STATE OF WISCONSIN : CIRCUIT COURT : MILWAUKEE COUNTY

CIVIL DIVISION

BRANCH 27

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NEIL J. RENNICK,

Plaintiff,

-vs- Case No.: 18 CV 003317

TELEFLEX MEDICAL INCORPORATED
and WEA INSURANCE CORPORATION,

Defendants.

- -

ORAL DECISION

- -

June 23, 2020 BEFORE THE HONORABLE

JUDGE KEVIN E. MARTENS

A P P E A R A N C E S:

ATTORNEY JAMES J. KRIVA, Attorney at Law, appeared on behalf of the plaintiff via Zoom.

ATTORNEY JEFFREY PECK and ATTORNEY PATRICK SULLIVAN, Attorneys at Law, appeared on behalf of the defendant, Teleflex Medical Incorporated via Zoom. Also present via Zoom for Teleflex was in-house counsel, HOWARD CYR.

PAULINE GARRY, Official Court Reporter

* * * T R A N S C R I P T * * *

THE CLERK: Case No. 18 CV 3317. Neil J. Rennick versus Teleflex Medical Incorporated, et al. Appearances, please?

MR. KRIVA: Good afternoon, Your Honor. Jim Kriva of Kasdorf, Lewis, & Swietlik for the plaintiff, Neil Rennick.

MR. PECK: Good morning, Your Honor. Jeff Peck, Ulmer & Berne for the defendant, Teleflex Medical Incorporated.

MR. SULLIVAN: And Pat Sullivan from Siesennop & Sullivan also for Teleflex, Judge.

THE COURT: I understand we've got Howard Cyr here also on the line. He's appearing by audio only. He's in-house counsel for Defendant Teleflex and is here to observe and obviously hear the Court's order or ruling.

This matter was before the Court last as I review our minutes on May 22nd, and that was for a hearing on a defendant's motion for summary judgment. We've completed the arguments, but I needed some time to consider further, and I think we also had some time limitation, so I set the matter over for oral ruling today.

I know Mr. Kriva did submit a letter and sent it after the hearing in which he addressed some additional matters post-hearing or at least additional argument post-hearing. I believe Mr. Peck submitted a response to that asking that the Court not consider that argument after the hearing. I don't believe any of it's material, and I'm not going to consider it therefore.

This is going to maybe seem a little bit awkward, I hope not too disjointed as I go through -- I'll do my best to render some findings and obviously conclusion on the summary judgment motion. I've got paper in front of me, but I'm going to need to be toggling back and forth from screens as well, and that's again a little bit of an awkward process.

Doing these things orally and not in writing also gives us the benefit of the Court having a decision rendered more quickly. Again everybody understands that more time and deliberation and putting things in writing might make it a little more seamless as far as how I address it, but I'll do my best. Again I do apologize if at times I may be jumping back and

forth, or if I think I may have missed something and I have to go back and address it, it's just the nature of things.

I'm going to mute all the attorneys, and again I'm not always going to have the screen in front of me where I can see you, but I will be toggling back and forth. So if at some point we run into an issue, if somebody does feel you need to address something immediately and you can't wait until I'm done or again we lose somebody, you know, do your best to signal, and again I may not see you right away, but I will I'm sure see you at some point.

If somebody loses your connection, if you call back in, it should give me the notice prompt, and then I'll be able to let you back into the Zoom meeting.

So let me start with some facts and the factual background, again a lot of facts set forth in the briefs. I don't know that I necessarily would find there to be a significant number of what I guess I would call contested facts, but obviously different facts that each party -- that parties highlight and then further argue form a basis to support either their

argument for or against the motion for summary judgment.

That motion by defendants is primarily, though not exclusively, geared towards the issues involving what's called the Learned Intermediary Doctrine and whether or not it applies to our case and applies indeed in the State of Wisconsin, so I will be getting into that primary issue in just a moment.

With regard to the background of the case, again I am going to just give a summary of what I understand the facts to be. Again if I don't state everything, its not because I'm making any necessary conclusions regarding any contested facts, but I believe this is a summary that would really not be contested though both parties may have certainly supplements or additional facts they might believe are part of the case, and again I will be going back to some of that as we go forward.

In 2015 the plaintiff in this matter Neil Rennick, who is also I believe a doctor, began experiencing a series of symptoms that did cause him then to visit first his urologist who then did ran some tests, and those tests revealed

a renal mass which them prompted a referral to a specialist, Dr. Mark -- and again I can't remember if it's pronounced Wapels (phonetic) or Waples, it's W-A-P-L-E-S. I'm just going to use Waples.

The plaintiff did meet with Dr. Waples in 2015 in April, had a consult; and then ultimately after being provided information, the plaintiff decided the best course of action was to undergo some procedure called a robotic assisted laparoscopic -- for the reporter L-A-P-A-R-O-S-C-O-P-I-C -- partial nephrectomy, that's N-E-P-H-R-E-C-T-O-M-Y. And the purpose of that procedure was to remove the mass or tumor while sparing the rest of the kidney with the goal of retaining function of the kidney itself.

During this procedure once the tumor's removed, the kidney must be sutured and closed, and that process is called I believe renorrhaphy, R-E-N-O-R-R-H-A-P-H-Y, again I may be mispronouncing.

The technique that Dr. Waples used to do that, that is to suture and close involved using what's called a sliding clip renorrhaphy using a product or clips called the Weck, W-E-C-K

Hem-o-lok, that's capital H-E-M-hyphen, capital-O-hyphen, capital-L-O-C, Polymer Locking Ligation System or Weck clips; and those are apparently placed over the sutures to anchor and bolster the sutures to reduce risk that the sutures may pull out.

These Weck clips are manufactured by defendant company, Teleflex Medical Incorporated, and have an intended use for procedures involving ligation of vessels or tissue structures.

The process of this sliding clip or renorrhaphy I think is adequately characterized as an off-label use of not an intended use, and that's obviously by itself is just a way to describe it, it's not a qualitative description.

The use in doing the sliding clip technique was something that Dr. Waples learned by observing other physicians perform it and also by attending national meetings where the procedure was reviewed and discussed.

It's believed that the procedure and the technique has benefits that include reducing the time blood to the kidneys are shut off during the procedure and will hopefully maximize the chances of full recovery and kidney functioning.

Dr. Waples and his partner did perform the proceed on the plaintiff on April 17th of 2015. On that date the surgeons did remove a mass from the plaintiff's left kidney and closed the opening of the kidney using again among other thing this sliding clip technique with the Weck clips. The Weck clips were also used to resecure connective tissue surrounding the kidney and to secure the kidney itself to other structures -- internal structures to prevent rotation.

I believe the evidence is and some controverted that the clips that were used were not implanted inside the kidney itself, and at least at completion of the surgery is believed by the surgeons that there weren't any complications.

Plaintiff saw Dr. Waples for follow-up several weeks after the surgery and reported, that is the plaintiff, did have his presurgery symptoms many had returned along with several new symptoms. Dr. Waples ordered an ultrasound of the kidney and recommended an appointment with an oncologist.

The plaintiff continued experiencing worsening or debilitating pain and symptoms, and

at a second a follow-up visit with Dr. Waples on June 29th, 2015. Dr. Waples was unable to determine the source of the symptoms and suggested that the plaintiff obtain additional opinions from specialists.

Post-surgical pain and other symptoms continued unfortunately for the plaintiff; and on March 4th, 2016, the plaintiff expelled an intact Weck clip during urination. He still continued to experience pain and other symptoms thereafter and sought out medical treatment and advice from providers other than Dr. Waples in 2016.

Ultimately the plaintiff did undergo a surgical procedure in November of 2016, and observed apparently during the procedure was an exposed Weck clip with calcification embedded in the plaintiff's renal collecting system that was unable to be removed.

The plaintiff continued to experience internal bleeding and pain, and then after further consultation it was determined that the plaintiff needed to have part of his kidney removed along with some other surrounding tissue, that procedure occurred on December of 2016.

And during the procedure the surgeon

noted severe inflammation at a location where several Weck clips were found. Some of the clips were intact while others were broken, and after the surgery then the plaintiff's symptoms began to slowly improve.

The plaintiff brought action -- or brought this case, this action on April 16th, 2018, alleging four causes of action:

The first, common law negligence.

The second, strict product liability under Wisconsin Statute Section 895.047.

Third cause of action titled as a strict liability misrepresentation pursuant to the Restatement of Torts Section 402(B).

And then finally the fourth cause of action, a violation of Wis. Stat. Section 100.18, alleging strict liability misrepresentation.

Teleflex filed its summary judgment motion in December, again the matter was fully brief and heard by the Court on May 22nd.

As the parties know, summary judgment is appropriate when pleadings, deposition -- this is under the statute itself, of course -- when pleadings, depositions, answers to interrogatories and admissions on file, together

with affidavits, if any, show two things:

First, that there is no genuine issue as to any material fact.

And then secondly, that the moving party is entitled to judgment as a matter of law, again under 802.08(2) of the Wisconsin Statutes.

Summary judgment's intent is to eliminate unnecessary trials in circumstances where there is no triable issue of fact to present to a jury, that's the Maynard case, M-A-Y-N-A-R-D, 98 Wis. 2d 555.

The Court will take evidentiary facts in the record as true if not contradicted by opposing proof, and the inferences to be drawn from facts presented are to be viewed in a light most favorable to the party opposing the motion, in this case obviously in favor of the plaintiff.

Doubts as to the existence of a genuine issue of material fact are resolved against the moving party, again in this case then to be resolved again the defendant. And again that well understood case or legal proposition comes from the Lambrecht case, L-A-M-B-R-E-C-H-T, and others, that found at 241 Wis. 2d 804.

It is the burden of the party moving

for summary judgment to demonstrate the absence of genuine issues of material fact. The material fact is defined as one that is of consequence to the merits of the litigation. Factual issues are genuine if the evidence is such that a reasonable jury could return a verdict based on that issue for the non-moving party. Again a number of cases stand for those propositions as well, including and not limited to the Central Corporation versus Research Products, 272 Wis. 2d 561; Schmidt versus Northern State Power, 305 Wis. 2d 538; and Baxter versus Wisconsin Department of Natural Resources, 165 Wis. 2d 298.

Once a moving party has satisfied or met its initial burden, its then incumbent on the non-moving party to not simply rest on the mere allegations or denials in pleadings but instead to set forth its own specific facts showing that there indeed is a genuine issue for trial. Again it's only if the Court is satisfied that there is no genuine issue of material fact that the Court can consider then entering judgment as a matter of law.

In its summary judgment brief, again the defendant first argues the applicability of

the Learned Intermediary Doctrine, and argues that the doctrine indeed is applicable here. And because it applies, that the plaintiff therefore cannot establish a necessarily element on any of its four claims, that element being causation.

On Page 8 of the defendant's brief, the defendant notes that causation is again a requirement of each alleged cause of action citing the Warner case, which is a Federal case from the Western District of Wisconsin, which cites Wisconsin cases to establish that to prove negligence, the plaintiff must establish a causal connection between conduct and injury, that specifically that the conduct is a substantial factor in producing the injury.

Defendant cites the Dippel case, D-I-P-P-E-L, 37 Wis. 2d 443, for the proposition that a strict liability claim requires a showing that the defect was a cause of the plaintiff's injuries or damages. Defendant cites the Ollerman case, O-L-L-E-E-R-M-A-N, for the proposition that strict liability misrepresentation claims require that the plaintiff believed the representation to be true and realize on it to his or her damage.

And then finally the Norvell case, N-O-R-V-E-L-L, which addresses actions for strict liability misrepresentation under -- strike that -- misrepresentation actions under Section 100.18 of the Wisconsin Statutes and states that the representation must materially induce or cause pecuniary loss to the plaintiff, and the defendant then argues that the Learn Intermediary Doctrine applies.

That doctrine as would be applied here states that a manufacturer -- is a proposition that a manufacturer of a medical device or a physician who otherwise prescribes a drug to a patient has no duty to warn the patient as long as the manufacturer provides adequate warnings to the physician.

And again there's I think and what the defendant cites in setting forth the doctrine and arguments' applicability is primarily from the Zimmer case, which is a 7th Circuit case, it's Zimmer versus -- I think it's NexGen, N-E-X-capital-G-E-N, Knee Implant Products Liability Litigation. I should say In Re Zimmer NexGen Knee Implant Products Liability Litigation, 7th Circuit decision found at 884 F.

3rd 746, and it's a decision from 2018. That decision's authored by a former Wisconsin Supreme Court Justice, Diane Sykes, and involved circumstances involving a knee implant.

The allegations were that after having a knee implant that the plaintiff was suffering pain and loss of movement, and alleged that that was due to the implant itself being prone to premature loosening.

The plaintiff brought a cause of action against the manufacturer of the implant under several theories, including defective design, defective manufacturer, and inadequate or failure to warn.

The defendant moved for summary judgment, and that motion was originally granted. The basis for the grant of summary judgment at the trial court level was due to the trial court excluding a plaintiff's witness. It therefore rendering the plaintiff unable to proffer required expert testimony on issues relating to defective design and manufacturer, and then found further that without -- that that left a causal gap regarding the plaintiff's ability to then provide or prove an inadequate warning claim as

well.

Plaintiff appealed, 7th Circuit addressed the matter and noted that:

First, the appeal related only on the claim of the defective warning. The plaintiff arguing that the defendant had failed to issue proper warnings directly to the plaintiff as the recipient of the knee replacement.

And secondly, that the defendant had failed to issue proper warnings to the surgeon who implanted the device.

The Zimmer court and Judge Sykes analyzed Wisconsin law noting that their duty, first of all, was to apply the law in the State of Wisconsin, this was a case that involved Wisconsin law, and that in those circumstances the Wisconsin Supreme Court had not addressed the issue of Learned Intermediary Doctrine and whether it applies in the State of Wisconsin.

Actually the court indicated at Page 751 that neither the Wisconsin Supreme Court nor the State's intermediate appellate courts have addressed the doctrine, that was what the 7th Circuit said, then went through its obligations then in those circumstances to determine how the

State's highest court would rule; that is, to be predictive.

In that case the 7th Circuit felt confident that it could predict how the Wisconsin Supreme Court would address or whether or not it would apply the Learned Intermediary Doctrine. It felt it could do so without certifying the issue itself to the supreme Court.

The court did, the 7th Circuit did note that there were Federal -- other Federal courts, including district courts in Wisconsin that had applied the doctrine, and that there was I think as argued by the defendants on the last hearing date sort of an overwhelming list of other jurisdictions that had adopted and applied the doctrine as well.

The 7th Circuit recognized that at least 35 states, this was from that citation that had been provided from the Texas Supreme Court case:

That the highest courts of at least 35 states have adopted some form of the Learned Intermediary Doctrine within the prescription drug products liability context or cited favorably to its application too within this

context, and that the intermediary appellate courts in another 13 States have applied the Learned Intermediary Doctrine or predicted that their Supreme Courts would do so, believe that ultimately there may have been only one court that rejected it, and that I think was a West Virginia court perhaps.

The 7th Circuit concluded that there was "good reason to think that given the opportunity the Wisconsin Supreme Court would join the vast majority of State Supreme Courts and adopt the Learned Intermediary Doctrine for use in defective warning cases like this one involving a surgical implant. Then concluding that to the extent that the plaintiff's defective washing claim is based on the defendant's duty to warn the plaintiff directly, that that's foreclosed by the Learned Intermediary Doctrine.

But their failure to warn the surgeon, what the plaintiff argued in the Zimmer case was that there was an -- that the surgeon should have used essentially more cement to -- as part of the implant procedure, and that that had not been something that was included as part of the instructions from the manufacturer.

The 7th circuit concluded that that argument and that theory was not enough to support a defective warning claim as there was no evidence supporting the contention that it was the defendant's responsibility to instruct surgeons about the amount of cement they should use in implant surgery, and that the record itself indicated that surgeons are primarily guided in their technique by the basic medical training receive during residency and or fellowship, that that's indeed what the surgeon at issue had testified to.

The court noted further on Page 754 that there was no evidence suggesting that the doctor would have followed an improved instruction on cementing techniques had the defendant Zimmer provided one.

The plaintiff argued that the judge should allow the claim to go forward nonetheless based on -- and this is something that we also heard at the last hearing, an argument -- that the case should nonetheless go forward on what's called a heeding presumption which would permit the fact-finder to presume in the absence of proof that a proper warning would have been read

and heeded, heeded being H-E-E-D-E-D.

The 7th Circuit though noted that again the State appellate courts in Wisconsin have not addressed the doctrine, but that the 7th Circuit in its words seriously doubt that they would adopt it in this context. This was again the argument in the briefs, and that the parties had an argument that was whether or not the Kurer, K-U-R-E-R, case or the Tanner case is more applicable. Kurer is again K-U-R-E-R.

And in Kurer, I just want to find the citation here which I'm not finding at the moment, I'll get back to that if I do. In Kurer, the case itself, that was a circumstance where plaintiff alleged she developed a rare disease from taking prescription birth control pills, that the disease developed after she experienced bothersome headaches.

The warnings on her prescription directed her to call the doctor if she experienced headaches, however she did not seek medical attention for many months. And when -- it's citation 272 Wis. 2d, I think it's 390 -- when determining whether the lack of warning caused the plaintiff's injuries, the Court of

Appeals in that said, and I'm quoting, that "proximate cause is not presumed" in a failure to warn case.

The court went on to state that:

"A plaintiff who has established both a duty and a failure to warn must also establish causation by showing that if properly warned he or she would have altered behavior and avoided injury."

And the court said "that absent proof that a more complete or explicit warning would have prevented use of the drug, that the plaintiff could not establish that the defendant's failure to was the approximate result of her injuries," that case again from 2004.

The plaintiff then arguing against that proposition and arguing that the heeding presumption should apply cited the Tanner case, that case found at 228 Wis. 2d 357, a Court of Appeals case from 1999. That case apparently involved injury caused by an exploding I think it was car battery, and that occurred after the plaintiff scraped off a corroded part of the battery with a penny.

The plaintiff did not read warning

labels on the battery, that there was an expert who testified that someone other than the plaintiff had previously struck the battery or hit it with great force.

When determining whether a lack of warning was a substantial factor in causing the plaintiff's injuries, the court said that:

"A fact-finder could reasonably assume that the warning would have been read and heeded by the user." The court relied on the Restatement Second to support that proposition that warnings will be read and heeded.

The court determined in that case that even though the plaintiff did not read the warning label, a reasonable jury could find the lack of warning to be a substantial factor in causing the injury. The court focused on the fact that another person again had previously hit the battery, and that if that person had read a warning label, it could have prevented the plaintiff's injuries.

So these competing cases or sort of theories were addressed by the 7th Circuit in Zimmer. And Zimmer highlighted the fact that in the Tanner case, the facts involved and what that

involved specifically was the heeding presumption as it would apply to the prior users of the battery before the plaintiff, not the plaintiff him or herself.

The court determined that the heeding presumption did not apply in the factual scenario in Zimmer because the physician did not read the instructions on how to implant the medical device, but rather relied on his training and experience, again distinguishing it from the circumstances of Tanner where again the issue involved a user prior to the person to whom the duty would be owed.

Again in Zimmer then the Court concluded that summary judgment was appropriate as there was no evidence to support the plaintiff's proposition that if properly warned, the physician would have actually altered his own behavior.

I'm satisfied that in Wisconsin and I think it's a good analysis that the 7th Circuit gives of the Learned Intermediary Doctrine, its applicability and what I believe also is the likelihood that the Supreme Court itself would indeed adopt the doctrine, that the doctrine is

applicable and therefore should be applied in this case.

The doctrine applying then again under the facts presented in the support of the motion is uncontroverted I believe that Teleflex did not provide warnings regarding migrating Weck clips. So the issue is whether or not there is a genuine issue of material fact as to whether or if indeed it provided those warnings, whether that would have been -- was a substantial factor in causing the injuries; or maybe to state it another way, again whether or not there would have been any different result.

From the testimony of Dr. Waples, again both parties go into some detail about that, the -- again I may be jumping around a little bit back and forth with regard to this part. I believe the facts are uncontroverted that Dr. Waples never learned the sliding clip technique from any Teleflex representative, and that his use of the technique was based on his own education, training, and experience.

In this circumstance I believe its -- or its believed that he may have used somewhere in the range of 29 to 33 Weck clips. He

testified that he -- as far as the number of clips that he would use for the technique, that that was based again on his own clinical experience and judgment.

He has continued to use Weck clips when performing these procedures even after again the circumstance involved in this case, and estimated that he's performed at least a couple hundred of the same procedures since the plaintiff's operation in April of 2015.

In his deposition testimony, Dr. Waples described the sliding clip technique as a "game changer in terms of allowing more complex partial nephrectomies to be done."

I believe the facts are uncontroverted that Dr. Waples did not provide any information to the plaintiff himself about Weck clips before the operation or about any risks associated with migrating Weck clips.

Dr. Waples I believe in his deposition testimony stated that he never seen a migration prior to the actual surgery involved here. And I'm going to actually quote because I think this is important. He stated the following on Pages 166 and 167 of his deposition. He said:

"I've never seen it. At that time I don't even know if I've ever seen is reported. You know, it's a high complexity surgery with a lot of steps to it, and I don't have a replacement for a Weck clip to do partial nephrectomy, and I'm not aware of any high volume national guys that I go to courses to that are using something other than Weck clip.

There is a competing product that, you know, we've looked at and we have some concern about it, and I probably would wait until, you know, quote, unquote, some of the other big dogs were using that before I would switch."

Dr. Waples testified that he does not warn patients about the risks associated with Weck clip migration, again that he hasn't done that even after this particular and surgical incident or result. That the Weck clip migration is not one of his top 100 concerns when performing this particular procedure. He did state or acknowledged that "maybe this is something I should start to disclosing."

In the -- strike that. I'm not going to get into line-by-line and read everything. I'm just going to refer to the plaintiff's

response brief, Pages 5 through 7 that set forth a number of different bullet points involving the background of these particular Weck clips and include listings of some concerns or issues that have been raised in medical literature and perhaps through other sources regarding use and problems that resulted from use with these particular clips.

One of those bullets points at the bottom of Page 6 notes that the 2013 version of Teleflex's H-as in Henry-hyphen-O-hyphen-L, product instructions for use booklet was delivered with defendant's sale of Hem-o-lok clip products to Aurora Health Care which Aurora provided as surgical supplies in it's St. Luke's operating suite when Dr. Waples performed the 2015 surgery on plaintiff.

And that it's further the case that those instructions for use do not disclose and warn about the risks of patient injury due to clip failures and clip migration in laparoscopically implanted patients. And again those are facts that I -- or at least those facts set forth are to be viewed in the light most favorable to the plaintiff regarding both the

history, inferences about what may be known to the defendant, and again the circumstances involving the instructions themselves.

With regard to Dr. Waples, I know I'd also refer to Pages 8 through -- this is a little more substantive, but 8 through 14, 13 I'm sorry, of the plaintiff's brief as well with regard to specifically other things that Dr. Waples may have indicated in his deposition.

Again I'm not going to go through all of it. Again just highlighting perhaps on Page 9, that at least 29 of the clips or possibly as many as 33 were implanted inside plaintiff. That Dr. Waples believed that each clip was closed, sealed and firmly attached during the operation, and that no loose clips were left inside the plaintiff.

Dr. Waples testified that he'd never been instructed or warned by Teleflex to restrict or limit the number of clips being implanted in a single surgery. Again in his deposition testimony he testified that he did not put clips on the inside of the kidney, that they were placed on the outside; and that again his preference, of course, would be that after

placing the clips at a specific location that they remain so situated.

Page 11, that when asked about safety information received from Teleflex regarding Hem-o-lok clip migration and asked specifically, quote, have you received any kind of safety information from the manufacturer of this clip prior to 2015 that provided you with recommendations or they suggested medical protocol for timely diagnosing and properly treating clip migration complication injuries," that Dr. Waples answered "not that I know of, no."

He also testified that prior to the 2015 surgery of the plaintiff, that he had not encountered an occasion of the clips moving and migrating from the location that they were implanted and becoming located in the collecting system of the kidney.

I think I've addressed again the facts and circumstances surrounding Dr. Waples. In my view our fact are very similar to the circumstances as they presented in the Zimmer case as well with regard to this particular issue. Again in our case it's the plaintiff's

position that the Court should presume that had Teleflex provided warnings in its instructions or otherwise, that would have then been brought to Dr. Waples' attention regarding clip migration, that Dr. Waples would have heeded that warning or changed his conduct or otherwise acted in a manner that would have resulted in the clips either not being used or presumably the procedure not taking place. And again I believe that that is contrary to all of the testimony that Dr. Waples provided in the deposition.

And specifically that Dr. Waples says -- there's no factual basis I believe in the record for the Court to find that Dr. Waples would have heeded any warning had it been provided and had he reviewed it, again similar to Zimmer.

Similar to again the surgeon in Zimmer, Dr. Waples did not learn the technique itself from Teleflex or a Teleflex representative. He learned the sliding clip technique from other doctors and peer-reviewed research. Again the procedure itself being described as an off-label use.

There's no evidence in the record that

Dr. Waples would have altered his use of the clips and or the sliding clip technique itself. In his own words he said that he doesn't have a replacement for the Weck clip to do a partial nephrectomy. He's not aware of any other -- again in his words, high volume national guys that are using anything other than the Weck clips. He continued to use those clips, and the same technique even after the circumstances involving clip migration that occurred with regard to plaintiff.

He also indicated that he's not issued warnings to patients or provided patients with any further warnings of the risks associated with migrating Weck clips even after again the circumstance involving the plaintiff, though I recognize again at one point he did simply state maybe he should going forward.

So there is no evidence in the record then that I believe allows for the Court to find that Dr. Waples would have altered his technique or any further relay of risk to the plaintiff with regard to the use of Weck clips or migration for this particular type of off-label use.

Again the plaintiff has argued that the

Court should make a presumption, should apply the heeding presumption in these circumstances or that it applies at least to the point where it can defeat summary judgment, but again I'm in agreement with the Zimmer case analysis that that presumption would not apply to ours, that the heeding presumption that is discussed and applied to the Tanner case is only applied to cases where it's unclear whether the person would have heeded the warning, and that case again involves a prior use or user before the matter had gone to the plaintiff. In our case again we've got specific and direct evidence from Dr. Waples himself.

I just -- again so I can make sure the record is clear on this, again with regard to the actual circumstances, facts relating to migration and determinations or for that matter, you know, any facts whether they're disputed or not regarding proper installation of the clips or those types of facts, those are -- again the Court's reviewing all those facts, the prior issues involving any prior knowledge of Teleflex regarding other problems with the clips in the past in the context of nephrectomies and migration, we know again both points that were

highlighted in the plaintiff briefs, I'm again viewing all of that in the light most favorable to the plaintiff and not addressing specifically those issues.

I understand those again at least at some point may well be contested facts, but simply addressing the application of the Learned Intermediary Doctrine and what I believe are the facts that relate to that doctrine, and what I believe are the uncontroverted facts that relate to that doctrine and the inferences that the Court must draw from those.

Again causation being a necessary element on each of the causes of action, the Court believes that therefore based on those findings and conclusions that the Court as a matter of law must grant the defendant's motion and order dismissal of the claims.

The plaintiff has at least pled and I believe in the response brief and also did argue apart from the arguments regarding either failure to warn or misrepresentation were made in all four claims, but also at least with regard to negligence and strict product liability, the first two claims, also make further arguments or

highlights at least it's pleadings with regard to other issues besides warnings or representation, that is specifically the arguments that the product itself, the Weck clips are either the subject of defective design or defective manufacture.

I believe it's uncontroverted through the facts that the use of the clips again is what is deemed an off-label use. The defendant cites on Page 7 of the reply brief that the Wisconsin product liability statute requires that in a design defect claim, that it must be based on the product's intended use, and then it cites (a) and (3c) with regard to that.

And again the plaintiff has not made a showing that the use here was again part of the product's intended use, or I don't believe that it has been able to cite or at least I don't believe the plaintiff was able to cite any cases that would otherwise apply to the Wisconsin product liability statute in circumstances like ours to support a designed defect claim.

To support that and any claim regarding manufacturing defect would also require expert testimony. I don't again recall or I don't

believe I saw in at least the submissions expert testimony to support those types of claims proffered through the plaintiff, and again we're nonetheless dealing with off-label use.

All right. I believe I've hit on what I needed to and what I intended to address by way of the facts and conclusions and again the arguments brought by counsel. So for those reasons, the Court again applying the standards of summary judgment believe that I am required to grant the defendant's motion for summary judgment with regard to each of the four claims and order then that the matter be dismissed.

I'm going to stop. I'm going to -- I don't need anybody obviously to repeat what you have argued previously, but I do want to just make sure you have a chance to have a complete record if anybody feels at this point there is anything else that needs to be made part of record for purposes of appeal? Mr. Kriva?

MR. KRIVA: I'll stand on my record, Your Honor.

THE COURT: Okay. Mr. Peck, you need to unmute?

MR. PECK: You mean that big thing that said

unmute on my screen that I should have clicked the box on, I apologize for that. Nothing further here, Your Honor. Thank you.

THE COURT: All right. Then I'm going to just need a written order. Prevailing party, Mr. Peck, if you can submit that and just do so under the 5-day rule.

MR. PECK: Yes, Your Honor.

THE COURT: All right, thank you. That will conclude the hearing and the live stream. Thank you, I appreciate again counsel your time, your patience, and I think a very good job in briefing and arguing the issues.

MR. KRIVA: Thank you.

MR. PECK: Thank you, Your Honor.

THE COURT: All right, that will conclude the hearing.

(Proceedings concluded.)

* * *

STATE OF WISCONSIN)
) SS.
COUNTY OF MILWAUKEE)

I, PAULINE GARRY, R.P.R., do hereby certify that the foregoing transcript of said proceeding is a true, complete and correct report of the entire proceedings, together with such other matters and things as counsel for the parties present and the Court at the taking of said proceeding desire to have appear of record.

I further certify that I am not counsel for nor am I interested in any manner in the said cause or in its outcome.

IN WITNESS WHEREOF, I have hereunto set my hand this 12th day of October, 2020, A.D.

Pauline Garry

PAULINE GARRY, RPR
OFFICIAL COURT REPORTER