

**STATE OF MICHIGAN
IN THE SUPREME COURT**

(ON APPEAL FROM THE COURT OF APPEALS)
(Cavanaugh, P.J. and Owens and M.J. Kelly, JJ.)

JEFFREY CULLUM

Plaintiff-Appellee,

v.

Supreme Court No. 149955
Court of Appeals No. 313739
Lower Court No. 10-007013-NH
(Wayne County Circuit Court)

FREDERICK LOPATIN, D.O.

Defendant-Appellant,

and

DEARBORN EAR, NOSE AND THROAT
CLINIC, P.C.,

Defendant.

**PLAINTIFF-APPELLEE'S ANSWER TO APPLICATION
FOR LEAVE TO APPEAL**

CERTIFICATE OF SERVICE

149955

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STATEMENT OF APPELLATE JURISDICTION

Plaintiff-Appellee does not contest the jurisdiction of this Court to consider this application.

**STATEMENT IDENTIFYING THE JUDGMENT
OR ORDER APPEALED FROM AND INDICATING THE RELIEF SOUGHT**

Plaintiff-Appellee accepts Defendant-Appellant's Statement Identifying the Judgment or Order Appealed From and Indicating the Relief Sought, with one exception. In the first paragraph of his statement, defendant alleges that plaintiff's avascular necrosis only manifested itself months after the administration of the corticosteroids. As a discussion of the facts below demonstrates, the initial manifestation of the destructive process came within days of ingestion of the last of the corticosteroids, even though the diagnosis was not made until months later. This is critically important to this appeal because plaintiff's expert depended heavily on this fact in forming the opinion now under attack.

COUNTER-STATEMENT OF QUESTIONS PRESENTED

I. WHERE THE TRIAL COURT IGNORED SUPREME COURT PRECEDENT REQUIRING IT TO CONSIDER ALL THE FACTORS UNDER MCL §600.2955, CAN ITS DISCRETION BE UPHELD?

Plaintiff-Appellee says: "No"

Defendant-Appellant says: "Yes"

Trial Court said: "Yes"

The Michigan Court of Appeals says: "No"

II. WHERE PLAINTIFF'S EXPERT USED SOUND SCIENTIFIC METHOD IN THE FORM OF DIFFERENTIAL DIAGNOSIS, SUPPORTED BY A WEALTH OF STUDY AND EXPERIENCE, AND BASED HIS OPINIONS ON SPECIFIC CLINICAL FINDINGS AND EVENTS IN THE PATIENT'S HISTORY; AND WHERE ALL AVAILABLE LITERATURE SUPPORTS THE EXPERT'S OPINIONS ON PROXIMATE CAUSE, WAS IT AN ABUSE OF DISCRETION FOR THE TRIAL COURT TO FIND THE OPINION UNRELIABLE AND UNSUPPORTED UNDER MRE 702?

Plaintiff-Appellee says: "Yes"

Defendant-Appellant says: "No"

Trial Court said: "No"

The Michigan Court of Appeals says: "Yes"

III. WHERE THE TRIAL COURT DID NOT PASS ON THE FORESEEABILITY ARGUMENT MADE BY THE DEFENDANT BUT WHERE THAT ARGUMENT DEPENDS EXCLUSIVELY ON AN UNSCIENTIFIC, STATISTICAL ANALYSIS OFFERED ONLY BY DEFENDANT'S ATTORNEYS AND NOT BY EXPERTS, IS LACK OF FORESEEABILITY AN ALTERNATIVE GROUND UPON WHICH THE TRIAL COURT COULD BE AFFIRMED?

Plaintiff-Appellee says: "No"

Defendant-Appellant says: "Yes"

Trial Court said: The trial court did not answer this question.

The Michigan Court of Appeals says: "No"

INTRODUCTION

This is yet another application in which the applicant misapprehends the function of the Supreme Court. As the U.S. Supreme Court observed in distinguishing between the functions of the Michigan Supreme Court and our Court of Appeals:

Michigan's Supreme Court too, sits not to correct errors in individual cases, but to decide matters of larger public import. *Halbert v Michigan*, 545 U.S. 605, 619 (2005) (citing MCR 7.302(B)(2-3); *Great Lakes Realty Corp. v Peters*, 336 Mich 325, 328-329 (1953)).

Indeed, MCR 7.302 reinforces this premise. Defendant recognizes in this case the need to capture the attention of this Court with “. . . important and recurrent issues in Michigan law.” Application at P 1. In his effort to do so, defendant claims that the decision below would throw out *Daubert*¹ analysis altogether in favor of a return to yesteryear in which experts could render any opinion irrespective of reliability. Application at P 17. Yet, even the most cursory review of the Court of Appeals opinion (Ex. B, Application) shows that it did no such thing,stead faithfully tracking MCL §600.2955 (which the trial court had wholly failed to do.) Defendant then argues that this Court should accept leave because the Court of Appeals merely accepted the purportedly *ipse dixit* opinion of plaintiff's expert, Michael McKee M.D., when, again, examination of the decision shows that the Court of Appeals explained in detail *why* it found the opinion of the expert reliable. Defendant next argues that this Court must accept leave to protect the discretion afforded to trial judges in their gatekeeper role, without acknowledging that the trial judge (as the Court of Appeals observed at P 8) did not discuss *any* of the statutory factors that *Clerc v Chippewa Co War Mem Hosp*, 477 Mich 1067; 729 NW2d 221 (2007) *requires* be considered by the trial court before deciding a motion brought under MRE 702 or MCL

¹ *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993).

§600.2955. Finally, the defendant argues that this Court must intervene because studies were presented to the trial court in support of plaintiff's expert's opinion that the expert did not himself rely upon. But there is no requirement that an expert who has preeminent knowledge and experience in the field rely upon a study or article that is offered to show general acceptance of the expert's views or, in this case, that the expert himself has been favorably cited in peer reviewed literature. In short, the Application falls far short of demonstrating that this Court needs to be involved.

This is a fact-intensive case in which both parties, the trial court and the Court of Appeals all cite the same court rules and propositions for the same reasons. It ultimately comes down to the application of the facts of this case to the accepted legal principles. The Court of Appeals' opinion is a thoughtful exposition of the law and a meticulous application of the law to the facts of this case. If this Court is to deal with the case at all, it is to disagree with an analysis of the facts, not overarching legal principles. There are no novel or important issues of law presented in the Application that require elucidation by this Court at this time. Accordingly, this case does not merit the Court's attention, and plaintiff respectfully requests that the Application be denied.

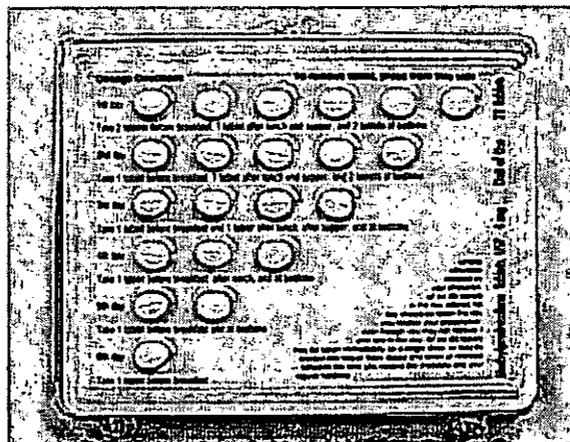
COUNTER-STATEMENT OF FACTS

The defendant-appellant's statement of facts deviates markedly from the description in MCR 7.212(C)(6) that such statements cite both favorable and unfavorable facts and be presented without argument or bias. Therefore, it is necessary that the plaintiff submit this counter-statement.

A. The Facts leading to the Filing of Suit

Plaintiff is a 34 year old male who works at the Motor City Casino in Detroit. Until very recently, he was a parking attendant, requiring substantial, walking and other activity involving the extensive use of his lower extremities. Ex. 1, Cullum Dep P 105 L 16-21. On January 15, 2008, Mr. Cullum first saw the defendant (Ex. 2, Lopatin Dep P 16 LL 16-18) on referral from his family physician (Ex. 1, Cullum Dep P 48 LL 13-14) for evaluation and treatment of what appeared to be a nasal infection. Ex. 2, Lopatin Dep P 42 L 10. The defendant, an ear nose and throat specialist, correctly determined that, although plaintiff did indeed have an infection causing his acute symptoms, he also had a deviated septum (*Id.* P 44 LL 7-9) that could only be addressed through surgery. *Id.* P 61 L 21 – P 62 L14. Defendant prescribed an antibiotic for the infection (with which plaintiff has no quarrel) but chose to treat the deviated septum issue by the administration of a corticosteroid known as Medrol.² Medrol is commonly delivered in a blister pack consisting of six rows of pills.

² Medrol actually is a more potent derivative of Prednisone, resulting in the fact that the sixty-three 4 mg pills taken by plaintiff were equivalent to 315 milligrams of Prednisone. McKee Trial Dep P 35 L 18, Application, Ex. I.



(The foregoing image is not an image of the dosepaks taken by Plaintiff; it is merely offered for demonstrative purposes.) The first row has six tablets; the second row has five tablets, etc. down to the sixth row with a single tablet: 21 in all. The idea is that on day one the first row is taken with the maximum number of pills (6) and then each successive day another row with one less pill is taken, until the dose has been tapered to zero.

Plaintiff took the medication as directed and returned to the defendant on February 5, 2008, 21 days after his initial visit. Plaintiff's symptoms were largely unabated. (Ex. 2, Lopatin Dep P 44 L 24 – P 45 L 2. Defendant therefore "...changed to a very strong antibiotic and also gave him the very strong steroid..." (*Id.* P 64 L 19-20) which he did not note in his chart at all³. Defendant gave the "very strong steroid" by prescribing two more Medrol Dosepaks to be taken side-by-side. In other words, plaintiff would take row one out of the first Dosepak on day one; row one out of the second Dosepak on day two; row two out of the first dosepak on day three, etc. Thus, from the time that plaintiff began treating with defendant through the end of his course of steroids, he had received three Dosepaks in approximately 30 days, two of them over less than 10 days.

³ Defendant conceded that if one had not known to find the prescription in the pharmacy's records, there would have been no evidence of this at all. *Id.* P 47 L 25 – P 48 L 5.

On February 19th, just a few days after finishing the third Dosepak, plaintiff called Defendant complaining of “excruciating pain” in his right upper leg and hip that had begun just as he was finishing the final Dosepak. Ex. 1, Cullum Dep P 73 L 25 – P 78 L 21. Plaintiff specifically asked if his hip pain could be a consequence of the steroids. *Id.* P 80 LL 4-22; (Ex. 2, Lopatin Dep P 65 LL 11-20. Defendant’s advice was simply to take a warm bath and a couple of Advil and that he would be fine. Ex. 1, Cullum Dep P 78 LL 14-21. Plaintiff’s pain seemed to subside for several months, but returned and persisted, at which point plaintiff sought treatment and ultimately was diagnosed with avascular necrosis of the right hip (the same side in which he had had his severe pain.) Plaintiff underwent a surgical repair at the hands of Dr. David Mayo, M.D., but Dr. Mayo concedes that the usual course of this disease is that plaintiff will need further treatment in the future. Application, Ex. H, Mayo Trial dep P 92 LL 3-4.

B. History of Proceedings

1. The Lawsuit

Plaintiff filed suit on June 18, 2010 (Application, Ex. C) alleging in the following paragraphs that:

6. As part of the treatment for the sinus infection and swelling defendant Lopatin prescribed a Medrol Dosepak. Medrol is the brand name of methylprednisolone a corticosteroid. *Id.* The “dosepak” prescribed to the plaintiff consisted of twenty-one, four milligram doses of Medrol which are meant to be taken over the course of six days in a tapered fashion (six pills on the first day, five on the second day and so on).

7. Avascular necrosis of bone, particularly of the femoral and humeral heads, is a well-known potential side effect of corticosteroid therapy. Plaintiff was not advised of this potential side effect by defendant Lopatin prior to, or at any point during, the corticosteroid therapy he prescribed to plaintiff.

8. Following a visit to defendant Lopatin’s office on February 5, 2008, plaintiff was prescribed two additional Medrol Dosepaks to be taken consecutively. Lopatin’s notes from this visit do not discuss this prescription but they do discuss the “chronic sinusitis” which the plaintiff continued to suffer from.

9. Towards the end of this second phase of Medrol therapy, plaintiff began to feel severe pain in his hips and legs. He called defendant Lopatin and specifically asked about

whether the Medrol could be causing the pain. Lopatin's advice was to "take 3 Advil and take a warm bath."

10. The pain in plaintiff's hips and legs, particularly the right hip/groin area, intensified in the months after the Medrol therapy ended. By October of that year, plaintiff could only walk with the aid of crutches. Finally, an MRI examination performed on October 10, 2008 resulted in the diagnosis of osteonecrosis (or avascular necrosis) of the right femoral head.

11. On November 13, 2008 plaintiff underwent core decompression surgery on his right hip. He had to use crutches to walk for over six months after this operation and was not walking without a cane until the end of July 2009.

Plaintiff also alleged that the defendant was negligent in prescribing three significant doses of corticosteroids because:

16. ... defendant Lopatin:

- a. prescribed prednisone when it was not indicated for the patients presenting condition;
- b. prescribed prednisone in the form of three separate Medrol Dosepaks administered within a period of just over a month;
- c. failed to inform the plaintiff of potentially serious side effects of the Medrol Dosepak which he prescribed to plaintiff;
- d. did not properly monitor the effects of the prednisone which he had prescribed to plaintiff and, in fact, ignored clear signs that the steroid was causing damage to plaintiff's right leg and hip;

The Complaint was supported by affidavits of merit as required by MCL §600.2912bError! Bookmark not defined.. The first was from Dr. Charles Hood, an ear nose and throat specialist. Dr. Hood's affidavit (Application, Ex. C) stated what the Complaint alleged: that steroids should never have been prescribed in the first instance because they could not be effective (*Id.* ¶10) and that they were prescribed in excessive amounts without giving the patient adequate warning of the potential risks (*Id.* ¶11). Dr. Hood, though indicating that he was aware of the risks of inappropriate use of steroids, limited his opinion to standard of care, breach and general foreseeability. Not being an orthopedic surgeon and not treating avascular necrosis, it was never contended that Dr. Hood could render an opinion on the actual causal connection

between the administration of steroids in this case and the patient's development of avascular necrosis. Ergo, another affidavit by an expert in AVN was necessary in order to establish causation.

The second affidavit of merit was signed by Dr. Michael McKee (Application, Ex. C), an orthopedic surgeon with particular expertise⁴ in avascular necrosis. Dr. McKee's affidavit (since he is not an ear nose and throat specialist and could not, under MCL §600.2169, have rendered opinions with respect to the standard of care for ENT specialists) confined itself to issues of proximate cause. Dr. McKee stated that, given the specific clinical history in this case as well as his knowledge and experience in the field, it was his opinion that the avascular necrosis had been caused by the administration of steroids prescribed by the defendant in this case. Dr. McKee published a paper in 2001 making this connection based upon a series of patients in his practice. He has studied the problem ever since (Application, Ex. I, McKee trial deposition, P 9 L 21 - P 10 L 12), and based upon his evaluation of the medical records in this case, opined that, more likely than not, the steroids prescribed by Dr. Lopatin were the proximate cause of the plaintiff's AVN. (*Id.* P 10 L 13 - P 11 L 1).

2. Discovery

Discovery ensued which included the depositions of plaintiff, plaintiff's longtime girlfriend (now wife), his father and mother and the parties' experts. Plaintiff's experts' testimony was consistent with their affidavits of merit. After listing the various potential causes of AVN in this case, Dr. McKee testified that a review of the plaintiff's records had ruled them all out, with the exception of the steroid administration. Application, Ex. E, McKee Discovery

⁴ Dr. McKee's curriculum vitae, Ex. 6 to Appellant's COA Brief, demonstrates 221 articles in the field of orthopedics, 119 lesson papers and 154 presentations of which 8 of his articles are specifically directly to avascular necrosis.

Dep P 44 LL 6-19. It was his opinion that the probable cause of plaintiff's AVN was steroids, and that there were four reasons why he did not believe that alcohol was the more likely cause: 1) Steroids are the most common cause; 2) the timing of the steroids and the presentation of symptoms was consistent with the steroids, not alcohol; 3) the dosages and duration of the steroid use in this case were sufficient to cause AVN; 4) he had seen "dozens, if not hundreds" of cases just like plaintiff's in the course of his clinical practice. *Id.* P 14 L 7 – P 15 L 9. Dr. McKee discounted alcohol as the primary cause because the amount of consumption was not enough in his experience to produce the disease "in isolation without some other precipitating event or cause." *Id.* P 15 L 10-18. While relying primarily on his own experience, Dr. McKee also found support in three additional research papers that he identified by name and source. *Id.* at P 12 LL 11-25.

The only defense expert deposed during discovery, Dr. John Jacobs, was an ear nose and throat specialist who, though acknowledging that he had no experience with treating avascular necrosis or studying any connection between AVN and steroids was critical of Dr. McKee's analysis. Ex. 3, Jacobs Dep, P 25 LL 1-18. He admitted that he had not been asked to testify on that point (*Id.* at P 26 LL 1-3) and the only research he had done on the question of causation between AVN and low-dose steroids was his review of Dr. McKee's paper. *Id.* at P 37 LL 13-20.

3. Defendant's First Motion for Summary Disposition

As stated by the defendant, following the close of discovery but before the taking of trial depositions of the experts, defendant brought a motion for summary disposition based upon a *Daubert* challenge to Dr. McKee's testimony. The motion explicitly referenced the statute, MCL §600.2955, as well as MRE 702. Defendant argued that there was an insufficient scientific basis for Dr. McKee's opinion with respect to the causal connection between low dose steroids and

avascular necrosis and that his opinions should therefore be stricken, resulting in summary disposition of plaintiff's claim. Plaintiff countered the motion with seven articles on the subject including not only Dr. McKee's article, but other articles and references citing favorably to Dr. McKee. No article was cited by any party that was critical of Dr. McKee's research paper or any of the observations or conclusions rendered therein. Defendant did not argue at any time during the course of the first motion for summary disposition that any articles presented to the court in opposition to defendant's *Daubert* motion had to be admissible in evidence or had to have been acknowledged as authoritative by any witness. The trial accepted without criticism during this motion hearing the article⁵ that it rejected *sua sponte* on the second motion for summary disposition.

As stated by the defendant, the trial court denied defendant's *Daubert* challenge and the parties proceeded to the taking of trial depositions to be used in lieu of some of the experts' live appearances at trial.

4. The Trial Depositions of the Experts

Dr. McKee, consistent with his deposition testimony, testified that, in his opinion, the most likely cause of plaintiff's avascular necrosis was the use of steroids by the defendant to treat the plaintiff's nasal condition. Dr. McKee had already testified at his earlier deposition that he had considered all other possible known causes of AVN and had rejected them based on his review of the medical records. Application, Ex. E, McKee Discovery Dep P 44 LL 6-19. Dr. McKee acknowledged that he was not specifically aware that the plaintiff had received injections of steroids into his face some months prior to his treatment by the defendant, but had already

⁵ Langer, et al, Survey of Orthopaedic and Sports Medicine Physicians Regarding Use of Medrol Dosepak for Sports Injuries, *Arthroscopy*, Vol 22, No 12 (December), 2006: pp 1263-1269 (Ex. 4 attached and included as Ex. 11 to Plaintiff's Response to Defendant's Motion for Summary Disposition Against Frederick L. Lopatin, DO dated January 5, 2012)

testified that, even if that were true, the injections received in the amounts utilized, were not capable of being a factor in Mr. Cullum's avascular necrosis. *Id.* P 23 L 16 – P 24 L 1. Dr. McKee also acknowledged not having read the deposition of plaintiff's girlfriend, which discussed the plaintiff's alcohol use (in amounts actually lower than Dr. McKee assumed), but stated that he had been aware in forming his opinion of the fact that plaintiff was believed to have been a significant alcohol user in the years preceding his diagnosis, drinking as much as three beers a day at some points in his life and up to 20 beers in a weekend at others. Application, Ex. I, McKee Trial Dep P 22 L 7-14. Dr. McKee specifically denied that plaintiff's alcohol use could overshadow the steroids as the most probable cause of plaintiff's avascular necrosis because of the unique timing of the onset of symptoms and the use of the steroids. *Id.* P 22 LL 19-23.

On the issue of his initial paper and the ongoing basis for his opinions about low-dose steroids and AVN, Dr. McKee testified at length that, in the years between 2001 when he had published his initial study from the time that he had given his testimony in this case, he had treated hundreds of patients suffering from avascular necrosis and that this extensive experience over an additional decade had reinforced his medical opinion concerning the causal connection between the administration of low dose steroids and the occurrence of avascular necrosis. *Id.* P 12 L 6 – P 15 L 13.

Dr. McKee was examined, as the defendant states on the incidence of avascular necrosis in relation to the total number of patients in Canada (where Dr. McKee now exclusively practices⁶) who receive low dose steroids for one reason or another. Dr. McKee was never asked

⁶ Dr. McKee has practice experience in the United States, as he completed a fellowship at Massachusetts General Hospital. Curriculum Vitae of Dr. Michael McKee, Ex. 6 to Appellant's COA Brief.

to opine on the subset of those patients receiving low dose steroids who receive a triple dose over the same period of time as did the plaintiff in this case.

The defendant relied upon the testimony of Dr. David Mayo, who had treated plaintiff for his avascular necrosis. Dr. Mayo acknowledged that he had never studied the question of low dose steroids and avascular necrosis (Mayo Trial Dep P 83 LL 17-22). He had authored a total of three papers in his career on medical matters, none of them on avascular necrosis. *Id.* at P 84 LL 4-17, His only research into the issue was a few weeks before his deposition. Mayo Trial Deposition P L 16). He had looked at perhaps three articles on the subject but did not bring them to the deposition and could not cite the dates (other than year) or even the specific names of any of them. *Id.* P 89 L13 - P 90 L 10.

As the defendant states, Dr. Mayo disagreed with Dr. McKee that the avascular necrosis in this case was caused by steroids. Dr. Mayo acknowledged, however, that, what happened to plaintiff (sudden onset of pain shortly after steroid use and then diagnosis several months later) was one of the recognized ways in which AVN presents. (Application, Ex. H, Mayo Trial Dep P 93 LL 12-17. Dr. Mayo also admitted that literature that he gives to his own patients identifies steroid exposure as one of the most likely causes of AVN. *Id.* P 93 LL 12-17.

5. The Second Motion for Summary Disposition

After the conclusion of the trial depositions and shortly before trial was due to begin, defendant brought a second motion for summary disposition⁷, which was based on grounds different from the first. Whereas, where the initial motion was a *Daubert* challenge, the second motion made only the argument that, even if plaintiff's AVN was in fact caused by the steroids

⁷ Defendant's Motion for Summary Disposition, dated May 25, 2012, ¶¶5-6.

in this case, the chances of that happening were so remote as to be unforeseeable as a matter of law. As defendant observes, plaintiff both contested the mathematical analysis that defendant asserted without the benefit of any expert testimony but also pointed out that, under well-settled Michigan law, once evidence of negligence is properly before the jury, foreseeability is almost never decided as a matter of law.

Although defendant's oral argument at the hearing continued to be based upon proximate cause, the trial court's remarks indicated what the opinion ultimately stated: that the trial court saw this as a *Daubert* issue after all. Its principal criticism of the plaintiff's case came not in whether the statistical chances of anyone getting AVN from low dose steroids was too remote to be foreseeable, but rather whether the opinion on cause-in-fact was adequately supported. (Application, Ex. J, TR 6/15/12, P 8 L 26 – P 9 L 1). The court indicated its inclination to grant the motion, but wanted to read the full text of the expert depositions. *Id.* P 16 LL 18-23. The court then took it under advisement and issued its opinion five months after, granting defendant's motion and dismissing the case. Application, Ex. A, Opinion and Order dated November 19, 2012.

The trial court did not discuss the grounds for the foreseeability argument made by the defendant, giving it only a passing reference at the end of the opinion. Instead, the analysis was under MCL §600.2955 and MRE 702. The opinion does not contain an express discussion of the statutory factors required in consideration of a *Daubert* challenge. It states at one point that, apart from Dr. McKee's own initial article, the plaintiff supplied the court with no literature to support Dr. McKee's opinion. No mention was made of the articles proffered at the time of the

extensive *Daubert* challenge nor those supplied with the second motion on foreseeability. The trial court found the entire set of opinions from the plaintiff's experts on the issue of proximate cause to be speculative.

6. The Court of Appeals Decision

Plaintiff timely appealed and argued what he believed to be the deficiencies in the trial court's analysis, principally lack of consideration of the statutory factors and failure to take into account the ample literature support that had in fact been supplied to the court. Defendant countered by arguing, as he does here, that plaintiff's case is based solely on a fourteen year-old case study of fifteen patients of which only two used low dose steroids.

The Court of Appeals reversed the trial court, accepting the arguments advanced by the plaintiff: that Dr. McKee's opinion was based primarily upon his own prodigious experience and his observation that the timing of the onset of plaintiff's initial pain and ultimate diagnosis made steroids the far more likely cause than alcohol use which, if excessive at all, had been a constant in the plaintiff's life for years, without the development of AVN.

The Court of Appeals also rejected the defendant's alternative theory on foreseeability, pointing out the logical flaws in the statistics put forth by defendant.

The defendant filed a timely application to this Court, which plaintiff respectfully contends should be denied.

SUMMARY OF ARGUMENT

A. Lack of Grounds for Appeal to This Court

As plaintiff points out in the introduction and more fully below, this case is no more or less than an application of established law to the particular facts of this case. If the Court is to take up this matter for consideration, there is no reason to think it should not take up every

Daubert challenge that arises. While defendant has attempted to sound several alarms in order to attract the attention of this Court, the Court of Appeals opinion is thorough, well-reasoned and entirely within the precedents of this Court. Contrary to defendant's claim, this is not novel science upon which a pseudo-expert is extrapolating shaky data to make a statistical argument for proximate cause. Plaintiff's expert is eminently qualified, and spends the overwhelming bulk of his professional time in clinical practice diagnosing and treating orthopaedic injuries and diseases including 30-40 AVN cases per year. The rest of his time is spent in the highest academic pursuits in orthopedic medicine having authored a staggering number of papers in the field of orthopedics, including osteonecrosis (See note 4). In this case he rendered a diagnosis and opinion on causation based in part on his knowledge of the literature but much more on years of actively treating hundreds of patients afflicted with avascular necrosis stemming from a variety of causes. The defense expert, relying on no science whatsoever, came to a different conclusion on the same facts. That is not the stuff of which *Daubert* challenges are made. The courts are uniformly faithful to the precept that a court may not look at the conclusions reached, only the methods used. As the Court of Appeals noted⁸, the trial court crossed that line and simply chose the defense testimony as being more persuasive. This application should be denied on the basis that it does not warrant review at this time. The balance of the arguments herein is intended to satisfy the Court that nothing irregular happened below that should motivate intervention.

B. The trial court cannot properly exercise discretion under MCL §600.2955 without considering all the factors that the statute enumerates

If the goal of the application is to have the trial court affirmed, that cannot happen if this Court is to remain committed to its decision in *Clerc v Chippewa Co War Mem Hosp*, 477 Mich

⁸ Application, Ex. A, Slip Op. PP 8-9.

1067; 729 NW2d 221 (2007). That case *requires* that the trial court consider the factors set out in MCL §600.2955. The trial court clearly did not do so. The trial court must be reversed for that reason alone.

C. Plaintiff's expert did not use novel theories or the extrapolation of shaky data to reach his conclusion. He relied upon valid and prodigious experience as a treater of patients with this disease.

This is far from being a case in which plaintiff's eminently qualified expert simply opined that 1) low dose steroids can cause avascular necrosis in some patients; 2) plaintiff had low dose steroids; therefore, 3) his avascular necrosis must be caused by the low dose steroids. Dr. McKee identified a specific pattern of occurrences in this case: the administration of three times the normal dose of Medrol, a potent steroid, followed by the immediate onset of severe pain in the plaintiff's right hip; followed by a hiatus consistent with the time that it takes the painful deprivation of blood supply to the hip to cause bone death; followed by the diagnosis of the bone death (AVN) itself. No witness or proffered article suggested that alcohol-induced AVN presents this way. This is simply *not* the pattern associated with AVN from chronic alcohol use.

To be sure, *Daubert* analysis, whether in the federal courts where *Daubert* was created or Michigan courts where the analysis is governed by MRE 702 and MCL §600.2955, does not give a "pass" to doctors to opine without a scientific basis. But it *does* allow doctors to use the same method they use on a daily basis to diagnose and treat patients: differential diagnosis. In this method, the patient's condition is assessed and all possible causes arguably consistent with the facts are considered. Each is either ruled in or ruled out based on the evidence. So long as the expert uses reliable methods to do both, *Daubert* is satisfied. Both experts engaged in this process and both recognized the same potential causes, including alcohol, steroids and direct

trauma to the joint. Both ruled out all but alcohol and steroids. Defense expert Dr. Mayo picked alcohol as the most likely cause, and Dr. McKee picked steroids. As the Court of Appeals observed, the trial court "...improperly weighed the relative value of testimonial evidence provided by each party and inappropriately made credibility determinations in reaching its decision to exclude Dr. McKee's causation testimony." Application, Ex. A, Slip Op. P 8.

Although the differential diagnosis methodology does not require that the proponent of the challenged opinion also prove proximate cause by literature, the defendant is simply not correct to state that there is no literature support for Dr. McKee's opinion. On the contrary, articles provided to both the trial court and the Court of Appeals make the same observations that Dr. McKee did, frequently citing his work—and never critically. The notion that these articles had to have been established as authoritative by one of the witnesses before they could be relied upon by the court in a *Daubert* analysis, is completely without precedent in any federal or state court in the land. Indeed, the defendant has cited not a single case that says that the court may not consider literature support for an expert's opinion until that literature has been established as authoritative.

A brand new study just released in July of this year⁹ involving almost 100,000 patients who received the same medication as did plaintiff wholly supports what Dr. McKee and others have been saying for over a decade; in some patients, even a dose one-third of what plaintiff received can cause AVN. This not only answers the defendant's demand for a large, controlled study, it provides a good illustration as to why such studies should not be deemed an essential ingredient in allowing expert testimony, where other evidence strongly supports the legitimacy of the expert opinion under attack. This large study cited plaintiff's expert and the paper

⁹ As is explained below, plaintiff is moving to supplement the record in this Court to include the study.

submitted by plaintiff and that the trial court refused to even consider and reached the same conclusion. In short, the new study demonstrates conclusively that the literature support relied upon by plaintiff was never junk science to begin with.

D. The statistical analysis proffered by the Defendant in its second motion for summary disposition was fatally flawed from the outset, as the Court of Appeals demonstrated

No expert attempted to make the statistical analysis that was proffered by the defendant in his motion for summary disposition. Not even the defendant himself supported the statistical argument through a supporting affidavit. It was solely the work of defense counsel in his brief. Wholly apart from the *Daubert* issues immediately apparent in such an approach, the analysis is quite obviously flawed. While it may be true (though defendant offered no real evidence of it) that hundreds of thousands—perhaps millions – of people receive the typical *one* Medrol Dosepak for treatment of their ailments, no evidence was offered on the number of people receiving *three such packs* in a short period—two of them side-by-side. Given the fact that it is alleged that the level of steroids received by the plaintiff in this case was at the low end of the amount linked to AVN, the administration of steroids at a level only *one third* of what the plaintiff received would be irrelevant. The trial court did not attempt to go this route, and the Court of Appeals properly exposed it as invalid analysis.

Plaintiff is entitled to have these fact questions determined by a jury, not as a matter of law.

STANDARD OF REVIEW

The standard for acceptance or rejection for applications for leave to appeal is set forth in MCR 7.302(B) and states the application must show that:

- (1) the issue involves a substantial question as to the validity of a legislative act;

- (2) the issue has significant public interest and the case is one by or against the state or one of its agencies or subdivisions or by or against an officer of the state or one of its agencies or subdivisions in the officer's official capacity;
- (3) the issue involves legal principles of major significance to the state's jurisprudence;
- (4) [bypass appeals not involved here]
- (a) delay in final adjudication is likely to cause substantial harm, or
- (b) the appeal is from a ruling that a provision of the Michigan Constitution, a Michigan Statute, a rule or regulation included in the Michigan Administrative Code, or any other action of the legislative or executive branch of state government is invalid;
- (5) in an appeal from a decision of the Court of Appeals, the decision is clearly erroneous and will cause material injustice or the decision conflicts with a Supreme Court decision or another decision of the Court of Appeals; or
- (6) [Attorney Discipline orders not involved here].

ARGUMENT

I. THIS CASE DOES NOT MERIT REVIEW AT THIS TIME

None of the factors enumerated in MCR 7.302(B) favor review. No provision of the Constitution is involved nor is the validity of a statute or court rule. Defendant simply asserts that this is a recurring issue of importance and leaves it to the Court to infer that defendant is also arguing that manifest injustice will result from a clear error in the Court of Appeals. On the first point, it is true that *Daubert* issues recur. In fact, they recur with such frequency that this Court would have little time for its other business if it took up every matter involving a disputed *Daubert* challenge. If the Court of Appeals were employing a novel interpretation of the statute or the court rule in this case, it would be one thing, but this is a fact-intensive application of established law to disputed facts. Even if this Court were concerned that the Court of Appeals opinion did not apply the law exactly as this Court would have, the fact that it is an unpublished opinion is also relevant; it clearly will not have binding effect.

With regard to the argument that the decision is clearly erroneous and will cause manifest injustice, this involves two separate inquiries. First, there is the question of error. As is more thoroughly discussed below, the Court of Appeals was entirely correct, not only in its methodology (detailing the factors enumerated in MCL §600.2955, which the trial court had failed to do) but also in its recognition that plaintiff's expert had relied on far more than his own study from 2001. The Court of Appeals recognized that Dr. McKee had principally relied upon his decades of experience as an orthopedic surgeon, diagnosing and treating between 30 and 40 AVN patients per year.

Importantly, Dr. McKee did not simply state that certain patients who received low dose steroids develop AVN, and plaintiff received low dose steroids and developed AVN; therefore,

the steroids are the cause. He specifically correlated the onset of symptoms with the administration of steroids and referred to a "classic" presentation whereby pain was virtually immediate following the administration of the steroids but the diagnosis of AVN was made much later after the bone had fully collapsed. For these reasons and other reasons set forth in detail in the Court of Appeals opinion, it cannot be credibly argued that the court was so clearly in error on this as to require extraordinary intervention by this Court.

On the issue of manifest injustice, while it is true that a defendant who is entitled to summary disposition undergoes potential injustice by having to defend himself at trial, if there are deficiencies in the plaintiff's case that would warrant summary disposition, one can only assume that the outcome at trial will be no better for the plaintiff. In other words, if the defendant is entitled to prevail, he will prevail one place or the other. On the other hand, if summary disposition is improvidently granted, the plaintiff can never correct that injustice. There will be no trial at which a full exploration of the facts could lead to the better result. *That* is manifest injustice.

II. WHERE THE TRIAL COURT IGNORED SUPREME COURT PRECEDENT REQUIRING IT TO CONSIDER ALL THE FACTORS UNDER MCL §600.2955, ITS DISCRETION CANNOT BE UPHELD

This Court has established a hard and fast rule where *Daubert* challenges in the trial courts are concerned; there *must* be consideration of all the factors that the statute enumerates. No matter how clear it may appear to the trial court that there is a fatal flaw in the expert's opinion, warranting it being barred, the trial court must complete the analysis. *Clerc v Chippewa Co War Mem Hosp*, 477 Mich 1067; 729 NW2d 221 (2007). As the Court of Appeals correctly noted in this case:

Here, despite quoting the language of MCL 600.2955(1), the trial court did not specifically discuss any one factor, and instead found only that Dr. McKee's "opinion on causation is speculative and unsupported." Thus, if the trial court intended to exclude Dr. McKee's testimony under MCL 600.2955(1), the trial court abused its discretion by failing to consider each factor before finding Dr. McKee's opinion inadmissible under that rule. See *Clerc*, 477 Mich at 1068.

Nor can a trial court finesse the issue by claiming to decide the matter under MRE 702.

Where the Court of Appeals had remanded in *Clerc* based on failure to hold the "searching inquiry" required by MRE 702. *Clerc v. Chippewa County War Memorial Hosp.* 267 Mich.App. 597, 607, 705 N.W.2d 703, 709 (Mich.App. 2005). This Court remanded "... on a basis different from that articulated by the Court of Appeals." This Court ruled that the searching inquiry required by MRE 702 had to include consideration of "...all of the factors listed in MCL 600.2955(1), 477 Mich at 1067. In this case, remand is not necessary because the Court of Appeals has performed the analysis that the trial court skipped. This is unlike *Clerc*, where the Court of Appeals declined to do that and was remanding the case anyway, making remand by this Court, albeit with different instructions, thoroughly appropriate. But remand or no remand, the one thing that this Court would likely not wish to do is condone the trial court's failure to follow *Clerc* by endorsing its incomplete analysis with a reinstatement of the order dismissing Plaintiff's case. Even if the Court could get beyond the procedural error, the substance of the trial court's decision was seriously in error, for all the reasons expressed by the Court of Appeals.

III. WHERE PLAINTIFF'S EXPERT USED SOUND SCIENTIFIC METHOD IN THE FORM OF DIFFERENTIAL DIAGNOSIS, SUPPORTED BY A WEALTH OF STUDY AND EXPERIENCE, AND BASED HIS OPINIONS ON SPECIFIC CLINICAL FINDINGS AND EVENTS IN THE PATIENT'S HISTORY; AND WHERE ALL AVAILABLE LITERATURE SUPPORTS THE EXPERT'S OPINIONS ON PROXIMATE CAUSE, IT WAS AN ABUSE OF DISCRETION FOR THE TRIAL COURT TO FIND THE OPINION UNRELIABLE AND UNSUPPORTED UNDER MRE 702.

A. This is not a case about novel scientific methodology or junk science; it is about sound medical methodology used by physicians from time immemorial

The correlation between corticosteroids and AVN is not new or novel. Both experts agreed that it is either the number one cause of AVN (Application, Ex. E, McKee Discovery Dep P 43) or the number two cause (Application, Ex. H, Mayo Dep P 15 LL 18-19). The drug manufacturer notes osteonecrosis of the femoral head (exactly what Plaintiff had) on its short list of Adverse Reactions in the warning label that it published prior to and after the time that plaintiff was treated by defendant. Ex. 5, Medrol label Nov. 2006 and Ex. 6, Medrol label April 2012. In the survey article¹⁰ that the trial court refused to consider, a majority of the 1290 physicians responding reported that they did not prescribe these Medrol Dosepaks for their patients, and the number one reason for not doing so was fear of causing osteonecrosis. *Id.* at 1266. Yet, Defendant makes it appear as though, even under these circumstances, Michigan's brand of *Daubert* analysis requires every feature of an expert's opinion to be supported by a double-blind, placebo controlled study – actually several of them. But the law does not require this. One of the recognized methodologies that experts – physicians in particular – may follow is

¹⁰ Langer P, Fadale P, Hulstyn M, Fleming B, Brady M. Survey of orthopaedic and sports medicine physicians regarding use of medrol dosepak for sports injuries. *Arthroscopy*. 2006; 22(12):1263–1269 at 1266. Ex. 4 attached and included as Ex. 11 to Plaintiff's Response to Defendant's Motion for Summary Disposition Against Frederick L. Lopatin, DO dated January 5, 2012.

the same methodology they use on a daily basis in treating their patients: the differential diagnosis. In fact, this meets one of the criteria under §2955: “(f) Whether the basis for the opinion is reliable and whether experts in that field would rely on the same basis to reach the type of opinion being proffered.”

Michigan has not focused in its *Daubert* jurisprudence on differential diagnosis as a specific methodology, but other courts have, including the Sixth Circuit.¹¹ In *Best v Lowe's Home Centers, Inc.*, 563 F.3d 171 (2009) plaintiff claimed loss of his ability to smell when pool chemicals spilled on his face and clothing. His physician linked the exposure to his claimed loss of smell (“anosia”) relying principally upon his general knowledge as an otolaryngologist of the effects of the active ingredient in the pool chemicals on the sensitive tissues of the nasal membranes. He also considered the MSDS (material data safety sheet) for the product to confirm what the active ingredient was and its ability to cause irritation to tissues on inhalation exposure. In applying the differential diagnosis method to arrive at his opinion that the anosia was a consequence of the chemical exposure, the expert examined other potential causes, including other medications that the patient had been taking, virus, an accident, tumors to the brain, surgery into the brain, or exposure to other chemicals. *Id.* at 174. After consideration of these alternatives he came to the conclusion that the most likely cause was the pool chemical. *Id.* at 175. However, the analysis was not without flaws. The expert was unfamiliar with one of the medications that plaintiff was taking and therefore had not taken its potential effects into account in determining it as a possible alternative cause. *Id.* He could not determine the actual level of exposure that plaintiff had experienced or the threshold level at which it could be expected that

¹¹ Plaintiff agrees with defendant that because MRE 702 is nearly identical to its federal analogue, FRE 702, reference to federal cases interpreting the *Daubert* standard is permitted under Michigan law. See, e.g., *Powers v City of Troy*, 28 Mich App 24 (1970).

harm would occur. *Id.* The trial court, based on these weaknesses, rejected the opinion and granted summary judgment against the plaintiff. The Sixth Circuit reversed, ruling that the differential diagnosis methodology used by the expert was well recognized as appropriate scientific method under *Daubert* and that the weaknesses in the foundation for and substance of the expert's opinion were a matter of weight, not admissibility:

All of Lowe's attacks on Dr. Moreno's efforts to ascertain whether Best is anosmic amount to factual disputes suitable for cross-examination. *See Daubert*, 509 U.S. at 596, 113 S.Ct. 2786 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."). Where, as here, a doctor has used a reliable method to conclude that the plaintiff has suffered an injury, potential problems such as those pointed out by Lowe's do not warrant the total exclusion of plainly relevant testimony.

563 F.3d at 180

The Sixth Circuit noted that the expert had employed differential diagnosis as his primary method and that this methodology is

...“an appropriate method for making a determination of causation for an individual instance of disease.” *Hardyman* [*v. Norfolk & W. Ry. Co.*, 243 F.3d 255, 258 (6th Cir.2001)]... at 260. An “overwhelming majority of the courts of appeals” agree, and have held “that a medical opinion on causation based upon a reliable differential diagnosis is sufficiently valid to satisfy the first prong [reliability] of the Rule 702 inquiry.” *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 263 (4th Cir.1999) (collecting cases from the First, Second, Third, Ninth, and D.C. Circuits). Differential diagnosis is considered to be “a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated.” *Hardyman*, 243 F.3d at 260 (quoting *Westberry*, 178 F.3d at 262). [. . .]The Third Circuit noted that “differential diagnosis generally is a technique that has widespread acceptance in the medical community, has been subject to peer review, and does not frequently lead to incorrect results.” *Id.* at 758. It also emphasized the individual nature of each differential diagnosis. *Id.* (“[T]he steps a doctor has to take to make [a] (differential) diagnosis reliable are likely to vary from case to case.”). As a result, the court stated that, “to the extent that a doctor utilizes standard diagnostic techniques in gathering ... information,” a finding that “the doctor's methodology is reliable” is “more likely.” *Id.* Another observation by the court was that “performance of physical examinations, taking of medical histories, and employment of reliable laboratory tests all provide significant evidence of a

reliable differential diagnosis,” and that “their absence makes it much less likely that a differential diagnosis is reliable.” *Id.* “The core of differential diagnosis is a requirement that experts at least consider alternative causes.” *Id.* at 759.

Id. at 178-79

The Sixth Circuit therefore formally endorsed the differential diagnosis as a method that passes muster – if properly applied – under *Daubert*.

We hereby adopt the following differential-diagnosis test, adapted from the Third Circuit’s well-reasoned opinion: A medical-causation opinion in the form of a doctor’s differential diagnosis is reliable and admissible where the doctor (1) objectively ascertains, to the extent possible, the nature of the patient’s injury, see *id.* at 762 (“A physician who evaluates a patient in preparation for litigation should seek more than a patient’s self-report of symptoms or illness and ... should ... determine that a patient is ill and what illness the patient has contracted.”), (2) “rules in” one or more causes of the injury using a valid methodology, and (3) engages in “standard diagnostic techniques by which doctors normally rule out alternative causes” to reach a conclusion as to which cause is most likely. *Id.* at 760.

Id. at 180.

Because the trial judge had failed to consider this methodology, the Sixth Circuit declined to give the deference ordinarily accorded to trial court decisions on *Daubert* matters¹².

Best is on all fours with the instant case, and Dr. McKee’s approach easily passes muster under *Best*. The rules laid down by the court there requires that the expert first “...objectively ascertain..., to the extent possible, the nature of the patient’s injury ...” *Id.* Here the injury, AVN, was undisputed. Next the expert must initially “... rule... in one or more causes of the injury using valid methodology.” *Id.* Dr. McKee did this, as evidenced by his testimony. After

¹² “Because the court did not recognize that differential diagnosis is a valid technique that often underlies reliable medical-causation testimony, its conclusions are not entitled to the deference that they would otherwise receive under the abuse-of-discretion standard of review. See *United States v 2903 Bent Oak Highway*, 204 F.3d 658, 665 (6th Cir.2000) (explaining that we will “extend[] a high degree of deference to the district court’s decision” under the abuse-of-discretion standard “only if the district court properly understood the pertinent law”).” 563 F2d at 178-179

having stated that he believed that the steroids that plaintiff had received were the cause, Dr.

McKee was questioned on other possibilities:

- 1 Q. Alcohol consumption to
2 excess, along with other factors, can cause
3 avascular necrosis. Correct?
4 A. Correct.
5 Q. What are the other potential
6 precipitating factors of avascular necrosis?
7 A. It's a long list. If you
8 look at the series and medical literature, there
9 are three common causes of avascular necrosis. One
10 is steroid medication. This is in order of
11 decreasing frequency. Steroid medication would be
12 the commonest. Alcohol consumption or excessive
13 alcohol consumption would be the next. Third would
14 be trauma. There are some specific kinds of
15 fractures or dislocations of the hip that would
16 cause avascular necrosis, and that would not
17 include repetitive motion. Fourth is there is a
18 section of other causes, which is a variety of
19 different things. That includes working under
20 pressure, such as in a mine or a deep sea diver.
21 It is called Caisson's disease. There is
22 hemoglobinopathy, so if there is something
23 intrinsically wrong with your hemoglobin. There
24 are various clotting abnormalities, so it's been
25 postulated that if your blood clots abnormally,
1 you're at a high risk for developing avascular
2 necrosis, and then a variety of lesser known
3 causes.
4 Q. What are the variety of
5 lesser known causes?
6 A. Various disorders in
7 triglyceride metabolism, various blood disorders,
8 various chemotherapeutic agents. It's been thought
9 increasingly that HIV is, in and of itself, a
10 potential cause for avascular necrosis, so there
11 are a number of other lesser known causes.

(Application, Ex. E, McKee Discovery Dep PP 43-44.)

Dr. McKee was then asked what he had done to rule out other causes:

- 12 Q. Have you done anything in
13 terms of reviewing records that would rule out any
14 other potential causes of avascular necrosis from
15 the list that you've just given?

16 A. I have gone through the
17 medical brief that I received looking specifically
18 for the causes in Mr. Cullum, and was not able to
19 ascertain any from the medical record.

[. . .]

6 A. I would state that Mr.
7 Cullum's alcohol use may have predisposed him to
8 develop osteonecrosis with a lower dose of
9 corticosteroid than typically would be seen since
10 as far as we understand it, it can be a
11 multifactorial condition. I think it's possible
12 that alcohol abuse would have been the cause of his
13 avascular necrosis, but I think on the balance of
14 probabilities that it's unlikely and that the more
15 probable cause would be the steroid administration.
[. . .]

13 . . . I believe Mr. Cullum's was an
14 individual who may have been susceptible to this
15 kind of complication because of his alcohol intake,
16 but that the precipitant or the most important
17 factor contributing to his development of
18 osteonecrosis was the short course of
19 corticosteroid medication that he received.
20 Again, as I stated before, it's my
21 firm belief that had he not taken those
22 corticosteroids, he would not have developed
23 osteonecrosis of the hip.

Id. at P 44, 46, 85.

Defendant has been critical of Dr. McKee for not being better-versed in the facial injections that plaintiff received from his dermatologist¹³. But, this criticism is entirely false, as this issue was actually covered as well, and rejected by Dr. McKee as a possible cause:

¹³ In any case, *Best* notes that not every possibility must necessarily be eliminated:

Lowe's makes much of Dr. Moreno's failure to eliminate Lescol as a possible cause. But doctors need not rule out every conceivable cause in order for their differential-diagnosis-based opinions to be admissible. E.g., *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 266 (4th Cir.1999) (citing *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 764-65 (3d Cir.1994)). Lowe's presented no evidence that Lescol might cause anosmia. If such evidence exists, or if Dr. Moreno failed to consider some other likely cause, Lowe's is free to attack Dr. Moreno's opinion on that basis at trial. 563 F3d at 181

20 Q. If Mr. Cullum received 400
21 milligram equivalent of prednisone through Dr.
22 Bonino over a period of several years, that would
23 also fall within your research paper of a potential
24 cause of avascular necrosis. Correct?
25 A. No.
1 Q. Why is that?
2 A. Because it's not just the
3 overall dose that is received, it's the method of
4 administration and the time in which it's received
5 that is also critically important. Relatively low
6 doses spread out over a number of years injected
7 intralesionally would not be associated with any
8 development of avascular necrosis that I'm aware of
9 either clinically or in research, and none of the
10 patients in the series that we reported had that
11 method of administration over that time course.
12 We are fixated on the actual dose
13 that he received, which is reasonable, but it's not
14 the only factor involved. How he received it and
15 the time course in which he received it is as
16 important in the subsequent development of AVN.

Id. at pp. 44-45.

Defendant in this case has made it appear that large-population controlled studies or their equivalent are a *sine qua non* of a viable opinion under MRE 702 and MCL §600.2955. So did the defendant in *Best*, but the Sixth Circuit properly rejected the argument:

Lowe's strongest argument is that no published material confirms that inhalation of the chemical in Aqua EZ can cause anosmia. But "there is no requirement that a medical expert must always cite published studies on general causation in order to reliably conclude that a particular object caused a particular illness." *Kudabeck v. Kroger Co.*, 338 F.3d 856, 862 (8th Cir.2003) (internal quotation marks omitted). Dr. Moreno did not arbitrarily "rule in" Aqua EZ as a potential cause, but instead concluded from the MSDS sheet¹⁴ and his own knowledge of

¹⁴ The equivalent of an MSDS data sheet where drugs are concerned is the package insert containing prescribing information. The trial court was provided with both the package insert in effect during the time that defendant was prescribing Medrol (Ex. 5) and the one in effect that the time of the second summary disposition hearing in May of 2012 (Ex. 6). Both contain the identical section (aseptic necrosis is another term for osteonecrosis/avascular necrosis):

ADVERSE REACTIONS

Fluid and Electrolyte Disturbances

- Sodium retention
- Congestive heart failure in susceptible patients

medicine and chemistry that the chemical it contains can cause damage to the nasal and sinus mucosa upon inhalation.

563 F3d at 180-181. In this case, Dr. McKee has, by his own testimony, treated numerous patients who presented exactly as did Plaintiff:

21 A. The basis for that opinion is
22 that, number one, steroids in most series are the
23 commonest cause of avascular necrosis. Number two
24 is that the time course of administration of the
25 steroids to the development of mechanical symptoms
1 in the hip is consistent with the medication being
2 the primary cause for his avascular necrosis.
3 Number three is that I believe that that duration
4 of steroid medication and the dose prescribed is
5 sufficient in an individual such as Mr. Cullum to
6 precipitate a case of avascular necrosis. **Number
7 four is that clinically, I have seen literally
8 dozens if not hundreds of similar cases with
9 exactly the same case description as Mr. Cullum's.**

(Application, Ex. E, McKee Discovery Dep P 14 L 21 – P 15 L 9) (Emphasis added)

This experience base is far beyond the expert in *Best*, who, although a specialist in ear nose and throat issues, had never in his career seen a case like the one in which he was testifying. The most he could say was that he had treated patients who had lost their sense of smell after inhaling *other* chlorine derivatives. 563 F3d at 181. Dr. McKee's vast experience in cases with "exactly the same case description as Mr. Cullum's" renders him eminently, and uniquely,

-
- Hypertension
 - Fluid retention
 - Potassium loss
 - Hypokalemic alkalosis
 - Musculoskeletal*
 - Muscle weakness
 - Loss of muscle mass
 - Steroid myopathy
 - Osteoporosis
 - Tendon rupture, particularly of the Achilles tendon
 - Vertebral compression fractures
 - Aseptic necrosis of femoral and humeral heads
 - Pathologic fracture of long bones

qualified to render a causation opinion in this matter. And, indeed, one of the key factors relied upon by Dr. McKee in his analysis – the time sequence of plaintiff's symptom onset – is a factor approved in *Best*. Dr. McKee testified:

21 Q. I want you to assume further
22 that he reported to his physician, who had
23 prescribed those medications, pain in his hip, and
24 that complaint came on or around February 19 of
25 2008, which would have been approximately 14 days

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1 after the prescription of the second course of
2 corticosteroids.

3 A. Yes.

4 Q. Would that history be
5 consistent with what you were talking about a few
6 minutes ago in terms of the kind of presentation
7 you can see?

8 A. Yes. And it's thought that
9 what happens in that situation is the pain, the
10 transient pain he experiences early, is the pain
11 from the death of the osteocytes in the hip, or the
12 avascular or the necrosis part. So the cells in
13 the hip die. That's the initial pain someone
14 experiences.

15 Then that pain diminishes or goes
16 away. It's only months later when the mechanical
17 effects of that are felt that the hip pain returns
18 in a more sustained fashion.

19 That is a typical history for
20 someone who has this type of condition induced by a
21 steroid medication.

22 Q. In this case, I want you to
23 assume that his pain subsided for a time and then
24 by August or September of 2008 he was experiencing
25 more pain and sought treatment for it, leading to

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1 the diagnosis in October of 2008.

2 A. Yes.

3 Q. Would that time sequence be
4 consistent or inconsistent with what you just told
5 us can happen?

6 A. That would be consistent and
7 very typical for a patient with a steroid-induced
8 osteonecrosis.

Application, Ex. I, McKee Trial Dep PP 24-26. Thus, the striking time sequence of the onset of plaintiff's symptoms is a major foundation for Dr. McKee's opinions. In *Best*, the Sixth Circuit approved reliance on similar temporal evidence. The expert in *Best* had heavily weighed the temporal relationship between the onset of symptoms in the plaintiff and the exposure to chemicals. 563 F2d at 175, 178. The trial court had been critical of that criterion, but the Sixth Circuit had no criticism of it. Similarly, Dr. McKee's testimony certainly passes muster in this matter.

In the application, defendant argues that because Dr. McKee's opinions are not without controversy, they are illegitimate. Application P 37 ("If the relationship is "scientifically controversial," then by definition it cannot be reliable."). Nonsense. MCL §600.2955 specifically directs that a court examine "[t]he degree to which the opinion and its basis are generally accepted within the relevant expert community[.]" If the statute required absolute scientific unanimity before an opinion could be admitted, surely the statute would require examination of "*whether*" the opinion has general acceptance; the fact that courts must inquire into *the degree* of acceptance necessarily anticipates the admissibility of opinions that are not universally accepted. This approach is entirely consistent with *Daubert*, wherein the U.S. Supreme Court noted that "it would be unreasonable to conclude that the subject of scientific testimony must be "known" to a certainty; arguably, there are no certainties in science." 509 U.S. at 590. Similarly, our Court of Appeals held in *McCall v Spectrum Health Hospitals*, 2009 Mich. App. LEXIS 1865, *lv. den.*, 488 Mich. 1000 (2010) that "[t]he unavailability of absolute, pinpoint certainty does not render a conclusion unreliable or unscientific." Thus, defendant's attempts to set a higher standard of admissibility than is contemplated by statute and case law must fail.

Inasmuch as Dr. McKee used the differential diagnosis method, the Court of Appeals was correct to accept it, and there is no reason for this Court to disturb that result.

B. Very recent literature supports plaintiff's expert

Both the defense and plaintiff experts agreed that AVN is a rare condition that does not lend itself to large studies¹⁵. Application, Ex. E, McKee Discovery Dep P 33 LL 18-19; Application, Ex. H, Mayo Trial Dep P 89 LL 4-7. Dr. McKee testified that it has been fairly well accepted that there is reason to be concerned about the use of even low-dose steroids, so there has been little concern for continued studies. Application, Ex. I, McKee Trial Dep P 36 LL 21-24. That notwithstanding, an article published just two months ago¹⁶ supports Dr. McKee¹⁷ totally. It represents a retrospective study of over 24 million patients receiving treatment in 14 major health systems across the country over a 12 year period. The focus of the study was precisely the medication used with plaintiff: methylprednisolone taper pack ("MTP") consisting of 21 pills, 4mg each, delivered in a tapering dose over 6 days. Of the total patient records reviewed, 98,390 patients were found to have been given one or more MTPs. Patients who had ever received corticosteroids in any other form prior to the first MTP, or who had been diagnosed with AVN prior to receiving any MTPs were separated in the study from those

¹⁵ Remarkably Dr. Mayo insisted that this rare condition had sparked literally thousands of papers on the subject (Application, Ex. H, Mayo Dep P 90 LL 7-9) covering thousands of patients. *Id.* P 81 LL 16-17, *none* of which he was able to specifically cite for any proposition in this case.

¹⁶ The article is Dilisio, M.F. Osteonecrosis following short-term, low-dose oral corticosteroids: a population-based study of 24 million patients. *Orthopedics*. 2014 Jul;37(7). Plaintiff is filing simultaneously herewith a motion to supplement the record to include this article. The grounds are that the article is highly relevant, was wholly unavailable at any time during the pendency of the case until after it had been argued in the Court of Appeals, and will aid in determination of the issues on the application. Plaintiff's reference to the article in this argument is respectfully submitted in anticipation that the motion will be granted. The article is the sole exhibit to the motion but is not attached to this brief, on the assumption that it should not be unless and until the motion to allow it is granted.

¹⁷ Dr. McKee's initial paper was cited in this article at footnote 15.

receiving MTPs for the first time in the study period. Patients who had received just one MTP were 59% more likely to be diagnosed with AVN than the control group receiving no MTPs. Patients receiving two or more¹⁸ MTPs were almost 3 times more likely to be diagnosed (2.763) with AVN than the controls. The author of this latest study stated:

This study demonstrates that even a single prescription of short-term, low-dose oral corticosteroid administration is associated with a low but significantly increased risk of being diagnosed with osteonecrosis. In patients who had received multiple MTP prescriptions, the risk is even greater when compared with the control population. Prior to this study, this association was presumed but never quantified. In a survey of 1290 sports medicine physicians¹⁹, 8.5% of those surveyed reported that they had seen a patient diagnosed with osteonecrosis as a complication of MTP use.³ Although there had been little evidence linking single MTP use and osteonecrosis, the most common reason that the physicians surveyed did not routinely prescribed MTPs was fear of osteonecrosis.

...
Corticosteroids are commonly prescribed to treat many dermatological, respiratory, gastrointestinal, neurologic, and musculoskeletal inflammatory conditions. As a result, corticosteroid use is the most commonly described nontraumatic risk factor for the development of osteonecrosis.(footnotes omitted)
The widespread use of MTPs for these common conditions in often otherwise healthy patients and the potentially devastating sequelae of osteonecrosis after their use can be a source of significant contention and litigation between the patient and prescribing physician. (footnote omitted) (Emphasis added)

Not only does this article wholly support Dr. McKee's opinion, the timing of its publication demonstrates the wisdom of allowing an otherwise qualified expert using appropriate methodology to render an opinion even when it has not yet been directly supported by a wealth of large, statistically-significant studies. If this article had been in existence at the time of Dr. McKee's trial deposition and he had referred to it, even though it did no more than to support his own substantial clinical experience and academic study, chances are the trial court would have been satisfied to deny the *Daubert* motion the second time, just as it had initially.

¹⁸ No separate category was reported on for exactly three MTPs.

¹⁹ This is the study that the trial court in this case refused to consider (Ex. 4, Langer P, Fadale P, Hulstyn M, Fleming B, Brady M. Survey of orthopaedic and sports medicine physicians regarding use of medrol dosepak for sports injuries. *Arthroscopy*. 2006; 22(12):1263–1269.)

When all this is considered, there is no reason for this Court to think that the Court of Appeals erred or approached the analysis any differently than it should have. Certainly on the ground of manifest error, the application should be denied.

IV. WHERE THE TRIAL COURT DID NOT PASS ON THE FORESEEABILITY ARGUMENT MADE BY THE DEFENDANT BUT WHERE THAT ARGUMENT DEPENDS EXCLUSIVELY ON AN UNSCIENTIFIC, STATISTICAL ANALYSIS OFFERED ONLY BY DEFENDANT'S ATTORNEYS AND NOT BY EXPERT'S, LACK OF FORESEEABILITY IS NOT AN ALTERNATIVE GROUND UPON WHICH THE TRIAL COURT COULD BE AFFIRMED

As is explained in the Statement of Facts and Summary of Argument, defendant actually based his second motion for summary judgment not on *Daubert* arguments but rather on the contention that, even if plaintiff's AVN was caused by the steroids in this case, the evidence from the experts shows that the chances were so remote, that Dr. Lopatin should not have had to worry about it; i.e., that it was unforeseeable as a matter of law. There are two fundamental flaws in this argument, not to mention that it is now contradicted by actual evidence.

The first flaw is that the statistical analysis itself was done by non-experts: defendant's counsel. There was never any actual evidence developed by any expert to demonstrate that, statistically, the chances of anyone getting AVN from steroids was too low to be important. Surely if the plaintiff is going to be required not only to use expert testimony, but to run any opinions so obtained through the *Daubert* gauntlet, defendant should not be permitted to make a factual argument upon which he would base summary judgment, without having a qualified expert check his work and support it by affidavit. That never happened.

The second flaw was succinctly demonstrated by the Court of Appeals in its footnote 4:

Defendant argues that, as only 15,000 cases of AVN are reported annually in the United States, which has a total population of slightly over 300 million people, the average incidence rate of AVN is only 0.0049 percent. Defendant then cites

Dr. Mayo's deposition for the conclusion that, if one were to ingest three grams of steroids in a span of three months, the expected incidence of AVN is only 0.6 percent. Defendant errs, however, by multiplying these numbers together to reach what he describes as an expected incidence of steroid-induced AVN of only 0.000029 percent. This final number actually represents the percentage of the entire population that is diagnosed each year with AVN caused by ingesting three grams of steroids in three months, an understandably small group of approximately 90 individuals, assuming a population of 308,745,538, as defendant stated in his brief in support of his second motion for summary disposition. This percentage would be relevant here only if it were also true that, in any given year, every person in the United States ingested three grams of steroids in a three-month period.

Application, Ex. A, Slip Op, n 4.

Not only did the Court of Appeals thoroughly debunk defendant's statistics simply by showing the flawed logic, the empirical data from an actual study²⁰ of 24 million patients, of whom almost 100,000 received steroids, demonstrates that the Court of Appeals was correct and the defendant was wildly incorrect. Whereas, defendant puts the incidence of AVN from all causes at .0049%, the Dilisio study puts it – on the basis of actual data – at .083% for those who had never had any steroids at all; .16% for those who had some unknown amount of steroids at some point in their lives before receiving the tapered dosepacks as were used here; .13% for those patients receiving a single dosepack; and .23% for those receiving 2 or more dosepacks²¹. Thus, even the baseline population receiving no known steroids at all have an incidence of AVN 16.9 *times* higher than defendant's "calculation." Then we get to the rest of defendant's extrapolation. Defendant concludes in his application that those who would suffer AVN even from an exposure of 10 times what plaintiff received is .000029%. Yet the Dilisio study showed that those receiving 2 or more dosepacks as did plaintiff had AVN rates of .23%: an astounding 7931 *times* higher than the defendant's projection.

²⁰ This is the article from July 2014, attached to Plaintiff's motion to supplement the record. See note 16.

²¹ All data derived from Dilisio, Table 1, lines 1 and 2.

No more need be said about the lack of reliability of the “data” presented to this Court and the courts below by defendant in support of his foreseeability argument, except that it is disturbing that even after the Court of Appeals had pointed out the mathematical absurdity of multiplying guess-work percentages together to produce an absurdly low incidence of AVN in a population exposed to steroids, the defendant not only repeated the groundless assertion, essentially word-for-word, in its Application, but also never bothered to explain why the Court of Appeals was not correct.

From there, defendant attempts to argue that, because Dr. Mayo reached a different conclusion as to causation than Dr. McKee, that plaintiff’s case cannot survive on causation. Nonsense. As an initial matter, if summary disposition was warranted whenever the plaintiff’s experts and the defendant’s experts disagreed on causation, because juries would be forced to “speculate along with the experts,” Application at P 46, summary disposition would be warranted in *virtually every medical malpractice case* – and indeed, in nearly every other case where expert testimony is required to establish causation. That premise is facially absurd, and also ignores all other tools the jury has at its disposal to evaluate the weight and credibility of expert testimony. As applied to this case, specifically, the defendant simply ignores Dr. McKee’s testimony about the hundreds of patients he has seen with precisely the history and presentation that plaintiff had, as well as Dr. McKee’s unequivocal statements discounting Mr. Cullum’s steroid injections and alcohol consumption as likely AVN causes. Defendant states instead that “Plaintiffs entire theory on the dose amounts at issue rests on one case in a population of 30,000,000 Canadians over 10 years ago.” Application at P 48. Zealous advocacy is one thing, but plaintiff respectfully submits that this level of argumentation is quite another and should not go unnoticed by this Court.

In any case, plaintiff argued, and the Court of Appeals agreed, that foreseeability is almost always for the jury:

Notwithstanding the flaws in his [mathematical] analysis,⁴ defendant's argument has no merit. "The determination of remoteness . . . should seldom, if ever, be summarily determined." *Lockridge*, 285 Mich App at 685 (citation omitted). Further, "the legal issue is not whether the patient's actual ailment is foreseeable, but whether the patient's injuries and damages . . . qualify as a 'natural and probable result of' the defendant's negligent conduct." *Id.* at 689 (citation omitted). Here, Dr. McKee testified that, based on his own research and experience, AVN results from short-course steroid therapy with some regularity. Dr. McKee also testified it was generally accepted in the medical community that short-course steroid therapy was a known cause of AVN. "Proximate cause is usually a factual issue to be decided by the trier of fact, but if the facts bearing on proximate cause are not disputed and if reasonable minds could not differ, the issue is one of law for the court." *Dawe v Bar-Levav & Assoc (On Remand)*, 289 Mich App 380, 393; 808 NW2d 240 (2010). In this case, plaintiff produced sufficient evidence to create a question of fact regarding whether developing AVN was a natural and probable result of defendant's allegedly negligent conduct. Accordingly, defendant's claim that he was entitled to summary disposition because plaintiff failed to present evidence creating a question of fact regarding legal causation is without merit.

There is no credible argument that the trial court can be affirmed on this alternate ground.

CONCLUSION AND RELIEF REQUESTED

Defendant's application for leave waves shiny objects at the Court but, when a closer examination is made, reality emerges. Dr. McKee is an extraordinarily well-qualified expert who spends the overwhelming bulk of his time in prodigious legitimate research and the actual treatment of patients. He made a reasoned analysis backed by his own wealth of experience, other literature besides his own and his general accumulated academic knowledge in the field. He used the same scientific method of analysis used by physicians all day, every day in the actual practice of medicine: the differential diagnosis. As noted by the Sixth Circuit in *Best*:

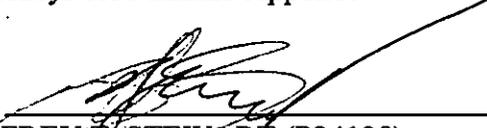
An "overwhelming majority of the courts of appeals" agree, and have held "that a medical opinion on causation based upon a reliable differential diagnosis is sufficiently valid to satisfy the first prong [reliability] of the Rule 702 inquiry."

The cases that have attacked case reports and other supposedly “anecdotal” evidence in support of an expert’s opinion have almost universally involved strong *Daubert*-qualified evidence in opposition to the plaintiff’s theory, often epidemiological studies showing little or no evidence of any connection between the alleged cause and the actual effect. *None* of that was present here. Defendant offered zero documentary evidence contradicting Dr. McKee’s initial observations and, in the approximately 44 (now 45 with the new Dilisio study) articles discussing side effects of steroids, not *one* author or commentator ever challenged the reliability of Dr. McKee’s observations that low dose steroids presented a small but statistically significant and important risk for this devastating disease. Indeed, Dr. Dilisio stated in his paper: “Prior to this study, this association was presumed but never quantified.”

Based on everything now before the Court, there is no reason to remand the matter to the trial court for further *Daubert* analysis. Contrary to the defendant’s assertions, the Court of Appeals got it exactly right. But, in any event, applicant’s sought reinstatement of the trial court’s decision is utterly impossible given that order’s utter disregard of this Court’s directive in *Clerc v. Chippewa County War Memorial Hosp.* 267 Mich.App. 597, 607, 705 N.W.2d 703, 709 (Mich.App.,2005) that trial judges examine all of the factors set out in MCL § 600.2955. The

decision of the Court of Appeals was well-founded in law, and well-justified in fact, and should be left to stand. Plaintiff therefore respectfully requests that the application be denied.

Respectfully submitted,
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