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PATIENT'S CLAIM FOR VOCAL CORD INJURIES FROM TEFLON PASTE INJECTION PREEMPTED

***Mathis v. E.I. Dupont de Nemours & Co.*, 2008 WL 162156 (W.D. La. Jan. 16, 2008)**

Mentor Corporation is a manufacturer of Polytef, a paste containing Teflon, that has been used since 1962 to restore voice functionality by injecting it into paralyzed vocal cords. In 1966, information about Polytef was submitted to the FDA for review and approval. Under the then-existing approval process, the manufacturer was required to submit a New Drug Application ("NDA") including data regarding results from animal studies, manufacturing and quality control procedures, possible side effects, summaries of surgical cases during the investigational use of Polytef, clinical trials, and post-operative complications, including Teflon granulomas. After this extensive review process, the FDA approved Polytef for use, allowing the manufacturer to sell Polytef as long as it conformed to FDA imposed conditions and sold Polytef with the precise packaging and labeling approved by the FDA.

In 1976, Congress passed an amended regulatory process known as the Medical Device Amendments ("MDA") by which the FDA approved devices. Under this new scheme, devices were classified into three categories depending upon the degree of risk the device posed to the public. Class 3 devices, which involved the greatest risk, were subject to a rigorous premarket approval process ("PMA") before they could be marketed for use. Devices such as Polytef, which had been approved through the old NDA process, were automatically grandfathered in as Class 3 medical devices and deemed to have attained PMA approval. At all times during and since the original approval, Mentor complied with the applicable FDA regulations.

In 1984, Wanda Mathis underwent surgery to have her thyroid removed, which resulted in the paralysis of her vocal cords and her inability to speak. One year later, Mathis underwent a procedure in which Polytef was injected in her throat to stabilize her vocal cords and restore her ability to speak. About twenty years after the surgery, in November 2004, Mathis began having difficulty breathing and was subsequently diagnosed with a Teflon granuloma. She underwent surgery to have the granuloma removed and filed this lawsuit against Mentor. Mathis made a claim based on the Louisiana Products Liability Act ("LPLA") and negligence for failure to warn her of the risks associated with Polytef.

Mentor filed a motion for summary judgment claiming that Ms. Mathis' negligence claim was barred by the LPLA and that her LPLA claim was preempted by federal law. The court quickly dismissed Ms. Mathis' negligence claim by holding that the LPLA provides the exclusive theories of recovery for claims made against a manufacturer.

The court then moved to Mentor's claim that any action under the LPLA was pre-empted by federal law. The court noted that the MDA contained a preemption section and then likened the facts of this case to the Fifth Circuit Court of Appeals case of *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir. 1993). In *Stamps*, the Fifth Circuit held that approval by the FDA of a device via the rigorous PMA process preempted any state law liability claim.

Next, the court distinguished this case from the Supreme Court case of *Medtronic Inc. v. Lohr*, 518 U.S. 470 (1996). The court noted that the *Lohr* case, which found state law claims were *not* preempted, involved a device that underwent an approval process that was much less rigorous than the PMA approval process. The court noted that Polytef had gone through extensive NDA review for approval of the design, chemical composition, and manufacturing process. The review included a review of the product labeling, namely the instructions for use and warning. Because the old NDA process was deemed by law to be equivalent to approval as a post-1976 PMA Class 3 device, the court held that Mathis' claims were preempted and to hold otherwise "would displace the FDA's exclusive role and expertise in this area and risk imposing inconsistent obligations." Thus, the court concluded awarded summary judgment in favor of Mentor.

This case emphasizes the comprehensive nature of certain FDA approval procedures and the necessity of distinguishing between the various levels of FDA scrutiny. If a product has undergone the rigorous approval procedures of the PMA, or the pre-1976 equivalent (the NDA), then any state law claims of inadequacy of warning will be pre-empted.

– *Sara C. Valentine*

HOSPITAL DISMISSAL REVERSED PENDING ONGOING CATHETER TESTING

***Jackson v. Bard Access Systems, et al.* 42,890 (La. App. 2 Cir. Jan. 9, 2008), ___ So.2d ___**

Braimian McMahon died at only 11 months old as a result of numerous complications which began at birth. Braimian's parents filed a medical malpractice and products liability lawsuit against a manufacturer, hospital, and treating doctor, alleging that a failed catheter resulted in Braimian's condition weakening, and thus contributed to his death. Specifically, the parents alleged that the catheter failed because either it was defective when implanted or because the hospital or treating doctor committed a negligent act.

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Braimian McMahon was born prematurely at Louisiana State University Health Sciences Center ("LSUHSC") at a gestational age of 26 weeks, weighing only 922 grams. Braimian was placed on the neonatal intensive care unit, where he remained for 158 days and was treated for various conditions, including renal insufficiency, sepsis, and meningitis. During this time, Dr. Celeste Hollands inserted a Broviac catheter to provide a stable access site. The catheter, which was manufactured by Bard Access Systems, broke off and migrated to Braimian's heart. The migrating part was subsequently retrieved through a non-invasive procedure. Braimian, however, died seven months later.

After suit was filed, a central discovery dispute quickly arose regarding how to test the catheter, which could potentially assist in determining fault. After nearly a year of discussions, the parties finally agreed upon a protocol for testing. When initial testing was completed, it was agreed that additional testing with an electron microscope was necessary to determine the cause of the catheter's failure. Before this second round of testing was completed, however, LSUHSC and Dr. Hollands filed a motion for summary judgment. In granting this motion, the trial court reasoned that the plaintiffs could not sustain their burden of proof in showing causation of damages. In particular, the trial court said, "[T]hat (based on the supporting affidavits) the child had sustained serious debilitating brain injury before this catheter was put in the vessel or vein..."

On appeal, the Second Circuit Court of Appeal reversed the trial court and remanded the case for further proceedings. The plaintiffs argued that the motion was premature, since there was conflicting evidence of whether or not the catheter harmed Braimian and testing of the catheter was not yet complete. LSUHSC and Dr. Hollands relied upon a doctor's affidavit which stated a defect in the catheter caused the deterioration in Braimian's condition. In rendering a decision, Chief Judge Henry N. Brown noted that there were genuine issues of material fact concerning causation. Since the electron microscope inspection was in progress and would possibly provide insight into the issue of fault, the granting of summary judgment was premature.

The appellate court's reversal emphasizes the role that timing plays in consideration of summary judgment. From a strategic perspective, counsel must assess whether enough discovery has been conducted so that the timing of summary judgment is appropriate. Here, a critical discovery investigation was still underway when the LSUHSC defendants moved for summary judgment. In a footnote, the appellate court noted that it had learned that the second round of testing apparently pointed blame towards the LSUHSC defendants, as opposed to the manufacturer, but these results were not in the trial court record and so were disregarded on the appeal.

– *Michael B. DePetrillo*

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CATHETER MANUFACTURER DISMISSED WHERE CAUSE OF FRACTURE WAS EXCESSIVE FORCE

***Howard v. Arrow Int'l, Inc.*, No. 04-2327, 2008 WL 393893 (W.D. La. Feb. 11, 2008)**

In 2003, Tracy Lynn Howard was admitted to Rapides Regional Medical Center to undergo an induction of a high risk pregnancy. During the procedure, an epidural catheter manufactured by Arrow International, Inc. was inserted into Howard's epidural space. The catheter fractured during removal, leaving two centimeters of the product inside Howard, but the fractured portion was never removed. Howard filed suit against Arrow in the United States District Court for the Western District of Louisiana asserting claims under the Louisiana Products Liability Act.

Arrow filed a motion for summary judgment and submitted "a concise statement of undisputed material facts." Under the Western District's local rules, a party opposing a motion for summary judgment must controvert the moving party's statement of material facts by providing a statement of material facts "to which there exists a genuine issue to be tried." However, Howard failed to marshal any evidence in contradiction of Arrow's statement of material facts and instead supplied conclusory statements and allegations in support of her assertion that "the fact of catheter fracture" provided a "sufficient basis to keep the manufacturer in the action." This failure, under the Western District's local rules, resulted in Arrow's material facts being deemed admitted. Judge Drell pointed out that the admitted facts affirmatively established that the catheter had proper warning labels and that the risk of fracture "was a known risk." Accordingly, Judge Drell granted summary judgment in Arrow's favor.

Interestingly enough, Howard chose not to bring suit against the hospital or the nurse who removed the catheter. The Court noted that evidence existed to suggest that the nurse exerted too much force in removing the catheter, thereby causing the fracture. Nevertheless, Judge Drell noted that even if the catheter was defective, Howard failed to controvert Arrow's statement of material facts; thus, even if Howard suffered actual damages and one of the entities was culpable, "under the uncontroverted facts presented . . . that entity, as a matter of law, is not Arrow." Although the result may appear harsh, Judge Drell was correct in granting summary judgment to the manufacturer who was the only defendant. The summary judgment procedure exists to save the parties from unnecessary expenses and is appropriately applied where, as here, no dispute as to material facts is shown to exist.

– *Eric Michael Liddick*

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WOMAN BURNED BY HEAT WRAP IGNORED WARNINGS SAYS FIFTH CIRCUIT

***Broussard v. Proctor & Gamble Co.*, ___ F.3d ____ (5th Cir. 2008)**

Rachel Broussard suffered from a congenital condition that left part of her spinal cord permanently exposed at a lesion in her back. Below the lesion, she had markedly decreased sensation, and the condition caused chronic pain and poor circulation. To ease her muscle soreness, Mrs. Broussard purchased a ThermaCare HeatWrap, an over-the-counter pain reliever manufactured by Proctor & Gamble. The packaging and insert on the ThermaCare wrap warned that consumers with poor circulation should ask a doctor before using the product. Further, the packaging and insert warned consumers not to use the wrap on areas of the body where heat couldn't be felt, and warned consumers to periodically check their skin if they were sensitive to heat or if their tolerance for heat had decreased over the years.

Mrs. Broussard used the ThermaCare wrap by strapping it around her lower back against her skin before she went to sleep. When she awoke, she found that the wrap had slipped and caused severe burns on her left buttock.

Mrs. Broussard and her husband sued Proctor & Gamble pleading claims under the Louisiana Products Liability Act. They asserted that they relied on representations on the packaging that the heat wrap could be used anytime, even when the user was sleeping. The LPLA requires that plaintiffs must establish that their damages were "proximately caused by a characteristic of the product that renders it unreasonably dangerous" and that their damages "arose from a reasonably anticipated use of the product." Proctor & Gamble filed a motion for summary judgment, arguing that Mrs. Broussard failed to demonstrate that her use of the wrap was "reasonably anticipated." The summary judgment was granted, and the Broussards appealed to the Fifth Circuit.

The Fifth Circuit made short work of the Broussards' appeal, finding that the matter was governed by an earlier Fifth Circuit decision, *Kampen v. American Isuzu Motors, Inc.*, 119 F.3d 1193 (5th Cir. 1997). In *Kampen*, the court held that a plaintiff who used a product in a manner that violated clear and express warnings can show their use was "reasonably anticipated" only by presenting evidence that the manufacturer had reason to know the warnings were ineffectual. Finding that the ThermaCare HeatWrap came with clear and express warnings applicable to Mrs. Broussard, and finding that the Broussards did not present any evidence to suggest that Proctor & Gamble knew or should have known that the wrap would be used in this manner, the Fifth Circuit upheld the summary judgment.

Given the controlling precedent, this ruling seems entirely correct. If a product expressly warns against certain uses, then it cannot be "reasonably anticipated" that a consumer will use the product in that manner. Accordingly, there can be no liability under the LPLA.

– *Emily E. Eagan*

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FUTURE JOINDER OF PARTY INSUFFICIENT TO REQUIRE REMAND FROM FEDERAL COURT

***McQuiston v. Boston Scientific Corp.*, No. 07-1723, 2008 WL 104210 (W.D. La. Jan. 9, 2008)**

During an angioplasty and stent procedure performed at Willis Knighton Medical Center, a stent, which was manufactured by Boston Scientific Corporation, allegedly malfunctioned causing injury to James McQuiston. In late 2007, McQuiston proceeded on two separate paths: first, McQuiston commenced a claim against Dr. Brown and the hospital invoking a hearing before a medical review panel pursuant to Louisiana law governing medical malpractice claims; and second, McQuiston filed a products liability action against the manufacturer Boston in Louisiana state court. Boston removed the case to the United States District Court for the Western District of Louisiana. Unhappy with the forum, McQuiston filed a Motion to Remand, which would have sent the suit back to state court. Magistrate Judge Hornsby ultimately denied McQuiston's motion.

United States District Courts are courts of limited jurisdiction. "Diversity jurisdiction" exists where the parties on opposing sides of the lawsuit are citizens of different states. Magistrate Judge Hornsby correctly concluded that McQuiston, a Louisiana citizen, and Boston, a Delaware corporation with its principal place of business in Massachusetts, were diverse parties.

McQuiston argued that the case should be remanded to state court, however, because once the medical review panel concluded its administrative review of the actions of Brown and the hospital (both Louisiana citizens), McQuiston would add the two to the ongoing dispute in federal court with Boston. The uniqueness of this case hinges upon Louisiana's medical malpractice laws, which require that a medical review panel review the actions of the qualified medical care provider *before* the injured individual files a lawsuit. McQuiston claimed that the potential "future destruction of diversity" by joinder of Brown and Willis as defendants dictated remand of the suit to state court. Magistrate Judge Hornsby disagreed and held that unless the complaint before the court at the time of removal actually names a *non-diverse* party, remand based upon a hypothetical destruction of diversity is inappropriate.

McQuiston attempted other procedural tactics, as well. He argued that he should be allowed to amend his complaint to add Brown and the hospital. Magistrate Judge Hornsby noted that amendment would be futile because Boston could object on the basis of prematurity because the medical review panel had not yet completed its review. McQuiston also requested a stay of the proceeding until "completion of the medical review process." A stay, under the right circumstances, might have been appropriate; however, citing insufficient facts, Magistrate Judge Hornsby set a scheduling conference at which discussion of this issue would occur.

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This decision presents the unique challenges facing plaintiffs when attempting to bring a medical malpractice action in conjunction with a products liability suit. Magistrate Judge Hornsby was correct to conclude that the possible "future destruction of diversity" could not act to divest a federal court of jurisdiction.

– *Eric Michael Liddick*

UNIFORM MANUFACTURER DEFEATS INJURED WORKER'S EFFORTS TO REMAND

***Spears v. Cintas Sales Corp.*, 2008 WL 53651 (W.D. La. Jan. 2, 2008)**

On November 3, 2005, Donald Spears, a shop foreman for Apeck Construction, Inc., was injured when his work uniform caught fire while he was performing his work duties. Spears filed suit in Louisiana state court against the manufacturer and launderer of the uniform, Cintas Sales Corporation, under the Louisiana Products Liability Act. He also joined his employer Apeck in the claim, alleging that Apeck should have provided "appropriate flame retardant uniforms" when it was "substantially certain" that Spears would be exposed to "welding, blow torches, open flames, and extremely hot equipment during his daily duties."

During an October 9, 2007 deposition of Spears taken by the manufacturer Cintas, he testified to facts concerning his employment with Apeck and the occurrence of the accident. Based on these facts, Cintas promptly removed the case to the federal court for the Western District of Louisiana based on diversity of jurisdiction. In its notice of removal, Cintas alleged that Apeck, a Louisiana company, was improperly joined because Spears was limited to workers' compensation against his employer and he had therefore had no possibility of recovering against Apeck in the lawsuit under Louisiana law.

On November 14, 2007, Spears filed a motion to remand, which the district court denied. Magistrate Judge C. Michael Hill agreed with Cintas' assertion that Apeck was improperly joined. The court's decision was based on the premise that there was no reasonable possibility that Spears could recover against Apeck, and that Cintas' notice of removal was timely because it was filed within 30 days of its knowledge that the case had become removable, i.e., the deposition of Spears.

– *Wade B. Hammett*

Remember that these legal principles may change and vary widely in their application to specific factual circumstances. You should consult with counsel about your individual circumstances. For further information regarding these issues, contact:

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