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Commonwealth of Kentucky

Court of Appeals

NO. 2009-CA-001349-MR

ANN SPARKS — APPELLANT

v.

APPEAL FROM WARREN CIRCUIT COURT
HONORABLE JOHN R. GRISE, JUDGE
ACTION NO. 07-CI-01448

JOHN DOWNING, M.D.
AND DOWNING-MCPEAK
VISION CENTER, P.S.C. — APPELLEES

OPINION
AFFIRMING

** ** ** ** **

BEFORE: DIXON AND KELLER, JUDGES; LAMBERT,[1] SENIOR JUDGE.

LAMBERT, SENIOR JUDGE: Ann Sparks (Appellant) appeals from a jury verdict and final judgment of the Warren Circuit Court for John Downing, M.D.

[1] Senior Judge Joseph E. Lambert sitting as Special Judge by assignment of the Chief Justice pursuant to Section 110(5)(b) of the Kentucky Constitution and Kentucky Revised Statutes (KRS) 21.580.

and Downing-McPeak Vision Center, P.S.C. (Appellees) in Appellant's medical malpractice and medical battery claims against Appellees. Appellant raises a number of evidentiary issues on appeal and also challenges the trial court's directed verdict in her battery claim prior to submission of the case to the jury. Upon review, we affirm.

FACTS AND PROCEDURAL HISTORY

In 2005, Appellant, a patient of Dr. Downing's, requested cataract surgery to improve her vision. On November 22, 2005, Appellant underwent a successful cataract extraction in her left eye via the use of an intraocular Alcon lens. She then underwent the same procedure for her right eye on December 21, 2005. Because Appellant also had astigmatism in this eye, Dr. Downing chose to use a different lens to correct this condition, as well. Testimony at trial reflected that this lens – the STAAR Toric TL – was the only lens on the market at the time that had Food and Drug Administration (FDA) approval for correcting astigmatism.

During the procedure, Dr. Downing encountered a slight tear in the periphery of the capsular bag where the lens was designed to go.[2] The parties agree that the presence of such a tear made it unsafe to implant the STAAR lens into the capsular bag. At this point, Dr. Downing chose to place the lens into the sulcus – the larger space in front of the capsular bag. This decision ultimately became the focal point of this lawsuit since it is undisputed that the FDA had only

[2] Appellant challenges this assertion, but this challenge does not have any relevance to the issues before us. Thus, it merits no further consideration.

expressly approved the lens for use in the capsular bag, which tends to contract around the lens in order to hold it in place. At best, and the testimony was disputed on this point, the FDA was non-committal as to whether the lens could be implanted in the sulcus.

Soon after surgery, the STAAR lens began rotating in Appellant's right eye and eventually became displaced in front of the iris, as a result of which Appellant suffered extreme discomfort and was rendered temporarily blind in that eye. Dr. Downing repositioned the lens the following day by using a needle to move the lens back into place. However, soon thereafter, Appellant began to have blurry distance vision because the lens had rotated again and was adding to her astigmatism.

On January 25, 2006, Dr. Downing removed the STAAR lens altogether and exchanged it for a different, sulcus-fixated, lens because he believed that Appellant's right eye could not adapt to the STAAR lens.[3] Because the new lens did not correct the astigmatism, Dr. Downing performed limbal relaxing incisions – which Appellant claims were excessive and unauthorized – to change the shape of Appellant's right eye to correct some of the astigmatism and give her better vision. However, Dr. Downing later admitted at trial that Appellant was still going to need to wear glasses or to undergo another procedure to fully correct her astigmatism. Several months later, Appellant developed swelling in the cornea of

[3] Dr. Downing acknowledged at trial that he had performed 14,000 to 15,000 surgeries, but this was the only occasion in which he had placed a STAAR Toric TL lens into a patient's sulcus.

her right eye, and she was referred to a specialist for additional treatment. She ultimately underwent a cornea membrane transplant in April 2007.

On September 10, 2007, Appellant filed a medical malpractice lawsuit against Dr. Downing and the Vision Center. She claimed that Dr. Downing had negligently performed the cataract surgery on December 21, 2005, as well as the attempted corrective procedure the following day. This lawsuit also included a claim of battery on the grounds that Dr. Downing had failed to obtain proper consent for the initial surgery and for the subsequent attempts to remedy the problems caused by that procedure.

The case was tried before a jury in April 2009. The parties relied on expert witnesses to present their theories of the case. Appellant presented testimony from Dr. Michael Krasnow, who asserted that placement of the STAAR lens in Appellant's sulcus was inappropriate medical practice because the lens was not intended for use in that manner. Appellants relied upon testimony from Drs. Richard Eiferman and Nate Kleinfeldt, both of whom claimed that implanting the lens in the sulcus was an appropriate use of the lens even though the FDA had not approved it for this purpose. The jury returned a unanimous jury verdict in favor of Appellees as to Appellant's medical malpractice claims. The jury specifically found that Dr. Downing did not deviate from the degree of care and skill expected of a reasonably competent physician specializing in ophthalmology and acting under similar circumstances. The court granted a directed verdict upon Appellant's battery claim before the case was submitted to the jury on the grounds

that she had consented to all medical procedures. Appellant's subsequent motions for post-trial relief were rejected. This appeal followed in a timely fashion.

ISSUES

On appeal, Appellant presents a number of grounds for a new trial, most of which focus upon the trial court's decisions to admit or to exclude certain items of evidence offered by the parties' expert witnesses. Appellant also challenges the trial court's dismissal of her battery claim. However, for reasons that follow, we do not believe that the trial court committed reversible error with respect to any of these issues.

I.

Appellant first argues that Appellees were erroneously allowed to introduce, via expert testimony, a "new" defense theory at trial centering on a claim that the STAAR lens in question was used in a permissible "off-label" fashion, *i.e.*, in a manner different from that expressly approved by the FDA.[4] According to Appellant, this testimony was allowed despite the fact that this defense: (1) had not been previously disclosed as required by pretrial orders; and (2) was not applicable under the facts of the case. As to the first claim, Appellant asserts that Appellees' opening statement at trial was the first indication that Appellees intended to argue as a defense that placement of the STAAR lens in Appellant's sulcus was a permissible "off-label use" of the lens. Because of this, she argues, evidence regarding this line of defense should have been excluded at

[4] *See Washington Legal Found. v. Henney*, 202 F.3d 331, 332 (D.C. Cir. 2000); *Cordray v. Planned Parenthood Cincinnati Region*, 911 N.E.2d 871, 878 (Ohio 2009).

trial because of Appellees' purported failure to properly disclose the defense as required by pretrial orders issued by the trial court.

As an initial matter, we question whether this issue was properly preserved for review. While Appellant did object to "off-label use" testimony offered by Dr. Downing, she has not shown that she objected to or moved to strike such testimony when offered by Appellees' actual expert witnesses, as is her obligation. CR 76.12(4)(c)(v). Indeed, it appears from our review of Dr. Eiferman's testimony that he was allowed to talk extensively about this subject without any objection being made. Moreover, Appellant has not established that any such error with respect to Appellees' expert witnesses was preserved via a request for a continuing objection to testimony regarding "off-label use." *See Davis v. Commonwealth*, 147 S.W.3d 709, 721 (Ky. 2004), *quoting* 75 Am.Jur.2d Trial § 402 (1991) ("At the *request* of a party or on its own initiative, the trial court *may grant* a continuing objection to a line of questions by an opposing party[.]") (Emphasis added in original). Nevertheless, even assuming that the issue is properly before us, we discern no error.

We review a trial court's rulings regarding the admissibility of evidence for abuse of discretion. *Goodyear Tire and Rubber Co. v. Thompson*, 11 S.W.3d 575, 577 (Ky. 2000). "A trial court's ruling on the admission of expert testimony is reviewed under the same standard as a trial court's ruling on any other evidentiary matter." *Id.* at 578. "The test for abuse of discretion is whether the

trial judge's decision was arbitrary, unreasonable, unfair, or unsupported by sound legal principles." *Commonwealth v. English*, 993 S.W.2d 941, 945 (Ky. 1999).

On November 19, 2007, the trial court entered a pretrial order setting forth, among other things, a discovery schedule and a list of required disclosures for any expert witnesses the parties intended to use. This list included the following items:

> ... a brief summary of the qualifications of any expert witness the party may call at trial, together with a report or statement of any such expert witness that sets forth the subject matter of the expert witnesses' anticipated testimony; the substance of the facts and opinions to which the expert is expected to testify; a summary of the grounds for each opinion; and dates the expert is available for deposition.

The order further provided that the exchange of information regarding expert witnesses was governed by Kentucky Rules of Civil Procedure (CR) 26.02(4) and warned that "[a] generalized statement outlining a broad subject matter about which an expert may testify does not sufficiently apprise the other party of the information needed to prepare for trial as contemplated and mandated by the notice requirements of CR 26.02(4)(a)." The order additionally warned that "[i]n absence of good cause shown, no witness shall be permitted to testify, except upon compliance with the conditions of this order."[5]

Appellant claims that Appellees failed to comply with these requirements because they did not disclose that they would be relying upon an

[5] The court subsequently issued other pretrial orders when the parties were unable to comply with the original schedule, but those orders contained essentially the same substantive requirements. Thus, they do not merit further description.

"off-label use" defense. She specifically asserts that the reports tendered by Drs. Eiferman and Kleinfeldt failed to contain any reference to an "off-label use" theory of defense. In fact, those reports fail to include the specific term "off-label use," and Appellant's argument is a bit of an exercise in semantics. The reports revealed that Appellees intended to argue that although the STAAR lens was not used in an FDA-approved manner, the manner in which it was used was a medically-acceptable alternative.

For example, on March 2, 2009, Appellees submitted a pleading entitled, "Defendants' Fifth Supplemental Expert Witness Disclosures." Attached to this pleading were reports from both Dr. Eiferman and Dr. Kleinfeldt. Notably, Dr. Eiferman's report provided his opinion that the STAAR lens could be placed in the sulcus in the manner performed by Dr. Downing. The report specifically provided:

> While the Staar plate haptic lens is intended for intracapsular placement, it can be positioned in the sulcus. In the article, "Long-term Safety and Efficacy of Repositioned Dislocated Haptic Intraocular Lenses in the Ciliary Sulcus" (Am J Ophthal 2005 (140) 918-920) the authors report successful repositioning of 15 subluxed plate haptic lenses into the ciliary sulcus. The lenses remained centered for an average of 48.7 months with best-corrected acuity of 20/40 or better in 93.3%.
>
> I have personally repositioned dislocated Staar lenses into the sulcus. The large positioning hole in the distal ends of the lens often will provide enough capsular support to stabilize the lens.

While Dr. Eiferman's expert report did not contain any use of the term "off-label," it clearly states his opinion that positioning of the STAAR lens in the sulcus was a permissible alternative use of the lens, despite its intended usage for intracapsular placement, based on his experience and the medical literature. Thus, Appellant was on notice that this position would be a part of Dr. Eiferman's opinion at trial. The fact that the specific term "off-label use" was not used is not controlling since the substance of the opinion was clear.

Dr. Eiferman reiterated this position during a discovery deposition conducted on April 16, 2009, and disclosed the following opinions regarding "off-label use" of the STAAR lens during questioning by Appellant's counsel:

> Q. If it is an easier surgery, would it not have made sense to place this in the sulcus?
>
> A. No.
>
> Q. Why not?
>
> A. Because the lens is not designed to go in the sulcus.
>
> Q. But you're saying it's perfectly acceptable in this case that it went in the sulcus?
>
> A. It is an off-label use of an FDA-approved product.
>
> Q. Well, let's talk about that. What exactly is your understanding of off-label use?
>
> A. The FDA approves drugs and devices for certain uses. It is within the practice of medicine to use an approved product in a different way and that does not violate a standard of care.

Q. Now, do you concede that the FDA – FDA has not approved this particular lens to be placed in the sulcus?

A. That's incorrect.

Q. Well, it has been – you do disagree with that?

A. No, sir. That's not correct, either.

Q. Okay. Well, let me ask you this way: Has the FDA approved placement of the STAAR Toric lens into the sulcus?

A. The – the – that – the FDA is silent on that issue.

Q. Well, it's – it's either approved or it's not.

A. No, sir, that's not correct.

Q. Explain that to me.

A. You have – you have a label use and you have an off-label use. Off-label things are not under the jurisdiction of the U.S. FDA.

Q. When does the FDA – what limitations do the FDA place upon off-label use?

A. It doesn't.

Q. There are no limitations by the FDA on off-label use?

A. That's correct, unless there is some specific medical contraindication.

Accordingly, Dr. Eiferman's expert report and deposition clearly put Appellant on notice that Appellees intended to rely on the defense that Dr. Downing's use of the STAAR lens was an acceptable alternative to its FDA-approved purpose.

Moreover, Dr. Kleinfeldt's expert report also contained an opinion supporting positioning of the STAAR lens in the sulcus:

> The patient then underwent cataract extraction in the right eye that was complicated by a tear in the patient's posterior capsule. Unfortunately, this is a common event. Dr. Downing subsequently placed a STAAR Toric TL intraocular lens in the patient's sulcus. I use approximately 170 STAAR Toric intraocular lenses annually and had I been in Dr. Downing's position would have acted similarly. There is no absolute contraindication to the placement of such a lens in the sulcus. The STAAR literature states that there is insufficient data to demonstrate the safety and efficacy for placement in the ciliary sulcus but provides no recommendation that this should not be performed. I can find no case review for patients with sulcus placement of the STAAR Toric TL lens that had adverse outcomes.

Dr. Kleinfeldt's report, then, states his opinion that there was nothing restricting a physician from using the STAAR lens in the manner done by Dr. Downing in this case. His deposition, which was used in place of live testimony at trial, also contained testimony regarding "off-label use" of FDA-approved products such as the STAAR lens:

> Q. Now Dr. Downing – excuse me, Dr. Kleinfeldt, I want to ask you another term and we may be talking about the same things, I'm not sure, but I've come across this. What do we mean by the phrase off-label use?
>
> A. Certain things, you know, in medicine, you know, are studied. There's an FDA and there's different governing bodies that study different things, whether that be medications or different surgical instruments or prosthetic implants, and they study it and they say this is what it's designated for. However, the FDA or all government agents can't study every possible use for everything that they approve. So there's something

> considered off-label use and that means that in medicine if something's been approved, even – you're able to use it for other indications, even if it's not for the exact thing that it was approved for because if not, there would be no progress in medicine, we couldn't do anything because you'd be waiting on government agencies to approve everything, all scenarios and it just would never happen.
>
> Q. And that is an acceptable use of a product in your –
>
> A. Yes. So I would say this would be an acceptable off-label use of the product.
>
> Q. You're saying that Dr. Downing's use of the STAAR lens was –
>
> A. Oh, I think it was completely acceptable. I don't even believe it was off label. I just – you know, Staar just didn't study it in that case. It would be impossible to study it in that case. You'd have to have enough patients. As we talked – if you say it would only occur in say one in 20,000, I mean how would you ever get enough numbers together to actually study it?

Once again, then, Appellant was made aware of Appellees' position that their use of the STAAR lens was appropriate even though the lens was not designed for that use.

Appellant relies largely upon this Court's decision in *Clephas v. Garlock, Inc.*, 168 S.W.3d 389 (Ky. App. 2004) for the proposition that a party's failure to disclose all of the opinions of its medical expert witness during discovery warrants exclusion of any evidence regarding those opinions. However, the facts of *Clephas* are distinguishable from those of this case. The defendant in *Clephas* had failed altogether to produce its expert for deposition although ordered to do so and had waited until trial had commenced before providing its expert with the

materials necessary for him to evaluate in order to form an opinion as to the plaintiff's medical condition and its cause. Because of this, the plaintiff was completely unaware of what the expert's opinion would be on these matters. *Id.* at 392. We held that these circumstances merited a new trial because the discovery of the substance of an expert witness's expected testimony is essential to trial preparation. *Id.* at 394.

Here, in contrast, Appellant was able to depose both of Appellees' medical experts prior to trial and was made fully aware of their opinions via their expert reports. Thus, we are satisfied that Appellees did not act in a manner contrary to the spirit of the discovery rules, and that the trial court, therefore, did not abuse its discretion in admitting the expert testimony in question in the face of Appellant's challenge. The other authorities cited by Appellant are similarly unavailing.

Appellant also offers a related argument that the "off-label use" defense was invalid altogether as a matter of law; indeed, she describes it as "patently nonsensical." She specifically contends that the trial court should not have permitted testimony that Dr. Downing's use of the STAAR lens was an appropriate "off-label use" because it was an "experimental procedure" resulting in disastrous consequences. However, Appellant provides nothing in terms of legal or medical authority to support her contention.

Such an argument appears to attack the strength of Appellees' defense – not its admissibility. The primary allegation against Appellees in this case is that

Dr. Downing improperly used the STAAR lens by placing it in Appellant's sulcus as opposed to her capsular bag. It seems fairly obvious, then, that Appellees' defense to such an accusation was to assert that implanting the lens in the sulcus was medically appropriate despite not being its FDA-approved purpose – and they did so via their expert witnesses. Consequently, a claim that such a defense should not have been allowed to be proposed at all, particularly one unsupported by reference to authority, must be rejected. Appellant also argues that using the STAAR lens in a manner contrary to the manufacturer's written instructions and warnings was not a valid "off-label use." However, this claim also appears to be directed towards the strength of Appellees' evidence and not its admissibility. In sum, we see no grounds for a new trial based on these arguments.

II.

Appellant next contends that Appellees were erroneously permitted to obtain exclusion of a portion of the anticipated testimony of Appellant's expert witness despite their failure to file a motion *in limine* beforehand as required by pretrial orders. Dr. Krasnow, Appellant's expert, was prohibited from testifying at trial about an internet listserv survey conducted by Dr. Joe LoCascio, a colleague of Dr. Krasnow, as to whether the STAAR lens in question could be implanted in a patient's sulcus. This testimony was excluded because it was found by the trial court to be inadmissible hearsay and not the type of evidence reasonably relied upon by experts in the field of ophthalmology. The trial court further found that

this testimony would have little probative value and that any such value was outweighed by the prejudicial effect it would have on Appellees.

Appellant first argues that the exclusion of this evidence was inappropriate because Appellees failed to file a timely motion *in limine* on the matter. The trial court's pretrial order provided:

> Motions in limine and objections to questions in depositions to be read at trial will be heard. Any motions in limine to be heard at the pretrial conference must be filed at least ten (10) days prior to the pretrial conference. No motions in limine will be heard thereafter without good cause. **Motions will not be heard the morning of trial.**

(Emphasis in original). Appellees filed their motion to exclude the subject evidence at the end of the first day of trial. Dr. Krasnow was set to take the stand the following morning. The trial court nonetheless considered the motion, and Dr. Krasnow was questioned on the matters that were the subject of the motion outside of the presence of the jury. The trial court then decided to exclude the proposed testimony, which was that the respondents to the listserv survey – all of whom were allegedly ophthalmologists specializing in the issues at play in this case – agreed that the STAAR lens in question should not be implanted in the sulcus.

Appellees assert that they were not obligated to file any pretrial objections to Dr. Krasnow's proposed testimony because he was going to testify live at trial. Instead, they contend that they retained the discretion to move for a ruling on the admission or exclusion of evidence when they did per Kentucky

Rules of Evidence (KRE) 103(d).[6] However, we see some merit in Appellant's position that Appellees' motion to exclude should have been filed prior to trial in accordance with the trial court's pretrial order.

Dr. Krasnow raised the issue of the listserv discussion in his deposition and was questioned about it by Appellees; thus, they were fully aware of the possibility that it could be offered as evidence at trial. Yet they declined to challenge this material until just before Appellant intended to put Dr. Krasnow on the stand. In our view, such behavior seems designed to leave a party-opponent severely disadvantaged with no opportunity to obtain substitute or equivalent testimony. A party who is aware in advance of trial that evidence he proposes to introduce has been excluded may obtain other evidence of similar import. But when the exclusion of the evidence occurs in the morning of the second day of trial, as in this case, that party has no opportunity to obtain other evidence, and the opposing party who disregarded the trial court's order is thereby rewarded. Such behavior is highly discouraged and smacks of pure gamesmanship in disregard of the trial court's order.

With this said, however, even assuming that Appellees should have filed a motion *in limine*, we are still left with the fact that the evidence in question was clearly inadmissible. Therefore, we cannot hold that the trial court abused its

[6] KRE 103(d) provides, in relevant part: "Motions in limine. A party may move the court for a ruling in advance of trial on the admission or exclusion of evidence. The court may rule on such a motion in advance of trial or may defer a decision on admissibility until the evidence is offered at trial."

discretion in excluding it from evidence. As an initial matter, the proposed testimony was indisputably hearsay under KRE 801(c)[7] because it included statements from listserv members regarding their opinions as to whether a STAAR Topic lens should be implanted in the sulcus. Appellant nonetheless contends that it should have been admitted pursuant to KRE 703 because "experts are entitled to rely upon an exceedingly broad range of information in formulating their opinions," including information gleaned from listserv surveys, which she describes as "inherently reliable." Because of this, she argues, the results of the listserv survey should have been disclosed to the jury as part of Dr. Krasnow's testimony.

KRE 703(a)[8] and (b),[9] when read together, allow "[t]he facts or data in the particular case upon which an expert bases an opinion or inference" to "be disclosed to the jury even though such facts or data are not admissible in evidence" if they are "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject" and if they are "determined to be trustworthy, necessary to illuminate testimony, and unprivileged." Under this

[7] KRE 801(c) defines "hearsay" as "a statement, other than one made by the declarant while testifying at the trial or hearing, offered in evidence to prove the truth of the matter asserted."

[8] KRE 703(a) provides: "The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence."

[9] KRE 703(b) provides: "If determined to be trustworthy, necessary to illuminate testimony, and unprivileged, facts or data relied upon by an expert pursuant to subdivision (a) may at the discretion of the court be disclosed to the jury even though such facts or data are not admissible in evidence. Upon request the court shall admonish the jury to use such facts or data only for the purpose of evaluating the validity and probative value of the expert's opinion or inference."

standard, Appellant's claim must fail because Dr. Krasnow acknowledged during questioning that he did not rely upon the results of the listserv survey in reaching his opinions. Instead, he reached those conclusions on his own beforehand. Thus, KRE 703(a) and (b) do not provide any support for his position.

Moreover, Dr. Krasnow acknowledged that he was not a member of the listserv in question and did not even have access to it. He also did not assist in creating the survey and had no personal knowledge regarding the specific questions posed by Dr. LoCascio or the qualifications of the respondents to the survey. Dr. Krasnow also conceded that none of the respondents had been provided with specifics regarding Appellant's medical history. Accordingly, the trustworthiness of the responses was in question, particularly given that the respondents were unavailable for cross-examination and their credentials were otherwise unverified. The trial court also expressed doubt as to whether such a survey could be reasonably relied upon under these circumstances – a sentiment with which we are inclined to agree.

It should also be noted that Dr. Krasnow was otherwise free to testify extensively about his opinions regarding this case. Indeed, the trial court advised Appellant that Dr. Krasnow would be allowed to testify that he had talked to Dr. LoCascio and that Dr. LoCascio had agreed with Dr. Krasnow's opinions even though it is highly questionable whether a doctor is permitted to quote the opinions of other doctors at trial. *See Philip Morris Tobacco Co. v. Levan*, 459 S.W.2d 73, 75 (Ky. 1970). Thus, at least some bolstering of Dr. Krasnow's opinions was

allowed, so it cannot be said that the listserv responses were necessary to illuminate his testimony or were otherwise an indispensable part of his opinions. We emphasize that the decision as to whether to admit evidence rests within the "sound discretion" of the trial court and that decision will not be reversed in the absence of an abuse of that discretion. *Welsh v. Galen of Virginia, Inc.*, 128 S.W.3d 41, 51 (Ky. App. 2001). Under these circumstances, we do not believe that the trial court abused its discretion in excluding testimony regarding the listserv survey conducted by Dr. LoCascio from evidence. We also note that it does not appear from the record or Appellant's briefs that Appellant ever requested a continuance in response to the trial court's ruling on this issue so that comparable evidence could be obtained. Thus, we are disinclined to conclude that Appellant was unduly prejudiced or aggrieved by this ruling. Nevertheless, we reiterate our disapproval of Appellees' failure to object in conformity with the court's pretrial order.

Appellant also contends that Appellees' motion to exclude the subject evidence was also substantively flawed in that their arguments properly went only to the weight to be afforded that portion of the testimony – not to its admissibility. However, we disagree with this assertion for the reasons provided above.

III.

Appellant finally argues that the trial court erred in dismissing her medical battery claim prior to submission of the case to the jury. Appellant contends that her battery claim was viable because she did not consent to Dr.

Downing's use of the lens contrary to its FDA-approved use and because the lens was used in violation of the product's explicit warnings as to where not to place it. She further contends that a question remains as to whether the limbal relaxing incisions performed during the January 2006 lens exchange were proper and adequately explained to her.

The standards for reviewing a trial court's ruling on a motion for directed verdict were set forth succinctly by the Kentucky Supreme Court in *Bierman v. Klapheke*, 967 S.W.2d 16 (Ky. 1998):

> On a motion for directed verdict, the trial judge must draw all fair and reasonable inferences from the evidence in favor of the party opposing the motion. When engaging in appellate review of a ruling on a motion for directed verdict, the reviewing court must ascribe to the evidence all reasonable inferences and deductions which support the claim of the prevailing party. Once the issue is squarely presented to the trial judge, who heard and considered the evidence, a reviewing court cannot substitute its judgment for that of the trial judge unless the trial judge is clearly erroneous.
>
> In reviewing the sufficiency of evidence, the appellate court must respect the opinion of the trial judge who heard the evidence. A reviewing court is rarely in as good a position as the trial judge who presided over the initial trial to decide whether a jury can properly consider the evidence presented. Generally, a trial judge cannot enter a directed verdict unless there is a complete absence of proof on a material issue or if no disputed issues of fact exist upon which reasonable minds could differ. Where there is conflicting evidence, it is the responsibility of the jury to determine and resolve such conflicts, as well as matters affecting the credibility of witnesses. The reviewing court, upon completion of a consideration of the evidence, must determine whether the jury verdict was flagrantly against the evidence so as

> to indicate that it was reached as a result of passion or prejudice. If it was not, the jury verdict should be upheld.

Id. at 18-19 (Internal citations omitted).

In Kentucky, under certain circumstances, a claim of battery may be raised alongside a claim of medical malpractice. *Andrew v. Begley*, 203 S.W.3d 165, 171 (Ky. App. 2006). An action for battery "is different from a negligence action for medical malpractice because the claim depends on neither professional judgment nor the physician's surgical skill." *Vitale v. Henchey*, 24 S.W.3d 651, 656 (Ky. 2000). Instead, a battery claim requires proof of an absence of consent on the part of the patient. *Id.* at 658; *Andrew*, 203 S.W.3d at 172.

Appellant's battery claim primarily rests on a contention that she did not consent to the specific manner in which Dr. Downing implanted the STAAR lens. However, we believe that this claim is more properly characterized as presenting the question of whether Dr. Downing properly exercised his professional judgment in placing the STAAR lens in Appellant's sulcus after discovering a tear in the capsular bag where the lens was originally intended to go. Appellant clearly consented to cataract surgery but is now unhappy with the course of action taken by Dr. Downing in performing that surgery. Thus, her claim lies in medical malpractice and not battery. *See Vitale*, 24 S.W.3d at 656.

We further note that Appellant consented to the lens implantation and was apprised of the risks inherent in such a process. She was also given an opportunity to view a video discussing the possible complications that can be

caused by cataract surgery. Consequently, if the question of consent can be deemed to be in issue in this context, it is one of informed consent, which – again – is a matter of medical negligence, not battery. *See id.* at 655-56.

Appellant further contends, though, that her battery claim is also based on the relaxing incisions performed on her right eye during the January 2006 lens exchange. Dr. Downing testified that he performed these incisions to change the shape of Appellant's right eye in order to correct some of her astigmatism and to give her better vision. Appellant claimed at trial, however, that she did not give specific consent to these incisions and was not advised that they would be made in an effort to correct her astigmatism. Dr. Downing testified to the contrary. A consent form signed by Appellant prior to the January 2006 procedure provides:

> I, *Ann Sparks*, as a patient in The McPeak Surgery Center hereby authorize Dr. *Downing* (and whomever he may designate as his assistants) to administer such treatment as is necessary, and to perform the following operation: *Removal of an intraocular lens implant in the right eye. Insert an intraocular lens implant in the right eye* and such additional operation or procedures as are considered therapeutically necessary on the basis of findings during the course of said operation.[10]

"Kentucky courts have repeatedly recognized that valid consent to medical treatment is to be gleaned from evidence of the circumstances and discussions surrounding the consent process." *Kovacs v. Freeman*, 957 S.W.2d 251, 255 (Ky. 1997). "[C]onsent to an operation need not be express, but may be implied from the surrounding facts and circumstances." *Id.*

[10] The consent form was boilerplate in nature. Those portions above in italics reflect instances in which blanks were filled in with handwritten items.

In *Hoofnel v. Segal*, 199 S.W.3d 147 (Ky. 2006), our Supreme Court addressed the role that a consent form plays in a medical battery case. There, a patient asserted that her ovaries and uterus were removed during surgery to treat her colorectal cancer without her consent. Prior to surgery, the patient's surgeon had recommended to her that she have her ovaries and uterus removed, but she indicated that she did not want this. Despite this fact, she subsequently signed a consent form authorizing a "possible bilateral oophorectomy" to remove her ovaries and "such additional procedures as are deemed necessary" in the doctor's professional judgment should unforeseen conditions require additional or different procedures. During surgery, the doctor removed the patient's ovaries and uterus because of a fear that they were cancerous. *Id.* at 148-49.

The patient subsequently filed suit for medical battery, but the trial court granted the doctor's motion for summary judgment after finding that the consent-to-operate form was indisputable evidence that the patient had given the doctor consent to perform the procedures and that, accordingly, her battery claim must fail as a matter of law. The Court of Appeals affirmed this decision. *Id.* at 149-50.

The Supreme Court also affirmed the trial court's entry of summary judgment, holding that by signing the consent form, the patient had consented to the removal of her ovaries and uterus – despite her oral protestations to the contrary. The form explicitly provided for a "possible bilateral oophorectomy," thereby allowing for removal of the ovaries, and procedures "as are deemed

necessary" in the treating physicians' professional judgment. The Court held that this clause gave the doctor consent to perform the hysterectomy to remove the patient's uterus because it was abnormally large, potentially cancerous, and was impairing and impeding the doctor's ability to resect a lesion in the patient's colon. The Court further concluded that Appellant had failed to present sufficient evidence to rebut or to distinguish the clear and unambiguous words of the consent form. *Id.* at 150-51.

In reaching its decision, the Supreme Court noted that "[t]here is a trend toward holding that consent evidenced in writing is conclusively presumed to be a valid consent in the absence of a valid collateral challenge" such as fraud or misrepresentation. *Id.* at 151. The Court further noted that "[t]his presumption has been applied even where the consent form describes the procedures in medical terms (not laymen's terms) or refers to 'such additional operations or procedures as are considered therapeutically necessary on the basis of findings during the course of said operation.' "[11] *Id.* (Quotation omitted). Consequently, the Court held:

> The existence of a signed consent form gives rise to a presumption that patients ordinarily read and take whatever other measures are necessary to understand the nature, terms and general meaning of consent. To hold otherwise would negate the legal significance to written consent forms signed by the patient and render the consent form completely unreliable.

Id.

[11] This language is virtually identical to that within the consent form at issue herein.

Here, we are faced with a situation in which Appellant denies giving consent to the incisions in question, while Appellees assert that such consent was given. Notably, the consent form signed by Appellee – as was the case in *Hoofnel* – allowed Dr. Downing to perform "such additional operation or procedures as are considered therapeutically necessary on the basis of findings during the course of said operation." This language suggests that Appellant implicitly consented to the relaxing incisions to correct her astigmatism if Dr. Downing found such to be therapeutically necessary. Although such circumstances would seem to suggest a jury issue on the question of battery, the holding in *Hoofnel* compels us to conclude otherwise given the unequivocal language of the consent form signed by Appellant and the heft apparently afforded such documents in the wake of that decision. Consequently, we are compelled to conclude that the trial court did not err in dismissing Appellant's battery claim.

CONCLUSION

For the foregoing reasons, the judgment of the Warren Circuit Court is affirmed.

ALL CONCUR.

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