assert that S&N “mischaracterizes” the RFPs “by grouping them into broad categories and omitting crucial details.” Opposition pp. 13-14. In actual fact, S&N’s Motion tracks the same categories as Plaintiffs’ 5th RFPs. The only difference is that S&N distinguished the “Mod Head /R3 Metal Liner Promotion” Requests grouped in RFPs 1-27 between those directed to Dr. Schubert and those that were not. The remaining categories precisely track Plaintiffs’.

In its Motion for Protection, S&N demonstrated the overbreadth, disproportion, redundancy, and irrelevancy of the 5th RFPs. Plaintiffs’ Opposition hurls unsupported accusations but does not demonstrate that S&N should have to respond to these duplicative, overly broad requests.

B. Any Documents Sent by Anyone at S&N or Any of Its Sales Reps to Any U.S. Surgeon

RFPs 1, 4, 7, 10, 13, 16, 19, 22, and 25 are wildly overbroad and disproportionate. Plaintiffs’ Opposition makes clear that the focus is on the actual surgeon, Dr. Schubert, and the actual sales rep, Brian Childress, involved in this case. S&N should not be compelled to conduct extensive searches for and productions of documents that have little or nothing to do with the pertinent issues. These RFPs are the very definition of a fishing expedition.

Plaintiffs suggest that since S&N has a spreadsheet of 1,194 surgeons who used S&N’s modular femoral head, these Requests are somehow appropriate or narrowly tailored. However, Plaintiffs’ specification for searches for documents relating to 1,194 particular surgeons does not eliminate the disproportionate burden and overbreadth of the RFPs. As discussed in the its Motion, S&N has produced reams of documents related to communications with Dr. Schubert

and Childress specifically, as well as S&N's marketing plans generally. S&N has also produced a host of documents on the design, testing, post-market surveillance, and overall performance of these devices. Communications with surgeons generally by and between S&N and any of its sales reps are disproportionate and overly broad, and these Requests should be quashed.

C. Repetitive, Disproportionate Requests on Communications with Dr. Schubert, Sales Rep and Surgeon Training, Contracts with Health Care Providers, and Training Agendas

In its original Motion, S&N demonstrated that it is already searching for and producing the relevant communications with Dr. Schubert and the training materials for Dr. Schubert and Brian Childress. S&N is also searching for and producing the documents relating to the negotiation of the Baylor contract. S&N is not "withholding" the contract with North Central Surgical Center, Dr. Schubert's facility. As S&N has advised Plaintiffs' counsel, such a contract has not been located, but S&N continues to search for it. S&N is searching for and producing the relevant information in these categories. RFPs that are not related to Schubert, Childress, Baylor - like RFP 277, a request for every contract with any health care provider in Dallas, Texas before the date of Plaintiffs' surgery – are overly broad and disproportionate. To the extent Requests for communications, sales rep training, surgeon training, or training agendas relate to Dr. Schubert or Childress, they are redundant and disproportionate.

D. The Focus on Excellence "Payment"

Plaintiffs devote almost 100 RFPs to allegations that Dr. Schubert was involved in a "suspicious" S&N event in June 2007. The documents surrounding this event were produced in *Hutchens* long ago. Dr. Schubert was paid \$2,500 for eight hours of work. He performed the services before the contract with him was memorialized in writing, did not submit his reimbursement until 2008, and was paid in 2009. There is absolutely no indication that these

services were not actually performed. All of the evidence is to the contrary and shows that it has no connection with the allegations in this dispute.

Plaintiffs also attempt to paint a \$20,000, 2008 consulting budget line estimate for Dr. Schubert as something illicit. This number appears on the Needs Assessment Budget, but Dr. Schubert did not perform \$20,000 worth of services in 2008. And while Plaintiffs allege that the federal monitor was concerned about improper conduct in Henderson, Nevada, in 2008, Plaintiffs do not identify the conduct, provide any documents to support the assertion, or even allege that Dr. Schubert was involved. This pursuit of a rabbit trail of irrelevant and unrelated topics is the worst kind of excess that constitutes an improper fishing expedition and is disproportionate to the needs of this case.

E. “Celebrity Endorsements”

Plaintiffs contend that the Requests as to Mark Cuban and Martha Stewart are appropriate because “S&N broke the law” by telling sales reps about their procedures. Providing information to sales reps is not “promotion” and violates no law identified by Plaintiffs, aside for the complete disconnect between this avenue of inquiry and any issue presented in this dispute. Seeking evidence to suggest bad “character” on the part of S&N could not be relevant or admissible nor could it lead to admissible evidence. Again, another unrelated fishing expedition.

F. “Compliance Monitoring”

Plaintiffs state that RFPs 489-525 are “narrow” and merely “an attempt to get unredacted copies of documents that Plaintiffs have some knowledge about.” Opposition, p. 16. The actual Requests belie this characterization. The RFPs in this group seek all “hotline reports” and all “Quarterly Reports” without any limitation to Childress or Schubert. They also seek training, reporting, certification and auditing documents that are not limited to Dr. Schubert or Childress

or the issues in this case. They also seek generalized Business Condition Reports that are not limited to Schubert or Childress. The Requests are overly broad and disproportionate.

G. Expert Communications

S&N has provided the disclosures required by the Texas Rules of Civil Procedures, and Plaintiffs' attempt to circumvent the rules is improper. TEX. R. CIV. P. 195.1. The RFPs in this group are overly broad and not limited to the issues in the case. They are disproportionate as well.

H. "Miscellaneous"

The RFPs asking for "any communications" to and from Linda Schubert, Dr. Schubert's wife, are overly broad and disproportionate. They are not limited to the issues. The Requests for videos of revision surgeries are disproportionate as well.

III. CONCLUSION

S&N has made available over 2.1 million pages of documents to Plaintiffs, and S&N is continuing to respond to the more than 4,000 RFPs previously served. S&N has agreed to produce the requested information on Dr. Schubert's (and Dr. Talbert's) participation in educational activities. S&N has provided fulsome production on the pertinent issues, and the RFPs identified in this Motion should be quashed.

Respectfully submitted,

By: /s/ Brian P. Johnson

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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 30th day of April 2020 via email:

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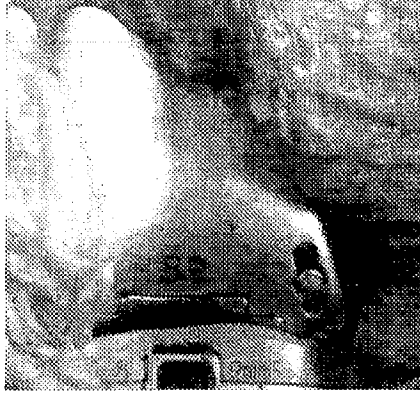


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- Surgeons can customize their training needs by attending the sessions of their choice. They are not required to attend all three days.
- We offer a faculty-to-attendee ratio that optimizes the learning experience.
- There is an experienced faculty member at each station teaching the procedure.
- Attendees are encouraged to ask questions and are given many opportunities to interact with our surgical faculty.
- Attendees are encouraged to bring X-Rays and case studies for discussion with faculty.

This course is a NON-CME Course sponsored by Smith & Nephew, Inc.
Please Note: Attendance by federal, state or local US officials requires the authorization and approval of the employing agency. No reproduction of any kind, including audiotapes and videotapes, may be made of the course presentations. Smith & Nephew, Inc. and its agents adhere to the AdvaMed Code of Ethics. Visit the AdvaMed website at www.advamed.org to review this policy.

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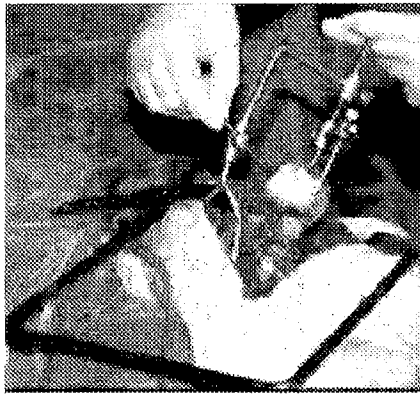


JOURNEY BCS Bi-Cruciate Stabilized Knee System

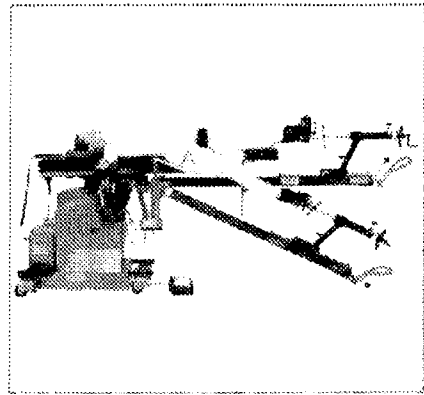


JOURNEY DEUCE Bi-Compartmental System

- The JOURNEY® Active Knee Solutions program focuses on treatment options for active patients. The course chairmen host a dinner preceding the course with lectures and discussions led by the faculty. The hands-on course includes surgical demonstrations, technique overviews and hands-on labs for the JOURNEY BCS and JOURNEY® DEUCE® systems, as well as lectures and demonstrations on related topics such as patellofemoral arthroplasty, pain management, computer assisted surgery and advanced bearing surfaces in knee replacement.



BIRMINGHAM HIP Resurfacing System



Mizuho OSI hana table

- BIRMINGHAM HIP® Resurfacing System (BHR®) program includes one or two live BHR hip surgeries broadcast via satellite, didactic sessions, templating, case studies and hands-on cadaveric training.
- Dinner with the Direct Anterior THA faculty, hosted by Dr. John Masonis, Chairman. Direct Anterior Total Hip Arthroplasty (with the ANTHOLOGY® system) Program includes surgical demonstration, didactic sessions and hands-on cadaveric training. Hana tables will be provided by OSI.

2008 Contemporary Solutions in Joint Surgery Schedule



San Diego, CA

March 26-29, 2008 San Diego, CA

- Day 1 JOURNEY DEUCE® Bi-Compartmental Knee System
JOURNEY BCS Knee System
- Day 2 BIRMINGHAM HIP® Resurfacing System
- Day 3 Direct Anterior THA, ANTHOLOGY® Hip System

April 17-19, 2008 Boston, MA

- Day 1 JOURNEY DEUCE Bi-Compartmental Knee System
JOURNEY BCS Knee System
- Day 2 BIRMINGHAM HIP Resurfacing System

April 30-May 3, 2008 Henderson, NV

- Day 1 Direct Anterior THA, ANTHOLOGY Hip System
- Day 2 BIRMINGHAM HIP Resurfacing System
- Day 3 JOURNEY DEUCE Bi-Compartmental Knee System
JOURNEY BCS Knee System

June 19-20, 2008 London, Ontario, Canada Master Series for BIRMINGHAM HIP Resurfacing System

June 25-28, 2008 Charlotte, NC

- Day 1 Direct Anterior THA, ANTHOLOGY Hip System
- Day 2 BIRMINGHAM HIP Resurfacing System
- Day 3 JOURNEY DEUCE Bi-Compartmental Knee System
JOURNEY BCS Knee System

August 14-15, 2008 Rosemont, IL

- Day 1 BIRMINGHAM HIP Resurfacing System
- Day 2 JOURNEY DEUCE Bi-Compartmental Knee System
JOURNEY BCS Knee System

August 21-22, 2008 London, Ontario, Canada

- Day 1 Revision Hips
- Day 2 Revision Knees

September 24-27, 2008 Orlando, FL

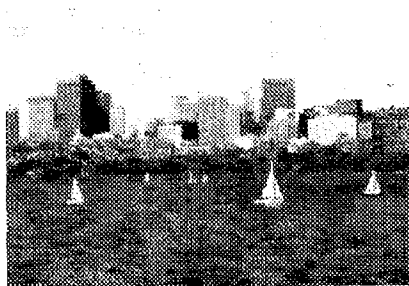
- Day 1 Direct Anterior THA, ANTHOLOGY Hip System
- Day 2 BIRMINGHAM HIP Resurfacing System
- Day 3 JOURNEY DEUCE Bi-Compartmental Knee System
JOURNEY BCS Knee System

October 16-18, 2008 Washington, DC

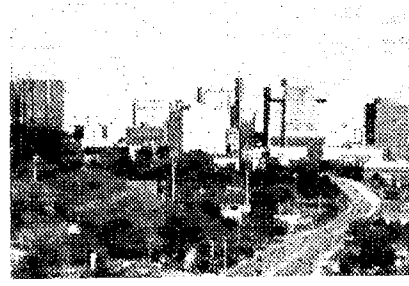
- Day 1 JOURNEY DEUCE Bi-Compartmental Knee System
JOURNEY BCS Knee System
- Day 2 BIRMINGHAM HIP Resurfacing System

November 5-8, 2008 Henderson, NV

- Day 1 Direct Anterior THA, ANTHOLOGY Hip System
- Day 2 BIRMINGHAM HIP Resurfacing System
- Day 3 JOURNEY DEUCE Bi-Compartmental Knee System
JOURNEY BCS Knee System



Boston, MA



London, Ontario



Orlando, FL