Affirmed and Opinion filed July 20, 2000.

In The

Fourteenth Court of Appeals

NO. 14-99-00616-CV

JOHN MCMAHON, Appellant

V.

SMITH & NEPHEW RICHARDS, INC., Appellee

On Appeal from the 152nd District Court
Harris County, Texas
Trial Court Cause No. 95-58737-A

O P I N I O N

Appellant, John McMahon, experienced multiple back surgeries including the implantation of an experimental or off label pedicle screw fixation device. He brought as many as fifteen different theories of recovery against appellee, Smith & Nephew, Inc. Prior to the hearing on appellee's summary judgment motion, these myriad claims were deferred in favor of appellant's central negligence per se claim, so far unaddressed by Texas appellate courts. Appellant maintained the failure of Smith & Nephew Richards, Inc. to obtain appropriate Food and Drug Administration approval of the Rogozinski device gave rise to his per se claims. This appeal is from both the trial court's striking the testimony of McMahon's expert

witness on causation and the court's subsequent grant of summary judgment under the senior summary judgment rule of McMahon's claim of negligence per se. Because appellant does not prevail on the causation issue, we do not reach appellant's arguments under the Food, Drug and Cosmetic Act or the Medical Device Amendments. We affirm.

Facts

In 1991, appellant suffered injuries to his head, neck and back when he collided with a loading dock in his eighteen-wheeler. His initial treatment was conservative, utilizing muscle relaxers, physical therapy, and traction. However, his symptoms worsened. He was evaluated by Dr. Clark, who diagnosed a disc herniation. Appellant underwent two surgeries but continued to experience persistent back and leg pain.

More than three years after the accident, appellant saw Dr. Dan Eidman, a board certified orthopedic surgeon, complaining of increasing neck, back, and leg pain and intermittent numbness and tingling in both legs. Dr. Eidman recommended a surgical decompression and fusion with the use of an internal spinal fixation device. Spinal fusion surgery attempts to fuse adjacent vertebrae and thereby prevent the abnormal motion of the joint between them. The specific implant chosen was the Rogozinski Spinal Rod System but it was attached to the pedicles via screws[1] vis a vis the attachment to the sacrum with hooks. Dr. Eidman thus attached the splint to appellant's spine by anchoring bone screws in the pedicles and fastened the Rogozinski "splint" device to these screws. This method was argued by appellee to be "off-label," which is a use not described in the label permitted by the FDA, but unregulated. Appellant argues the method is not off-label but experimental, thus precipitating FDA involvement and regulation.

[1] Considerable national mass tort litigation evolved on the use of pedicle screws. The Rogozinski System was FDA approved at the time for some spinal applications e.g. sacral attachment, but not for certain other uses including pedicle fixation. The FDA in 1998 apparently "downclassifed" pedicle screw systems. *See* 63 Fed. Reg. 40025, 40035-36, (July 27, 1998.) The pedicles are two short pieces of bone on each side of the spinal vertebrae body which extend back from the top of the vertebrae.

Appellant continued under Dr. Eidman's care over the next year and a half. During this time, Appellant continued to complain of persistent low back and leg pain. Conservative measures again failed to relieve his symptoms. Dr. Eidman recommended additional surgery to decompress the disk just above the fused area.

Appellant filed suit in 1995. Having abandoned other claims, his only extant liability claim is negligence per se. This, he avers, appellee committed when it allegedly violated FDA regulations by unlawfully marketing of the Rogozinski device for pedicle screw use. He complains that the unapproved use of the Rogozinski device itself, as opposed to the spinal fusion surgery in general, caused nerve damage or the formation of scar tissue. He asserts that the device is responsible for his disabilities, which continue to date.

Appellee moved for summary judgment under TEX. R. CIV. P. 166a(c) claiming that the pedicle implant did not cause appellant's ailments. In support of the motion, appellee offered the affidavit of Dr. Eidman, who implanted the device. Dr. Eidman states that the pedicle implant did not cause appellant any personal injury.

In response, appellant filed an affidavit and deposition excerpts from Dr. Kevin Gorin, a rehabilitation and pain management specialist. Dr. Gorin asserts that appellant's current complaints were caused by appellee's internal spinal fixation device, rather than any pre-existing or progressive disease.

Appellee then challenged the qualifications of Dr. Gorin to testify as to the cause of appellant's complaints. After a *Daubert* hearing, the district court, Judge Harvey Brown presiding, granted the challenge to the experts qualifications and testimony and issued a well-reasoned opinion, explaining his analysis in detail. *Baker v. Smith & Nephew Richards, Inc.*, No. 95-58737, 1999 WL 811334 (152nd Dist. Ct., Harris County, Tex., June 7, 1999).

Appellant's Expert

Appellant argues that it was error for the trial court to strike the testimony of Dr. Gorin, who was his sole causation witness. We review a trial court's decision not to admit expert testimony for an abuse of discretion. *See E.I. du Pont de Nemours and Co. v. Robinson*, 923 S.W.2d 549, 558 (Tex. 1995).

The trial court found that appellant failed to met his burden of proving that Dr. Gorin is qualified to testify as an expert in this case. Dr. Gorin is board-certified in both rehabilitation and pain medicine, and it is undisputed that he is an expert in those areas. Appellee, however, argued that, despite these qualifications, Dr. Gorin was not qualified to testify as to the *cause* of appellant's complaints. According to the affidavit of Dr. George William Wharton, an orthopedic surgeon, a pain management doctor (such as Dr. Gorin) lacks the necessary experience to determine whether or not a spinal implant is the cause of a patient's post-surgical pain.

The trial court noted that Dr. Gorin was not a surgeon and, therefore, had never performed or assisted in spinal surgery or the surgical explanation of any instrumentation. Additionally, the trial court correctly found no evidence that Dr. Gorin claimed expertise in biomechanics, biomedicine, or metallurgy. Dr. Gorin conceded that he could not offer an expert opinion regarding whether the instrumentation was appropriate in appellant's case. Nor could he describe the Rogozinski device or tell the difference between a Rogozinski System and similar systems. Finally, Dr. Gorin did not rebut or otherwise address Dr. Wharton's statement that a pain management specialist was unqualified to testify as to causation in this case. This omission was significant because appellant, as the offering party, bore the burden of proving his expert's qualifications.

The trial court concluded that, "despite Dr. Gorin's extensive training and experience in pain management and rehabilitation, there is no indication that he has been trained or attained adequate experience in actually diagnosing the *causes* of back ailment injuries in general, or more specifically, complaints of continuing pain after fusion surgery for patients with implants." (Emphasis added.) We are in accord with this finding.

The possession of a medical degree does not qualify a physician to offer expert testimony on every medical question. *See Broders v. Heise*, 924 S.W.2d 148, 152 (Tex. 1995) (upholding trial court's exclusion of testimony of emergency physician regarding cause of death from brain injury). Given the increasingly specialized and technical nature of medicine, such a rule would ignore the modern realities of medical specialization and eliminate the trial court's role of ensuring that those who purport to be experts truly have expertise concerning the actual subject about which they are offering an opinion. *Id.* at 152-53. The proponent of the testimony has the burden to show that the expert "possess[es] special knowledge as to the very matter on which he proposes to give an opinion." *Id*. [Citations omitted.]; *see also Gammill v. Jack Williams Chevrolet, Inc.*, 972 S.W.2d 713, 719 (Tex. 1998).

Though Dr. Gorin is qualified to testify as to the type of pain appellant was suffering and what kind of treatment will work, such expertise does not qualify him to testify as to causal factors which actually precipitated the pain or condition. As such, the trial court did not abuse its discretion in concluding that Dr. Gorin has not adequately shown his qualifications to state whether a Rogozinski Spinal Rod System affixed by pedicle screws, did in fact, cause post-surgical spinal pain or untoward result

We note that the trial court also struck Dr. Gorin because it found his methodology unreliable. Because the trial court's analysis of Dr. Gorin's qualifications is correct and thus dispositive, we need not additionally review the court's analysis of Dr. Gorin's methodology. *See* TEX. R. APP. P. 47.1.

Negligence Per Se

Summary judgment is proper when a movant establishes that there is no genuine issue of material fact and that the movant is entitled to judgment as a matter of law. TEX. R. CIV. P. 166a(c); *Randall's Food Mkts., Inc. v. Johnson*, 891 S.W.2d 640, 644 (Tex. 1995). Defendants are entitled to summary judgment if they conclusively negate at least one essential element of each of the plaintiff's causes of action. *See American Tobacco Co., Inc. v. Grinnell*, 951 S.W.2d 420, 425 (Tex. 1997). However, we make every reasonable inference in favor of the nonmovant and resolve any doubts in their favor. *Randall's Food Mkts., Inc.*, 891 S.W.2d at 644. If the movant establishes a right to summary judgment, the non-movant must produce summary judgment proof showing the existence of an issue of material fact

to preclude summary judgement. *See Westland Oil Dev. Corp. v. Gulf Oil Corp.*, 637 S.W.2d 903, 907 (Tex. 1982); *Cummings v. HCA Health Servs. of Texas*, 799 S.W.2d 403, 405 (Tex. App.–Houston [14th Dist.] 1990, no writ).

We need not address the FDA regulations and intricacies of Appellant's claim for negligence per se. Even if we were to assume, arguendo, that appellee's actions constituted negligence per se,[2] the plaintiff still must show the violation was the proximate cause of the injury. *See Missouri Pac. R. Co. v. American Statesman*, 552 S.W.2d 99, 103 (Tex. 1977); *Taco Cabana, Inc. v. Exxon Corp.*, 5 S.W.3d 773, 779 (Tex. App.–San Antonio 1999, pet. denied).

Dr. Eidman explicitly states that, in his expert opinion, "[N]one of the signs or symptoms which were present after the surgery were caused or contributed to by any component of the instrumentation used to stabilize the spine including the screws in the vertebral pedicles." Appellee's expert has thus conclusively negated the causation element of Appellant's claim. Left without an expert, appellant could not and did not raise a genuine issue of material fact on the material issue. We therefore overrule appellant's issues.

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[2] We specifically reserve and do not rule on merits of the negligence per se allegations. Much law has developed since the first pedicle screw cases were tried. For example, *see Talley v Danek Medical, Inc.*, 179 F. 3rd 154, 161 (4th Cir. 1999) rejecting appellant's theory.

The judgment of the trial court is affirmed.

/s/ Don Wittig
Justice

Judgment rendered and Opinion filed July 20, 2000.
Panel consists of Chief Justice Murphy and Justices Hudson and Wittig.
Do Not Publish — TEX. R. APP. P. 47.3(b).