

**United States Court of Appeals
FOR THE EIGHTH CIRCUIT**

No. 98-4063WM

Keith A. Knoth,

Appellant,

v.

Smith & Nephew Richards,
a/k/a Smith & Nephew North
America,

Appellee.

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* On Appeal from the United
* States District Court
* for the Western District
* of Missouri.
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Submitted: September 16, 1999

Filed: October 28, 1999

Before RICHARD S. ARNOLD, FLOYD R. GIBSON, and LOKEN, Circuit Judges.

RICHARD S. ARNOLD, Circuit Judge.

The plaintiff, Keith Knoth, appeals from the judgment in this products-liability case after the jury returned a verdict in favor of the defendant, Smith & Nephew Richards. The defendant is a manufacturer of surgical and orthopedic devices. The plaintiff argues ten points of error by the District Court.¹ Many of these arguments

¹The Hon. Dean Whipple, United States District Judge for the Western District of Missouri.

relate to his contention that the defendant violated the Medical Devices Amendments (MDA) to the Food, Drug, and Cosmetics Act, 21 U.S.C. § 360, and that such a violation was either negligence per se, evidence of negligence, or relevant to a strict-liability claim. We affirm.

I.

In September of 1993, the plaintiff, a muscular 215-pound man, fractured the area above his left knee in an auto accident. Dr. William Gondring treated plaintiff's fracture with an 11mm intramedullary supracondylar (IMSC) nail that was manufactured by the defendant. "Intramedullary" means placed into the center of a bone, the place where marrow is made. "Supracondylar" means above the condyles, a portion of the knee. The model of IMSC nails in issue had less than a 1% failure rate and evolved from other types of intramedullary nails also manufactured by the defendant. The IMSC nail was to serve as an internal splint to hold the broken pieces of bone together while the bone healed. Dr. Gondring reamed the inner canal of the bone to 13.5mm, and he wrapped stainless steel wires around the bone to stabilize the fracture. Dr. Gondring did not bone graft the affected area. He had plaintiff wear a knee immobilizer.

The plaintiff underwent physical therapy. Dr. Gondring ordered heavy exercising of the leg on November of 1993, and by December 2, 1993, he had plaintiff progress to 25% weightbearing. In January of 1994, plaintiff was fully weightbearing on his leg. Plaintiff was advised to reduce his weightbearing, because the leg was not healed. Dr. Gondring continued plaintiff at 50% weightbearing for two weeks and then 75% for two weeks. On January 23, 1994, the plaintiff sat down in a chair, and the IMSC nail broke. Dr. Gondring performed another surgery and replaced the 11mm nail with a 13mm nail. The plaintiff sued defendant for product defect and negligence.

The District Court's original scheduling order provided that amendments to the pleadings should be filed by March 1, 1996. Well after that date, plaintiff discovered that defendant had made no filings with the Food and Drug Administration before marketing the IMSC device. After discovering this, the plaintiff, on September 9, 1996 (18 months after the original complaint was filed), moved to modify the scheduling order so that he could amend his complaint to include a statutory issue. The plaintiff wanted to show that the defendant's failure to make FDA filings, or seek approval under the MDA prior to marketing the device, constituted negligence per se. The District Court denied the plaintiff's motion, citing its original scheduling order. The original scheduling not only fixed the closing date for pleadings, but also stated that the time provided was generous, no extensions should be expected, and all pretrial discovery should be completed on or before September 1, 1996. App. 75.

On June 30, 1997, the plaintiff filed a Motion to Reconsider Leave to Amend, which stated in part:

The proposed amendments previously submitted contained claims for relief specifically due to violations of the MDA amendments to the FDA Act and negligence per se claims which are omitted from the attached proposed First Amended Petition, which seeks to specify claims of "failure to warn" and seeks submission of punitive damages Wherefore, plaintiffs respectfully pray leave to amend their cause against defendant to add a claim for failure to warn and/or to add a claim for punitive damages.

Appellee App. 1. The Court denied the plaintiff's motion for reconsideration on December 30, 1997. However, on February 24, 1998, the Court, on its own motion, allowed the plaintiff to amend to add his claims for failure to warn and punitive damages.

After a 9-day trial, the jury returned a verdict in favor of the defendant. This appeal followed.

II.

The plaintiffs' first argument is that Instruction No. 11 was an incorrect statement of the law. This instruction stated:

The manufacturer of an Intramedullary Supracondylar Nail is not a guarantor that nobody will get hurt in using the article. What the manufacturer is required to do is to make a product which is free from defective and unreasonably dangerous conditions.

App. 131. Plaintiff argues that the Medical Devices Amendments, 21 U.S.C. § 360, required the product to be "safe and effective," and that Instruction No. 11 was erroneous because it failed to refer to this statutory standard. As the case went to the jury, however, there was no claim for violation of the federal statute as such. Plaintiff appears to concede, as a general matter, that the instruction was correct under the law of Missouri. Moreover, we do not see that inclusion of the "safe and effective" language would have materially changed the instruction. Plaintiff agrees that the first sentence of the instruction, to the effect that a manufacturer is not a guarantor that no one will get hurt, was correct. We do not believe that the Medical Devices Amendments change this standard. Even if, as plaintiff argues, defendant was in violation of the federal statute for failing to make proper filings with the FDA, this circumstance, in and of itself, has nothing to do with the safety and effectiveness of the device as such. On the whole, we are not persuaded that there was any error in the instruction, or that, if there was error, it affected plaintiff's substantial rights. The main issue argued to the jury in this case appears to have been defendant's contention that the plaintiff's difficulties were the physician's fault, and if, as seems likely, the jury

accepted this theory, any error in the instruction would have been harmless in any event.

Plaintiff also argues that the District Court erred in denying his motion to amend his complaint to add claims under the Medical Devices Amendments and implementing regulations, 21 C.F.R. Pts. 801, 807, and 820. Plaintiff argues that the defendant had not registered the IMSC device with the FDA, that it was therefore marketing the device unlawfully, which was proof of defendant's negligence per se. We find no abuse of discretion in the District Court's action. The motion to amend the pleadings was made after the deadline for amendments in the original scheduling order. It is well within the authority of the district courts to set such deadlines, and, within broad limits, it is up to those courts, not us, to determine when exceptions to these deadlines are appropriate. Here, plaintiff suggests that the lateness of his motion for leave to amend was due to discovery delays on the part of defendant. It was evidently the view of the District Court that any such delays were not a sufficient ground for allowing the late amendment. We are not persuaded that this decision was incorrect. In addition, plaintiff appears later to have abandoned his MDA theory, because, in his motion to reconsider the denial of the motion for leave to amend, the MDA and negligence per se claims were omitted from the pleading he sought leave to file. Significantly, the District Court did allow amendment of the complaint to assert claims for failure to warn and for punitive damages. Finally, any amendment to assert a claim under the MDA would probably have been futile, because the violation of the MDA that plaintiff sought to establish, a failure to make certain filings, was not relevant to the substantive quality of the devices. In sum, we are not persuaded that the District Court abused its discretion by not allowing the full scope of amendment to the complaint desired by plaintiff.

The plaintiff urges a number of other points, including the following: that the District Court erred in refusing to allow evidence of FDA statutes and regulations; that expert testimony on the relationship of the MDA to medical-industry standards was

incorrectly excluded; that the defendant was incorrectly allowed to offer an expert witness even though some of the opinions he presented had not been disclosed in a timely fashion; that it was error to require the plaintiff to pay a portion of the expenses of defense counsel in attending a deposition of plaintiff's expert; that the Court should have allowed plaintiff's request for expenses owing to defense counsel's late arrival at the deposition; and that the time for final arguments was unduly restricted. We have considered these and other points made by plaintiff. They all relate to evidentiary and discovery rulings which rest within the sound discretion of the District Court. We see no abuse of discretion.

Accordingly, the judgment is affirmed.

A true copy.

Attest:

CLERK, U.S. COURT OF APPEALS, EIGHTH CIRCUIT.