J. A15009/00

2000 PA Super 285

RICHARD COSOM, Appellant	:	IN THE SUPERIOR COURT OF PENNSYLVANIA
v.	:	
PAUL MARCOTTE, M.D. AND DANEK MEDICAL GROUP AND DANEK, INC., AND SOFAMOR-DANEK GROUP, INC., AND WARSAW ORTHOPEDICS, Appellees	:	No. 2499 EDA 1999

Appeal from the Judgment Entered February 7, 2000,
In the Court of Common Pleas of Philadelphia County,
Civil, No. 625 April Term, 1995

RICHARD COSOM	:	IN THE SUPERIOR COURT OF PENNSYLVANIA
v.	:	
PAUL MARCOTTE, M.D. AND DANEK MEDICAL GROUP AND DANEK, INC., AND SOFAMOR-DANEK GROUP, INC., AND WARSAW ORTHOPEDICS	:	
APPEAL OF: PAUL MARCOTTE, M.D.	:	No. 2805 EDA 1999

Appeal from the Judgment Entered February 7, 2000,
In the Court of Common Pleas of Philadelphia County,
Civil, No. 625 April Term, 1995

BEFORE: McEWEN, P.J., JOYCE and TAMILIA, JJ.

OPINION BY McEWEN, P.J.: Filed: September 27, 2000

¶ 1 This appeal has been taken from the judgment entered on the verdict of the jury in this medical malpractice action, following the dismissal of the post-trial motions filed by appellant, Paul Marcotte, M.D. As we find that appellant has failed to establish that the trial court committed an error of law or an abuse of discretion, we affirm.

¶ 2 The learned Judge Joseph D. O'Keefe, who presided over the trial in this matter, has provided a concise summary of the proceedings in the trial court:

> On September 30, 1993, Dr. Paul Marcotte performed spinal fusion surgery on Plaintiff to alleviate a prior and unrelated back injury. The surgery consisted of lumbrosacal fusion supported by a pedicle screw fixation device, TSRH internal fixation device instrumentation, to hold the spine stable until fusion occurred. This device was manufactured by Danek. Two screws were inserted into the L-4 pedicles of Plaintiff's spine. Subsequent film revealed fractures and breakage in the screws. Plaintiff alleged that these fractures caused further injury and pain, beyond that from his original condition. Plaintiff also alleged that Dr. Marcotte failed to obtain his informed consent prior to his surgery, by not disclosing the FDA status of the screws.
>
> This court granted summary judgment in favor of Danek, thus dismissing Danek prior to trial, for reasons stated in a separate opinion filed by this Court on October 21, 1999.[1] Dr. Marcotte was the only remaining defendant at trial and the only issue was whether he obtained Plaintiff's informed consent. At the conclusion of the trial, the jury found against Dr. Marcotte and awarded Plaintiff $150,000.00. Dr. Marcotte filed a Motion for Post-Trial Relief on July 26, 1999, which this Court denied by Order dated August 10, 1999. Thereafter, Dr. Marcotte filed this timely appeal.

¶ 3 Appellant has set forth the following claims of error in support of his request for judgment n.o.v. or a new trial:

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[1] Although appellee filed a notice of appeal at No. 2499 EDA 1999 challenging the grant of summary judgment, no brief has been filed by appellee in that appeal. We, therefore, grant the motion of Danek, Inc. and dismiss the appeal at No. 2499 EDA 1999.

Whether a physician has a duty as a matter of law to disclose to his patient information related to the FDA status of a medical device prior to performing a procedure involving that device where that information was not known to the physician and where it has not been established that the physician should have known that information;

Whether the plaintiff in an informed consent action is required to produce expert testimony to establish the risks and alternatives of a procedure and to establish a causal link between the injury suffered and the undisclosed risk;

Whether evidence related to the applicable standard of care is relevant to a determination of whether a prudent patient would want to know that the FDA has not approved a medical device as safe and effective;

Whether the trial court may take judicial notice of alleged facts contained in "updates" and letters from the FDA's Department of Health and Human Services where those alleged facts have not been established to be without reasonable dispute and are not relevant;

Whether testimony is properly admitted regarding the FDA status of a medical device prior [sic] when the plaintiff underwent the procedure involving that device; and

Whether testimony is properly admitted regarding whether a physician read a package insert that accompanied a medical device in order to establish the risks associated with the use of the medical device and where no foundation was laid or evidence presented to suggest that the insert was intended or required to be read by the physician.

I. INFORMED CONSENT

¶ 4 Appellant initially contends that he is entitled to judgment n.o.v.[2] pursuant to the holding of this Court in ***Southard v. Temple University Hospital,*** 731 A.2d 603 (Pa.Super. 1999), ***appeal granted,*** ___ Pa. ___, 756 A.2d 670 (2000), which appellant reads as providing that a physician is under no duty to disclose to a patient the fact that a medical device has not been approved by the FDA when the physician obtains the patient's informed consent to surgery intended to implant that device in the patient's body. We are unable to agree that ***Southard*** stands for such a proposition.

¶ 5 Pennsylvania has adopted the prudent patient standard for informed consent. Under this standard, a physician must inform a patient of the "material facts, risks, complications and alternatives to surgery, which a

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[2] Our standard of review when considering a request for judgment n.o.v. is well-settled:

> The entry of judgment notwithstanding a jury verdict to the contrary is a drastic remedy. A court cannot lightly ignore the findings of a duly-selected jury. Thus, in considering a motion for judgment n.o.v., the court must view the evidence and all reasonable inference that arise from the evidence in a light most favorable to the verdict winner. ***See Handfinger v. Philadelphia Gas Works,*** 439 Pa. 130, 266 A.2d 769 (1970); ***Northwest Savings Ass'n v. Distler,*** 354 Pa.Super. 187, 511 A.2d 824 (1986); ***Tonkovic v. State Farm Mut. Automobile Ins. Co.,*** 337 Pa.Super. 123, 486 A.2d 512 (1984). The court can enter judgment n.o.v. only if "no two reasonable persons could fail to agree that the verdict is improper." ***Northwest Savings Ass'n. v. Distler, supra*** 354 Pa.Super. at 191, 511 A.2d at 825. ***See also Olson v. Dietz,*** 347 Pa.Super. 1, 500 A.2d 125 (1985).

Neal by Neal v. Lu, 530 A.2d 103, 110 (Pa.Super. 1987).

reasonable [person] in the patient's position would have considered significant in deciding whether to have the operation." ***Southard v. Temple University Hospital, supra,*** 731 A.2d at 610 (citation omitted). ***Accord: Nogowski v. Alemo-Hammad,*** 691 A.2d 950, 957 (Pa.Super. 1997), ***appeal denied,*** 550 Pa. 684, 704 A.2d 638 (1997); ***Kratt v. Horrow,*** 687 A.2d 830, 835 (Pa.Super. 1996), ***appeal denied,*** 548 Pa. 682, 699 A.2d 735 (1997).

¶ 6 This Court, in ***Southard,*** specifically held that

> …the FDA's Class III classification of bone screws constitutes a conclusion by the FDA that the screws have at least unknown characteristics. Clearly, unknown characteristics are risks. Moreover, even if the FDA's classification were not a "risk," it most certainly is a "fact" regarding a surgical procedure as stated in Pennsylvania's informed consent definition. …
>
> …we think that a prudent patient would want to know that the FDA has not approved a medical device as safe and effective prior to deciding whether to consent to a surgical procedure involving that device. … At the very least, a genuine issue of material fact exists as to whether a prudent patient would want to know prior to surgery that the FDA has not approved a medical device as safe and effective. **That genuine factual issue must be presented to a jury to decide**.

Southard v. Temple University Hospital, supra, 731 A.2d. at 612–13 (emphasis added).

¶ 7 There was no dispute at trial that the screws that appellant implanted in the pedicles of appellee's spine during the 1993 surgery were Class III medical devices. Thus, contrary to the claims of appellant, ***Southard***

requires that **the jury** resolve the issue of whether or not a prudent patient would deem the FDA status of the screws to be a significant fact which the patient would consider material to his decision to consent to the surgical procedure. We find that, pursuant to ***Southard***, the trial court properly rejected the request for judgment n.o.v. on this ground.

¶ 8 Appellant also argues that he is entitled to judgment n.o.v. due to the absence of expert testimony to establish a *prima facie* case based on lack of informed consent. While the trial court determined that expert testimony was unnecessary under the circumstances of this case, we find that the expert testimony provided by the trial testimony of appellant was more than sufficient to establish the attendant risks and the alternatives to the procedure.

¶ 9 Expert testimony is generally required in informed consent cases to establish the risks and alternatives presented by a proposed surgical procedure.

> … In ***Festa v. Greenberg, supra,*** this court held that a plaintiff cannot prevail on an implied consent cause of action absent evidence of this kind. We recognized that Pennsylvania is one of a growing number of jurisdictions to adopt a "prudent patient" standard of informed consent. This standard tests the adequacy of the physician's pre-treatment disclosures by requiring the fact finder to determine whether the patient received all of the information that a reasonable person would deem "material." We concluded in ***Festa*** that even though the ultimate assessment of "materiality" is for the fact finder to make, expert testimony is nevertheless necessary on the important secondary issues that lie outside the knowledge of the lay person. ***See Festa, supra***, 354

> Pa.Super. at 360, 511 A.2d at 1378. ***See also Jozsa v. Hottenstein, supra***, ___ Pa.Super. ___, 528 A.2d at 607-08. Thus, only an expert is able to explain the harms that can arise from the procedure in question and estimate the likelihood that those harms will occur. Only an expert, moreover, can identify viable alternative treatments and discuss the risks involved. ***See Festa, supra*** 354 Pa.Super. at 356-60, 511 A.2d at 1376-78. Without an informed discussion of the risks and alternatives, the fact finder cannot determine rationally whether a reasonable person would have deemed the undisclosed knowledge "material."

Neal by Neal v. Lu, 530 A.2d 103, 111-12 (Pa.Super. 1987) (footnote omitted).

¶ 10 Dr. Marcotte testified in the instant case, on cross-examination, concerning the risks posed by the use of the non-FDA approved screws in the pedicles of the spine, risks he did not reveal to appellee, as follows:

> Q. There are additional risks and there are increased risks, correct?
>
> A. Yes.
>
> Q. And those risks include hardware failure, like the screws breaking, pulling out, loosening, correct?
>
> A. Those are a few of them, yes.
>
> * * * *
>
> A. The screws can damage arteries and veins, or instruments that put the screws in can damage arteries and blood vessels, but so can just decompressive surgery. And a laminectomy can do the same thing.
>
> * * * *
>
> Q. You'll agree that that was common knowledge in the community of spine surgeons that this device wasn't

> approved by the FDA for transpedicular instrumentation back –
>
> A. Yes.
>
> Q. -- in 1992 and '93?
>
> A. Yes.
>
> * * * *
>
> Q. We can agree, Doctor -- I think you told us a few moments ago that you told Mr. Cosom about two choices, surgery and no surgery, correct?
>
> A. Yes.
>
> Q. And you didn't offer him options of different types of surgery, correct?
>
> A. Well, no.
>
> Q. And we can agree, Doctor, that when you're going to implant a patient with a device like this, today, you offer that additional option of additional types of surgery, surgery without this device, correct?
>
> A. Yes, we do offer that now because of the controversy that's arisen regarding the pedicle screws.

¶ 11 Because appellant himself testified to the undisclosed risks[3] posed by the surgery actually performed upon appellee, appellee was not required to submit additional expert testimony regarding the risks of the surgery. The testimony provided by appellant was sufficient to submit to the jury the issue of whether a reasonable patient would deem the lack of FDA approval

[3] Appellant also admitted that the manufacturer advised that the device, a temporary fixation method which was intended to be removed after fusion occurred, was also subject to risks of fracture, bending, and breaking.

and the undisclosed risks, including bending and breakage and the need for explantation after fusion, to be material factors affecting the decision whether to undergo the surgery. Since "the patient need not prove that a causal relationship exists between the physician's or surgeon's failure to disclose information and the patient's consent to undergo surgery," ***Rowinksy v. Sperling,*** 681 A.2d 785, 790 (Pa.Super. 1996) (citations omitted), ***appeal denied,*** 547 Pa. 738, 690 A.2d 237 (1997), appellee satisfied all the requirements for a *prima facie* case based on lack of informed consent through the testimony of appellant which detailed the known risks and complications of the surgery which were admittedly not disclosed to appellee. This evidence was sufficient to allow the jury to determine the issue of informed consent. Thus, the request for judgment n.o.v. based on the insufficiency of the expert testimony was properly rejected by the trial court.

¶ 12 Appellant next contends that the trial court should have concluded that evidence of the standard of care in the medical community at the time of the surgery was relevant to the issue of whether a prudent patient would deem FDA approval of a medical device a significant factor in determining whether to undergo surgery. We disagree. In ***Southard***, this Court held that, "the fact that a physician may use a medical device without interference from the FDA and in a non-negligent manner does not justify the conclusion ... that the FDA's classification of bone screws need not be disclosed to obtain a

patient's informed consent." ***Id.*** at 612. The issue in an informed consent case is

> ...not what a reasonable medical practitioner would have done in the situation but whether the physician disclosed those risks which a reasonable man would have considered material to his decision whether or not to undergo treatment. ***Festa v. Greenburg,*** 354 Pa.Super. 346, 511 A.2d 1371, 1373 (1986).
>
> ***Sagala [v. Tavares,]*** 533 A.2d [165,] 167 [(Pa.Super. 1987)].
>
> The importance of the prudent patient standard of review was further emphasized in ***Sagala,*** wherein the court stated:
>
> > The primary focus of Pennsylvania law with respect to informed consent is to guarantee that a patient is supplied with all the material facts from which an intelligent choice as to medical attention may be reached, *regardless of whether the patient chooses rationally*. ***Cooper, supra,*** 286 A.2d at 650. Recovery is based on the administration of surgical procedure in the absence of the patient's informed consent, not whether the patient would not have gone through with the operation if warned of a particular danger. (emphasis in original)
>
> ***Sagala, supra*** at 580-81, 533 A.2d at 168-169.

Moure v. Raeuchele, 563 A.2d 1217, 1220 (Pa.Super. 1989), ***rev'd. on other grounds,*** 529 Pa. 394, 604 A.2d 1003 (1992). Thus, the trial court properly precluded, as irrelevant, evidence of the "standard of disclosure" in the community.

II. EVIDENTIARY ISSUES

¶ 13 Appellant next alleges that he is entitled to a new trial as a result of certain evidentiary rulings of the trial court which (1) permitted four facts to be judicially noticed, (2) permitted testimony regarding the contents of the manufacturer's package insert which accompanied the TSRH system, (3) precluded introduction of statements allegedly made by the manufacturer's representative, and (4) permitted testimony regarding the FDA status of the screws prior to 1993.

A. Judicial Notice

¶ 14 Appellant here contends that the trial court improperly took judicial notice[4] of rulings of the FDA.[5] At trial, however, appellant objected to the

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[4] Pennsylvania Rule of Evidence 201(b) provides that:

> A judicially noticed fact must be one not subject to reasonable dispute in that it is either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned.

Rule 201(d) provides that:

> A court shall take judicial notice if requested by a party and supplied with the necessary information.

[5] The trial court took judicial notice of the following facts:

> a. The United States Food and Drug Administration determined as of the time of Mr. Cosom's surgery that pedicle screws or bone screws intended for attachment to the spine had not been shown to have sufficient safety and effectiveness. Therefore, they were not approved for marketing for that use.

evidence on the ground that the statements were irrelevant, but did not object, as he does in this appeal, to the accuracy of the statements, or contend that the facts were not the type of evidence amenable to judicial notice. Thus, this claim has been waived.[6]

¶ 15 Judge O'Keefe disagreed with the relevancy challenge, citing the decision of this Court in ***Southard*** and concluded that the facts were not subject to reasonable dispute, and there was no challenge to the accuracy of the facts. While any challenge to the facts judicially noticed based on considerations other than relevancy has been waived, we note our agreement that the facts were of the type amenable to judicial notice.

> Matters of judicial notice have three material requisites: (1) the matter must be a matter of common and general knowledge; (2) it must be well and authoritatively settled; and (3) it must be known within the limits of the jurisdiction of the court. If there is uncertainty with respect to a matter in question, the court will not take

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> b. As of the time of Mr. Cosom's surgery, there were no pedicle screws which were cleared or approved for spinal fixation when used for attachment through the pedicle of a vertebrae.
>
> c. According to the United States Food and Drug Administration, any pedicle screw fixation to the lumbar vertebral column using the TSRH system was, in September of 1993, considered to be an investigational use.
>
> d. The FDA determined that pedicle screws used for fixation of the spine at the time of Mr. Cosom's surgery, in September of 1993, were Class III, significant risk, investigational devices."

[6] As the sole challenge at trial was one of relevancy, appellant may not argue a new and different ground on appeal. ***Sheppard Old Heritage Mut. Ins. Co.,*** 492 Pa. 581, 591, 425 A.2d 304, 310 (Pa. 1980); ***In re D.S. Appeal,*** 622 A.2d 954, 957 (Pa.Super. 1993).

> judicial notice. 8 Standard Pennsylvania Practice 2d § 49:68 (1982).

City of Philadelphia v. Pennsylvania Human Relations Commission, 684 A.2d 204, 207 (Pa.Cmwlth. 1996). ***Accord: Hoffman v. Misericordia Hospital of Philadelphia,*** 439 Pa. 501, 267 A.2d 867 (1970). Thus, this claim of error was properly rejected by the trial court.

B. Package Insert

¶ 16 Appellant next alleges that it was reversible error to permit appellee to introduce testimony, over objection, concerning appellant's knowledge of the package insert which accompanied the TSRH system.[7]

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[7] Appellant has premised his claim of error upon the following portion of his cross-examination by plaintiff's counsel:

> BY MR. MESSA:
>
> Q. Doctor, very clearly, you're aware that this device is considered investigational for the use you placed it in Mr. Cosom; isn't that right?
>
> A. No.
>
> Q. You didn't read the textbook?
>
> A. I didn't read that specific textbook. There are many textbooks on spine surgery out there.
>
> Q. You didn't read the package insert?
>
> A. I certainly didn't read that one from '91.
>
> Q. You didn't read the brochures and manuals that you were sent?
>
> MR. GESCHKE: Objection, You Honor.

THE COURT: Sustained.

BY MR. MESSA:

Q. You didn't educate yourself about the device, doctor, with regard to this information, whether or not the United States Food and Drug Administration thought this device was safe and effective for the use you stuck it in Mr. Cosom's spine?

A. Sir, I did educate myself. But just obtaining education just from the company itself is not adequate. If someone were to read one of these procedure manuals and just walk into the operating room and do it, that's not adequate. It's not a cookbook surgery. You just don't open the book up and go page by page and put it in someone's body. I spent a lot of time reading about this and training how to do it.

* * * *

BY MR. MESSA:

Q. You're familiar with this information in the package insert for this device, correct?

A. Yes.

Q. And that's all I'm referring to right now, what's here on No. 5 that we have before the jury. And the information provided [in the package insert] is that this TSRH spinal fixation device is a **temporary** internal fixation device, correct? (emphasis supplied)

A. That's what it says, yes.

Q. And that it **must** be removed, correct? (emphasis supplied)

A. That's what it says.

Q. That was what the manufacturer's recommendation was, correct?

A. That's correct.

Q. And in fact, you had received materials from the manufacturer before the surgery you did on Mr. Cosom, correct?

A. I believe I may have.

Q. You received techniques manuals, you received brochures, you received information, you went and spoke at their request at the seminar, correct?

A. I spoke at their seminar. I may have received some literature from them.

Q. And there's a whole list of complications listed here, Doctor, if the device is not removed, correct?

A. Yes.

Q. Corrosion, with localized tissue reaction or pain, you didn't tell Mr. Cosom about that, did you?

MR. GESCHKE: Objection, Your Honor.

THE COURT: Overruled. Did you tell him that, yes or no?

THE WITNESS: No.

* * * *

BY MR. MESSA:

Q. And, Doctor, you're aware that that same information is contained in the package inserts from other years from this manufacturer –

MR. GESCHKE: Objection.

BY MR. MESSA:

Q. – for this device?

THE COURT: If he's aware.

THE WITNESS: Repeat the question, please.

BY MR. MESSA:

¶ 17 This Court, in ***Southard***, held that the content of the package inserts

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Q. Sure. There are other package inserts from other years, correct, 1991, 1992, 1993, you're aware of that?

A. No.

Q. Let me show you this, Doctor.

THE COURT: What is it you're showing him?

MR. MESSA: I'm going to mark this as plaintiff's exhibit 5.

BY MR. MESSA:

Q. Doctor, I've marked as plaintiff's exhibit 5 another document. It's also entitled "Important Information on the TSRH Spinal System." This document on the last page also has the logo of Danek Medical and the date 1993 on it.

MR. MESSA: May I approach?

THE COURT: Yes.

BY MR. MESSA:

Q. Have you seen that before?

A. Yes.

Q. And, Doctor, on the last page of that document –

A. Yes.

Q. – can we agree there's also a No. 5 at the top half, about a third of the way down?

A. Yes.

Q. And it contains the same information as this?

A. It appears to.

was relevant to the issues presented by the informed consent claim, noting that "[e]vidence that the bone screws' manufacturer specified that the screws usually must be explanted, and that, if they are not, various complications could occur, certainly was relevant to the jury's decision regarding the materiality of the risk of explantation." ***Southard, supra,*** 731 A.2d at 616. In ***Southard***, the trial court had refused to allow cross-examination of the physician regarding the package insert and this Court found that "the trial court erred by precluding [the] Southards from cross-examining Clements regarding the content of the manufacturer's literature indicating the need for the bone screws' explantation. Moreover, we conclude that the trial court's error was harmful to Southards because it prevented them from presenting evidence to the jury crucial to their claim." ***Southard,*** 731 A.2d at 616.

¶ 18 The trial court in the instant case noted, "[o]nce Dr. Marcotte [appellant] testified that he did not disclose to plaintiff that the device might have to be removed based upon his training, what he had seen or the evidence he had seen, plaintiff [appellee] was properly permitted to impeach Dr. Marcotte's testimony with contrary evidence, just as was decided in ***Southard***." We agree. Since the manufacturer's literature – supplied with the TSRH device which appellant implanted in appellee's back - was relevant to the issue of the known risks associated with the use of the device, the court properly allowed this cross-examination.

C. Statements of Manufacturer's Representative

¶ 19 Appellant also contends that it was error to preclude his testimony, on direct examination, as to statements made to him by the manufacturer's representative concerning the use of the screws in the lumbar spine.

¶ 20 Contrary to the argument of appellant, we find that the trial court properly precluded this evidence as irrelevant.[8] Whether the screws were actually used in the manner intended by the manufacturer was irrelevant to the issue of whether appellant had obtained the informed consent of appellee for the surgery actually performed. The issue for resolution by the jury was not whether the surgery had been properly performed or performed as intended by the manufacturer, but rather what facts were required to be communicated to appellee in order to obtain his informed consent to the surgery. Thus, this claim of error is meritless.

D. FDA Status Prior to 1993

¶ 21 Appellant also contends that it was error to admit evidence of the FDA status of the Danek TSRH instrumentation screws prior to 1993, since "this testimony was prejudicial to defendant in that the jury was permitted to conclude that the FDA status of the screws prior to 1993 was relevant to whether defendant obtained plaintiff's informed consent regarding the

[8] During direct examination, appellant was asked, "During the course of the surgery, did the representative tell you that you should not place the screws in the posterior lumbar pedicles?" The trial court sustained an objection to the question.

procedure in 1993." This argument is wholly baseless as the record clearly reveals that counsel for appellee was attempting to establish the knowledge of appellant – **at the time he performed the surgery on appellee** – that "pedicular screws had not been approved for that intended use, posterior pedicular fixation." The sole purpose of the cross-examination was to establish the knowledge of appellant **at** the time of the surgery upon appellee:

> BY MR. MESSA:
>
> Q. Doctor, as of 1993, before you did this surgery that you implanted this device in Mr. Cosom, it was known in the community of spine surgeons like yourself that the United States Food and Drug Administration had not approved this device for pedicular fixation, correct?
>
> MR. GESCHKE: Objection.
>
> THE COURT: Overruled.
>
> THE WITNESS: Repeat the question, please.
>
> Q. Yes. Prior to 1993 when you did Mr. Cosom's surgery, it was knowledge in the community of spine surgeons, which you are one, that pedicular crews had not been approved by the FDA for that intended use, posterior pedicular fixation, correct?
>
> A. Correct. As far as I – back in '93 there was no controversy, *per se*. The surgeons used these devices commonly for lumbar and sacral fixation.
>
> Q. My question was a little bit different than that, Doctor. My question was, back prior to 1993 when you did the surgery on Mr. Cosom, it was known in the medical community, at least in the community of spine surgeons like yourself, that these devices were not approved by the

> FDA to be implanted in the pedicles of the spines of patients like Mr. Cosom, correct?
>
> A. Ask the question again. Can you repeat the question?
>
> (The court reporter read back the question as requested.)
>
> THE WITNESS: Technically speaking – again, I don't know when my understanding of this came about. I believe it may have been actually after this that I personally knew that, technically speaking, they were not approved from lumbar utilization, but they were approved for pedicles, for placement in the sacrum pedicle, and also they were approved as bone screws. …

This evidence was clearly relevant and probative to the issue before the jury. Moreover, any claim of prejudice as a result of this exchange is wholly meritless.

¶ 22 The judgment which is the subject of the appeal at No. 2805 EDA 1999 is affirmed.

¶ 23 The appeal at No. 2499 EDA 1999 is quashed.