IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

RONALD BERMAN, ET AL.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	No. 11 C 1309
	)	
STRYKER CORPORATION, ET AL.,	)	
	)	
Defendants.	)	

OPINION AND ORDER

Plaintiff Ronald Berman[1] received an artificial knee system implant manufactured by defendant Howmedica Osteonics Corp.[2] Problems occurred and it had to be replaced. Plaintiff alleges strict liability and negligence in the manufacture of the device. Presently pending is defendant's motion to exclude the potential testimony of plaintiff's biomedical engineering expert, Valentina Ngai,

[1]Ronald's wife Gail Berman brings a loss of consortium claim. For simplicity, today's opinion will refer to Ronald as the sole plaintiff.

[2]It is also alleged that defendant Stryker Corporation manufactured the device. In response to the summary judgment motion, plaintiff concedes Stryker is Howmedica's parent and not liable for plaintiff's claim. Summary judgment dismissing Stryker will be granted. Today's opinion will refer to Howmedica as the sole defendant.

Ph.D., P.Eng., as not meeting the requirements for admissible expert testimony. Defendant also brings a related motion to strike Ngai's supplemental report and an affidavit provided with plaintiff's answer brief as being untimely additions to Ngai's original report. Based on Ngai's testimony being inadmissible, defendant also moves for summary judgment on the merits in that there will be insufficient evidence to support plaintiff's claims. Plaintiff does not dispute that the summary judgment motion should be granted if Ngai's testimony is excluded. The first issue to resolve is whether the supplemental report and affidavit should be considered in determining whether Ngai has admissible testimony.

By agreement of the parties and approved by the court, plaintiff's expert report was to be disclosed and the expert deposed before defendant provided its expert disclosures. Ngai's May 23, 2012 report was disclosed that day and she was subsequently deposed on June 21, 2012. The expert report of defendant's biomedical engineer, Steven Kurtz, Ph.D., was dated and disclosed on July 24, 2012. After extensions of the discovery period and rescheduling, Kurtz's deposition was completed on November 29, 2012. After a further extension of the discovery period, the deposition of William Cymbaluk was taken on January 23, 2013. Cymbaluk is a non-retained expert from whom no expert report was

required. He is defendant's Vice-President of Regulatory Affairs, Quality Assurance, and Clinical Research. In defendant's Rule 26(a)(2) disclosure, it was stated Cymbaluk would testify about regulatory issues regarding adverse incidents and FDA warning letters and "the expert report and/or deposition of" Ngai.

The deadline for defendant's dispositive motion initially coincided with the deadline for deposing Cymbaluk, but after extensions, the motion was due on February 7, 2013. On February 6, 2013, plaintiff provided defendant with a supplement to Ngai's report which responds to and seeks to rebut Kurtz's criticisms of Ngai's initial report. Plaintiff represents that, in addition to waiting to prepare this report until after Kurtz's late November 2012 deposition, final preparation awaited Cymbaluk's deposition to determine what criticisms of Ngai's report he might have. After Cymbaluk's deposition, it was determined that no response to his testimony was necessary. Counsel for plaintiff did not advise defendant, which had a dispositive motion due, that Ngai was in the process of preparing a supplement. On February 7, defendant filed its summary judgment motion and motion to exclude Ngai's testimony. A week later, it filed its motion to strike plaintiff's supplemental report, still contending that Ngai's testimony should be excluded even if the supplement is considered. With plaintiff's April 11, 2013

response to defendant's motions, plaintiff provided an affidavit from Ngai addressing criticisms of her opinions. In its reply, defendant argues Ngai's opinion testimony should be excluded even if the supplemental report and new affidavit are considered. After the motions were fully briefed, the parties mediated their dispute, but were unable to resolve it. Defendant's pending motions are now ripe for resolution.

It is unnecessary to consider whether the supplemental report is an appropriate rebuttal report served within 30 days after both of defendant's possible opposing experts were deposed. *See generally* Fed. R. Civ. P. 26(a)(2)(D)-(E), 26(e)(2); ***Bowman v. Int'l Bus. Mach. Corp.***, 2013 WL 1857192 *3-4 (S.D. Ind. May 2, 2013). Even if plaintiff had failed to timely disclose an opinion of Ngai, it will not be excluded if the delayed disclosure is harmless.[3] Fed. R. Civ. P. 37(c)(1); ***Tribble v. Evangelides***, 670 F.3d 753, 760-61 (7th Cir. 2012); ***Greybill v. Zimmer, Inc.***, 2013 WL 593460 *5-6 (N.D. Ill. Feb. 14, 2013); ***Stuhlmacher v. Home Depot USA, Inc.***, 2012 WL 5866297 *2 (N.D. Ind. Nov. 19, 2012); ***U.S. Gypsum Co. v. LaFarge N. Am., Inc.***, 508 F. Supp. 2d 601, 615 n.3 (N.D.

[3]Since any disclosure deficiency was harmless, it is unnecessary to consider the alternative that it was substantially justified. *See* Fed. R. Civ. P. 37(c)(1).

Ill.2007). Factors to consider in determining harmlessness include: "(1) the prejudice or surprise to the party against whom the evidence is offered; (2) the ability of the party to cure the prejudice; (3) the likelihood of disruption to the trial; and (4) the bad faith or willfulness involved in not disclosing the evidence at an earlier date." ***Tribble***, 670 F.3d at 760 (quoting ***David v. Caterpillar, Inc.***, 324 F.3d 851, 857 (7th Cir. 2003)). While plaintiff should have advised defendant that he intended to submit and rely on a supplemental report, it should have come as little surprise that one was being prepared since Kurtz had criticized Ngai's opinions and the reasoning of Ngai's opinion is the central issue on which defendant's summary judgment motion is based. There is no prejudice to defendant since the opinions have been disclosed well ahead of any trial date and, through its reply, defendant has had a full opportunity to address the supplement and affidavit regarding the pending motions. *Cf.* ***Greybill***, 2013 WL 593460 at *6; ***Gypsum***, 508 F. Supp. 2d at 615 n.3. Since defendant continues to press for exclusion and summary judgment, late disclosure did not even cause defendant to incur expense for a motion it would not have otherwise brought. Plaintiff has a reasonable explanation for why he was waiting to complete the supplemental report--the depositions of Kurtz and Cymbaluk--so there is no basis for inferring

willfulness. The motion to strike will be denied. The opinions expressed in Ngai's initial report, supplemental report, deposition, and affidavit will all be considered in determining whether Ngai's testimony should be excluded.

Federal Rule of Evidence 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Defendant does not question Ngai's qualifications. Defendant's contention is that Ngai's conclusions are not reliable because not adequately reasoned and not based on acceptable methodologies. "[E]xperts' work is admissible only to the extent that it is reasoned, uses the methods of the discipline, and is founded on data. Talking off the cuff--deploying neither data nor analysis--is not an acceptable methodology." ***Naeem v. McKesson Drug Co.***, 444 F.3d 593, 608 (7th Cir. 2006) (quoting ***Lang v. Kohl's Food Stores, Inc.***, 217 F.3d 919, 924 (7th Cir. 2000)). "The court's focus must be solely on the

principles and methodology the expert used and not on the conclusions generated." ***State Farm Fire & Cas. Co. v. Electrolux Home Prods., Inc.***, 2013 WL 3013531 *12 (N.D. Ind. June 17, 2013). Still, "'[i]t is not the trial court's role to decide whether an expert's opinion is correct,' but it is instead 'limited to determining whether expert testimony is pertinent to an issue in the case and whether the methodology underlying that testimony is sound.' ***Smith [v. Ford Motor Co.]***, 215 F.3d [713,] 719 [(7th Cir. 2000)]. Indeed, '[t]he question of whether the expert is credible or whether his or her theories are correct given the circumstances of a particular case is a factual one that is left for the jury to determine after opposing counsel has been provided the opportunity to cross-examine the expert regarding his conclusions and the facts on which they are based.' ***Id.*** (citing ***Walker [v. Soo Line R. Co.]***, 208 F.3d [581,] 589-90 [(7th Cir. 2000)]). This is because 'soundness of the factual underpinnings of the expert's analysis and the correctness of the expert's conclusions based on that analysis are factual matters to be determined by the trier of fact.' ***Id.*** at 718." ***Peoples State Bank v. Stifel, Nicolaus & Co.***, 2013 WL 1024917 *4 (S.D. Ind. March 14, 2013). The burden is on plaintiff to establish that Ngai's testimony would satisfy the

applicable standards. ***Lewis v. CITGO Petroleum Corp.***, 561 F.3d 698, 705 (7th Cir. 2009).

Ngai reached the following conclusions regarding plaintiff's implant being defective:

> 1. The Stryker Triathlon PS total knee device implanted into Berman's right knee on 10 July 2008 was defective due to dimensional mismatching between the tibial polyethylene insert and tibial baseplate.
> 2. The dimensional mismatch between Berman's tibial polyethylene insert and tibial baseplate is consistent with excessive and accelerated wear of the insert resulting in Berman's inflammatory response and osteolysis.
> 3. Stryker's failure to provide adequate quality control practices caused increased wear debris in Berman's right knee.
> 4. Stryker's substandard quality control practices resulted in the early failure of Berman's right total knee replacement.

Ngai Rpt. at 13.

In contrast, defendant's expert concluded:

> 1. The articulating surface damage in Mr. Berman's tibial insert was due to third body damage most likely caused by bone cement.
> 2. The backside wear in Mr. Berman's tibial insert was less severe than the articulating surface damage, and hence was negligible and clinically insignificant.

3. The reasons for revision in this case were pain and inflammation.
4. The tibial insert implanted in Mr. Berman was neither defective nor unreasonably dangerous.

Kurtz Rpt. at 2.

Stated simply, plaintiff's expert opines that the problem was that two pieces of the Triathlon did not fit together properly while defendant's expert opines that an outside substance, most likely bone cement which is added by the surgeon, caused the problem.

Defendant contends Ngai's conclusions are insufficiently supported for the following reasons. Ngai relies on Manufacturer and User Facility Device Experience ("MAUDE") reports that are inappropriate for drawing conclusions as to defects and causation in this case. Ngai never measured the device implanted in plaintiff to determine whether there was a dimensional mismatch. Ngai did not measure wear on the device. Ngai did not perform a Micro CT scan to identify foreign particles on the device or to compare it to exemplars.

Physicians, hospitals, and medical device manufacturers are required to report adverse events in which a medical device "has or may have caused or contributed to" a death or serious injury. 21 C.F.R. § 803.1(a). These are the

publically available MAUDE reports. Ngai identified 70 MAUDE reports concerning a Triathlon device during the pertinent time period which indicated poor fitting between the insert and baseplate. The reports are not themselves conclusive evidence that such defects existed nor that any defect in plaintiff's implanted device was caused by deficient manufacturing controls. *Cf.* ***McClain v. Metabolife Int'l, Inc.***, 401 F.3d 1233, 1250 (11th Cir. 2005) (adverse event reports of consumer complaints regarding a drug). To the extent Ngai relies on the reports as arousing suspicion, that would be appropriate. *See* ***In re Levaquin Prods. Liab. Litig.***, 2010 WL 8399948 *9 (D. Minn. Nov. 12, 2010). It is also appropriate for an expert to consult MAUDE reports to find other possible causes to consider or investigate. *See* ***Theofanis v. Boston Scientific Corp.***, 2005 WL 731080 *3 (S.D. Ind. March 16, 2005). MAUDE reports may also be used as evidence that a manufacturer should be on notice of a possible problem. *See* ***Levaquin***, *supra*; ***Staub v. Breg, Inc.***, 2012 WL 1078335 *7 (D. Ariz. March 30, 2012). It is also possible that some MAUDE reports contain actual statements that can be attributed to defendant and are possibly admissible as a party-admission contained in a business or public record. *See* Fed. R. Evid. 801(d), 803(6), 803(8); ***Parkinson v. Guidant Corp.***, 315 F. Supp. 2d 754, 759 (W.D. Pa. 2004) (*dictum*).

It is necessary to consider that such reports can contain inaccurate and non-validated data. Denominator data are missing which makes evaluation of the incidence or prevalence of reported events impossible.

Ngai uses the MAUDE reports to contribute to the conclusion that there were quality control issues that contributed to a manufacturing defect. This goes to the issue of negligence and is distinct from the issue of whether the device implanted in plaintiff was defective. To the extent the MAUDE reports are the only support for the existence of quality control issues at the manufacturing plant, they appear to be insufficient by themselves to support such a finding.

Ngai relies on an FDA warning letter that was issued to defendant, with the MAUDE reports being relied upon to determine that problems at the plant included the manufacture of Triathlons. Neither side addresses the admissibility of FDA warning letters. FDA warning letters may be admissible for some purposes. *See* ***Sadler v. Advanced Bionics, Inc.***, 2013 WL 1311148 *1 (W.D. Ky. March 26, 2013). Defendant contends the warning letter is irrelevant because it does not identify the products for which there were insufficient controls. Ngai relies on the MAUDE reports to link the Triathlon to the warning letter.

Absent there being evidence presented at trial that is sufficient to support the existence of quality control issues, Ngai will not be permitted to testify based on there being quality control problems during the pertinent time period at the plant where plaintiff's device was manufactured and will not be allowed to rely on or cite MAUDE reports. At trial, plaintiff should not elicit any such opinion from Ngai prior to first presenting sufficient evidence supporting that there were quality control issues at the United States manufacturing plant that involved the Triathlon.

Not being able to present evidence of quality control problems at defendant's plant does not require dismissal of plaintiff's cause of action. It still must be considered whether there is a sufficient basis to permit admission of Ngai's testimony that plaintiff's implanted device had a dimensional mismatch. For present purposes, it is sufficient to view the Triathlon as having three key components. There is a metallic femoral component ("MFC"), which is a metal piece that attaches to the bottom of the femur, that is the upper leg bone. A metallic tibial tray/baseplate ("MTB") is attached to the top of the tibia, one of the lower leg bones. A tibial polyethylene insert ("TPI") goes between the MFC and

MTB. Ngai's finding as to plaintiff's implant is that the TPI did not fit properly on top of the MTB, that is, there was a dimensional mismatch.

Defendant contends it was not an acceptable methodology to find a mismatch without actually measuring the TPI and MTB of the Triathlon that had been removed from plaintiff or measuring the amount of wear. In her supplemental report, Ngai explains why measuring the device would not be a proper method to employ in this situation. It is her position that wear on the device cannot be measured without having measured the device before it was implanted. Without being able to measure wear, matching also cannot be measured. Ngai rejects Kurtz's method of comparing the plaintiff's device to exemplars because devices produced in different lots tend to differ somewhat in size. She cites studies supporting the variation in sizes. She does acknowledge that other types of knee implants can be measured, but those devices have screwholes which leave certain parts of the device unworn and thus available for comparison. Instead of measuring plaintiff's implant, Ngai relied on the surgeon's testimony that he could feel excessive motion in the device during procedures prior to full removal. Since any proper movement should be microscopic and therefore undetectable by touch,

Ngai concludes there must have been excessive motion due to dimensional mismatch. Further, such a conclusion is consistent with pitting found on the TPI.

As to not performing a Micro CT scan, Ngai evaluated the scan conducted by Kurtz. It did not produce evidence of damage caused by foreign substances. Kurtz did detect bone cement, but that was not between the TPI and MTB and it was not microscopic, Kurtz saw it with the naked eye. (Both experts acknowledge that some foreign particles could have been removed when the surgeon cleaned the device after removal.) Ngai explains that the bone cement could have been disturbed during the process of removing the device. She also explains that blaming plaintiff's problem on bone cement or another foreign substance is inconsistent with the condition of the device following removal. Pitting only occurred on the polyethylene of the TPI. If cement had caused that problem instead of a mismatch, the metal of the MTB should also have showed signs of pitting, which it did not.

Ngai's opinions regarding problems with plaintiff's implant being caused by a dimensional mismatch are supported by sufficient methodologies. She will be permitted to testify except that her opinions regarding insufficient manufacturing

controls based on MAUDE reports will not be admitted unless plaintiff presents sufficient evidence supporting the existence of a lack of quality controls.

Neither side fully discusses the nature, effect, or cause of the infection experienced by the plaintiff. Perhaps it is unnecessary to do so, but if that is the case some explanation should be provided for fact finding purposes.

Defendant Howmedica's motion for summary judgment will be denied.

The parties shall promptly meet to discuss the possibility of settlement in light of today's ruling. Absent a settlement, a final pretrial order shall be filed by the date set forth below. The pretrial order should be filed electronically with a judge's copy being presented in court at the time of the hearing

IT IS THEREFORE ORDERED that defendants' motion to strike [50] is denied. Defendants' motions to exclude testimony and for summary judgment [47, 48] are granted in part and denied in part. Dr. Ngai's testimony regarding manufacturing controls is excluded absent the presentation of a sufficient foundation. The claims against defendant Stryker Corporation are dismissed and defendant Stryker Corporation is dismissed from this action. In open court on October 24, 2013 at 2:00 p.m., the parties shall submit a judge's copy of a final pretrial order in full compliance with Local Rule 16.1 and Local Rule Form 16.1.1,

including trial briefs, proposed voir dire questions, motions in limine with supporting briefs, and proposed jury instructions.

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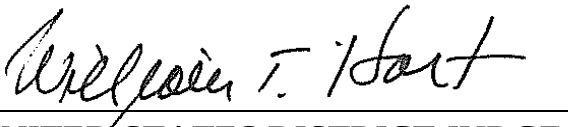

UNITED STATES DISTRICT JUDGE

DATED: SEPTEMBER 24, 2013