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Newsletters

Products Liability Bulletin - November 2010

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Expert's Testimony in Products Liability Case Inadmissible Under Evidence Rules and *Daubert*

Plaintiff patient sued defendant manufacturer in a negligence and products liability action, alleging that he was injured by one of the manufacturer's pumps. The patient proffered a physician as his single expert witness on the issue of causation. The district court determined that the methodology that the physician used to reach his conclusions was unreliable and, therefore, that his testimony was inadmissible under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals,* 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993). Without the physician's testimony, the district court determined that the patient could not establish the causation element in any of his claims, and it granted final summary judgment in favor of the manufacturer.

The case hinged on the question of whether the methodology used by the physician was reliable under*Daubert*. The district court exercised its discretion and found that each of the articles that the physician relied upon, both taken together and separately, were not sufficiently reliable to support his opinion on general causation. The U.S. Court of Appeals for the Eleventh Circuit held that the district court did not abuse its discretion in finding that the literature that the physician based his conclusions upon was insufficient to create a reliable methodology which passes muster under *Daubert*.

Kilpatrick v. Breg, Inc., 613 F.3d 1329 (11th Cir. 2010)

State Products Liability Claim Concerning Device Given Premarket Approval by FDA Pre-Empted by Federal Law

Plaintiff patient brought an action for breach of warranty, negligence, and breach of express warranty against defendant, the manufacturer of artificial discs that were implanted in the patient's spine. The patient alleged that the artificial disc was defective and unreasonably dangerous at the time it left the manufacturer's hands such that the device was not reasonably suitable for the ordinary uses for which it was sold. The patient further claimed that the manufacturer was negligent in the design, manufacturing and sale of the artificial disc.

The manufacturer moved for summary judgment, arguing that the products liability claim under Florida law was pre-empted by the Medical Device Amendments of 1976 (MDA), 21 U.S.C. § 360c *et seq.,* to the Food, Drug, and

Service Areas

Appellate

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Cosmetic Act (FDCA), 21 U.S.C. §301 et seq. The district court held that summary judgment was appropriate as to the products liability (breach of warranty) claim. That claim under Florida law was pre-empted by the MDA because the artificial disc was given premarket approval by the Food and Drug Administration (FDA), and the patient's claim was not premised on a violation of FDA regulations.

The MDA provides for premarket approval of devices "to provide reasonable assurance of [the device's] safety and effectiveness," and authorizes the Secretary of Health and Human Services to "conduct such activities as may be necessary to develop or obtain [sufficient information to establish a performance standard for the device]." 21 U.S.C. §360c(a)(1)(C). It was undisputed that the subject artificial disc had received the FDA's premarket approval in October 2004. Subsequent to the filing of the patient's case, the U.S. Supreme Court held in *Riegel v. Medtronic, Inc.,* 552 U.S.312, 128 S.Ct. 999, 169 L.Ed.2d 892 (2008), that the MDA's pre-emption clause barred common law claims challenging the safety and effectiveness of those medical devices given premarket approval by the FDA.

The only type of products liability claim not pre-empted by the MDA is a claim "premised on a violation of FDA regulations. " In the patient's matter, the manufacturer's motion for summary judgment was granted because the patient failed to state such a claim. The manufacturer was also entitled to summary judgment as to the claim that it negligently designed the disc because the patient was not able to establish that Florida has provided for a claim of negligent design that survives the MDA pre-emption test.

Wheeler v. DePuy Spine, Inc., 706 F. Supp. 2d 1264 (S.D. Fla. 2010)

Seller/Servicer of Crane Not Liable for Longshoreman's Death

Plaintiffs' decedent was run over and killed by a mobile crane. Plaintiffs brought a products liability claim against defendant seller, which had sold the crane to a settling defendant and entered into a service agreement to keep it in good repair, but did not design or manufacture the crane.

The decedent had placed a folding chair in front of the crane while it was in operation and its wheel assemblies were off the ground, lifted up by the crane's outriggers. After the crane completed its loading operations, it was readied for travel. The process of transitioning the crane from loading to travel involved the activation of revolving yellow warning lights, two warning bells, and an "all-clear" alert announced over the crane's public address system. The purpose of each of these measures was to alert those located on the dock that the crane was ready to move. The process preceding the machine's travel was captured on surveillance and lasted for approximately 90 seconds before the crane began to move. The decedent remained in her folding chair throughout the process, either at rest or asleep, and was subsequently crushed to death when the crane moved forward and the wheel assembly she was sitting in front of ran over her.

Plaintiffs alleged that: (1) the crane was defective in its design because it did not include lights and alerting devices underneath its chassis; (2) defendant should have retrofitted the crane with lights, horns, warning signs and the like; (3) a warning should have been provided with the crane, instructing persons not to go under it at any time; and (4) the warnings on the crane were inadequate because they were not "better placed." The seller moved for summary judgment, and the trial court ruled that, under a theory of negligence, the seller had neither a duty concerning the crane's design and manufacture, nor a duty to retrofit the crane with additional safety devices after the sale. However, the trial court denied the portion of motion for summary judgment regarding the seller's duty to warn. At trial, the jury found that the seller was negligent and that such negligence was a contributing factor in the death of decedent. The jury also found, however, that the crane was not defective when it left the seller's possession, or alternatively, that any defect was not a contributing factor in the death of the decedent.

On appeal, the court found that each of the bases upon which the seller might have been held liable had been rejected. The primary duty and responsibility of a seller and servicer of equipment such as the seller in this case is ordinarily found in the claim that, at the time of the sale, the equipment contained a defect that rendered it unreasonably dangerous to persons in the vicinity of the crane. *See West v. Caterpillar Tractor Co.,* 336 So. 2d 80 (Fla. 1976); *American Aerial Lift, Inc. v. Perez,* 629 So. 2d 169 (Fla. 3d DCA 1993). Because the jury found that the crane was not defective at the time of the

sale, the trial court's holding that the seller was negligent required reversal.

The appellate court further held that plaintiffs' alternative argument that there was an alleged breach of the seller's obligation to appropriately service the crane after its sale was also not viable. The fact that there was some evidence that two years after the sale one of the horns or other warning devices was not operating properly was not enough to give rise to liability absent evidence indicating that the failure had previously occurred or that the seller was on notice of such impropriety such that it was negligent in failing to repair it.*Siemens Energy & Automation, Inc. v. Medina,* 719 So. 2d 312 (Fla. 3d DCA 1998); *Advance Chem. Co. v. Harter,* 478 So. 2d 444, 447 (Fla. 1st DCA 1985); *Williams v. Joseph L. Rozier Machinery, Co.,* 135 So. 2d 763, 765 (Fla. 2d DCA 1962).

Finally, the appellate court held that any duty to warn was placed either on the allegedly negligent operator of the crane, who was the employee of another defendant, or on the owner of the property on which the decedent was an invitee or licensee, which was still another defendant. *See Foley v. Hialeah Race Course, Inc.,* 53 So. 2d 771 (Fla. 1951); *Food Fair, Inc. v. Gold,* 464 So. 2d 1228 (Fla. 3d DCA 1985); *Schatz v. 7-Eleven, Inc.,* 128 So. 2d 901 (Fla. 1st DCA 1961).

Liebherr-America, Inc. v. McCollum, 43 So. 3d 65 (Fla. 3d DCA 2010)

For more information, please contact your regular Hinshaw attorney.