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MEDICAL DEVICE AMENDMENTS OF 1976 PREEMPT STATE LAW CLAIMS AGAINST MANUFACTURERS

Gomez v. St. Jude Medical Daig Div. Inc., ___ F. 3d ____ (5th Cir. 3/14/06)

In this case filed in the Eastern District of Louisiana, the plaintiff claimed that she suffered injuries as a result of a defect in an Angio-Seal, a device used to close a hole in her artery created during a medical procedure. Plaintiff filed suit against the Angio-Seal's manufacturer under the Louisiana Products Liability Act claiming unreasonably dangerous design, failure to warn, failure to train medical personnel, breach of express and implied warranty and redhibition. Judge Lemelle granted the manufacturer's motion for summary judgment, based on the preemptive effect of federal law, on all but the plaintiff's manufacturing defect claims. After convening a jury trial and hearing the evidence put on by the plaintiff on the manufacturing defect issue, Judge Lemelle granted a direct verdict in the manufacturer's favor on that claim as well.

The United States Fifth Circuit Court of Appeals affirmed the district court's rulings on summary judgment, holding that the Medical Device Amendments of 1976 (MDA) preempted plaintiff's defective design claims, failure to warn and train claims, and breach of express and implied warranty claims. However, the Fifth Circuit reversed the district court's directed verdict on the manufacturing defect claim, finding that the evidence was sufficient to support an inference that the device used in plaintiff's surgery was defective because it was not manufactured in compliance with FDA-approved specifications. The Fifth Circuit held that such claims were not preempted by federal law.

The Angio-Seal received pre-market approval (PMA) under the Food and Drug Administration's (FDA) most rigorous review. Because the approval process is so rigorous, and falls exclusively under federal jurisdiction, Congress promulgated the MDA to, among other things, provide an express preemption provision, which sets forth the extent to which the MDA preempts state law. This provision specifically prohibits states from enforcing any laws with respect to a device intended for human use which is more restrictive than the MDA. Applying the Supremacy Clause of the federal Constitution, the Fifth Circuit held that, to the extent conflict exist between state law and the MDA, the MDA will govern.

The Fifth Circuit found that the FDA studied the Angio-Seal's design, warnings and instructions, and training materials through the PMA process and approved it. To permit a jury to second-guess the Angio-Seal's design, warnings and instructions, and training materials by applying the LPLA would risk interference with the federally-approved design standards and criteria. The Fifth Circuit found that the district court correctly held that federal law preempted the LPLA's challenge to the Angio-Seal. The court also held that any success on an LPLA claim would require a showing that the FDA requirements were deficient. Such a showing would be inconsistent with federal regulatory requirements.

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The Fifth Circuit reversed the district court's directed verdict on the manufacturing defect claim, holding that the testimony supported an inference that the lot supplying the majority of the devices shipped to the Ochsner Clinic during the relevant time period deviated from FDA standards requiring disposal of the entire lot. Therefore plaintiff's case was remanded to the district court for a new trial as to whether the Angio-Seal was defective because it failed to conform to FDA specifications.

—*Don A. Rouzan*

LOUISIANA 4TH CIRCUIT REVERSES AWARDS IN DOCK WORKERS' ASBESTOS DEATH CASES

***Palermo v. The Port of New Orleans*, 2004-1804 (La. App. 4 Cir. 3/15/06), ___ So. 2d ____**

Two dock workers who spent many years working on the wharves on the Mississippi River in New Orleans died of asbestos-related diseases. Their families brought suit against many defendants including the Dock Board and three ship repair companies, contending that the deaths (one lung cancer/suicide and one mesothelioma) were caused by asbestos exposure in the workplace. The trial judge found in favor of the plaintiffs and awarded damages. In this opinion, Louisiana's Fourth Circuit reversed the trial court and held that none of the defendants were liable.

The case was tried solely against the Dock Board and the ship repair companies, all other defendants having settled before trial. The trial court found that the Dock Board, which leased the premises to various stevedoring companies, was negligent because it should have supplied the dock workers with safety equipment and should have better maintained its facilities.

The Fourth Circuit rejected all theories of liability against the Dock Board. First, the court held that the Dock Board was not negligent. Negligence requires the existence of a duty. The Dock Board was not the employer of the dock workers. Therefore, the Dock Board did not owe a duty to provide them with a safe place to work. The Dock Board did not have control over the stevedoring operations and usually did not even know the nature of the cargo being handled until well after the cargo had been processed and left the docks. There was no showing that the Dock Board was aware of any increased danger due to asbestos debris in the warehouses that could have been alleviated by increased ventilation, and there was no showing that increased ventilation would have made any difference. Further, although there was evidence that boilers in the Dock Board's warehouse may have been insulated with asbestos, there was no evidence that that asbestos insulation had been disturbed such that it could have caused the dock workers to have been exposed to asbestos fibers.

Second, the court held that the Dock Board could not be strictly liable under the applicable versions of Civil Code articles 2317 and 2322. Article 2317 as it existed at the time of the dock workers' exposures provided for strict liability for the custodian of a defective "thing" that caused injury. The Fourth Circuit held that the cargo that came through the wharves was not something that was in the custody or control of the Dock Board. Article 2322 as it existed at the time of the dock workers' exposures provided for strict liability for the owner of a building that causes damage due to its "ruin". The Fourth Circuit found that, even if there was asbestos incorporated into the Dock Board's premises, *e.g.*, insulation on the boilers, there was no proof that the Dock Board's premises were in a "ruinous" condition.

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The Fourth Circuit next considered the liability of the ship repair companies and absolved each from responsibility in the case. The court noted that, like the Dock Board, the ship repair companies were not employers of the dock workers and therefore did not owe a duty to provide them with a safe place to work. However, the court stated that the ship repairers did have a general duty to prevent reasonably foreseeable harm to the dock workers from any asbestos activities that the ship repairers undertook.

In determining that the plaintiffs had not proved liability of the ship repair companies, the Fourth Circuit easily conceded that it had been shown that, due to their occupations, the dock workers had been exposed to large amounts of asbestos. There was no evidence, however, that any of the three ship repairer defendants had done any work that could have generated asbestos in the vicinity of *any* cargo workers, and certainly no evidence that they did such work in the vicinity of the two deceased workers. The most specific testimony regarding the decedents was given by an eyewitness who stated that he once saw one of the deceased workers within 15 to 40 feet of a pile of insulation left on the dock. However, there was no evidence as to *who* left the pile of insulation on the dock or that the insulation was disturbed while the worker was nearby. The court refused to find the ship repairers liable on the basis of generalities, and, without evidence of specific exposures, reversed the trial court.

The majority opinion in this case was written by Judge Patricia Murray, the same judge who wrote the opinion in *Zimko v. American Cyanamid*, 2003-0658 (La.App. 4 Cir. 6/8/05), 905 So.2d 465 (see LA. 4TH CIRCUIT TACKLES INTENTIONAL TORT AND HOUSEHOLD EXPOSURE IN ASBESTOS CASE in July 2005 issue). The *Zimko* case espoused an analysis of "duty" recycled by Judge Murray here: simplifying somewhat, every human being has a duty to every other human being to protect them against reasonably foreseeable risks of harm.

Judge Tobias concurred in the majority opinion here, but disagreed with Judge Murray's reliance on *Zimko*. Judge Tobias would have found simply that the defendants in this case had no duty to these plaintiffs under the facts and the law. Although Judge Tobias's concurrence was brief, it appears he disagreed with the "general duty" analysis recommended in *Zimko* and applied by Judge Murray here. He stated:

> *Zimko* was a 3 to 2 decision of this court. American Cyanamid was found liable to the plaintiff…. American Cyanamid has settled with the plaintiff [and] agreed not to pursue their appeal further. Any person citing *Zimko* in the future should be wary of the problems of the majority's opinion in *Zimko* in view of the Louisiana Supreme Court never being requested to review the correctness of the liability of American Cyanamid.

The discussion of *Zimko* in the present case is especially interesting because, even though the result in this case was a ruling in favor of the defendants, *Zimko* applies a very broad duty of care, regardless of the relationship (or total lack of relationship) of the defendant to the plaintiff.

The good news here is that the Fourth Circuit held the plaintiffs to an appropriate burden of proof in their case against both the Dock Board and the ship repairer defendants. Particularly, the Fourth Circuit required proof that *these* decedents were in fact exposed to asbestos fibers as a result of the activities of *these* ship repairers. The Fourth Circuit did not permit the plaintiffs to satisfy their burden through general testimony about the dusty conditions on the docks or through testimony that on some occasions the ship repairers' activities may have exposed some generic dock worker to asbestos fibers.

—*Madeleine Fischer*

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PLAINTIFF'S LETHARGIC DISCOVERY RESULTS IN DISMISSAL OF TRUCK SEAT DEFECT CASE

***Humphries v. Cooper Truck Center*, 40,586 (La.App. 2 Cir. 3/8/06), ___ So. 2d ____**

Glenn Humphries was a truck driver who claimed to have been injured in 1996 when the seat of the truck he was driving allegedly malfunctioned. The alleged malfunction prevented the seat from absorbing the impact of the road, supposedly injuring Humphries' back. Humphries sued Freightliner, Inc., the truck manufacturer, and Cooper Truck Center, the repair shop that serviced the truck. Specifically, he asserted products liability claims against Freightliner, alleging that the seat was unreasonably dangerous in construction and composition, in design, in lack of an adequate warning about the design defect, and in failing to conform to an express warranty. However, the petition did not describe any specific defect in the seat.

In 2003, the defendants filed a third-party demand against Bostrom Seating, Inc., the manufacturer of the seat. Humphries amended his petition to name Bostrom as a defendant and asserted the same products liability claims he asserted against Freightliner. Discovery continued, and plaintiff identified two experts whom he expected to testify about the condition of the seat, and its design and construction. However, plaintiff's supposed experts never generated any reports or issued any opinions.

In 2004, each of the defendants filed motions for summary judgment, asserting that after almost six years, the plaintiff lacked sufficient evidence to sustain his products liability and negligence claims. In response, the plaintiff asserted that he could not address the products liability claims until discovery was complete. In particular, he claimed that Bostrom had yet to respond to discovery requests intended to cover the "design, products and biomechanical issues relating to this case." The trial court was unmoved by this argument, noting that Humphries had known of Bostrom since 1997 or 1998, but did not name it as a defendant until 2003. Moreover, the plaintiff had made no effort to depose Bostrom, had not arranged for any expert to review certain drawings made available by Bostrom, and had not even asked for a continuance of the summary judgment hearing, even though he claimed he needed more time to complete discovery. Accordingly, the trial court granted the defendants' motions for summary judgment.

The court of appeals found that a motion for summary judgment may be considered even before the parties have completed discovery. While parties should be given a fair opportunity to present their claim, there is no absolute right to delay summary judgment until discovery is completed. Here, the court found that Humphries had ample time to conduct discovery, and had notice as early as 1998 that he should seek discovery from Bostrom. Despite having ample time for discovery and testing, plaintiff could produce no evidence of any actual defect in the seat in order to combat the defendants' motions for summary judgment. Accordingly, the court of appeals affirmed the decision of the trial court.

Significantly, both the trial court and the court of appeals noted that Humphries' allegations of defect were insufficient to overcome defendants' summary judgment motions. Defects are not presumed from the mere occurrence of an accident. If, after a reasonable amount of time for discovery, a defendant presents a motion for summary judgment on plaintiff's products liability claim, the plaintiff must be able to combat that motion with actual evidence of an actual defect in the product.

– *Emily E. Eagan*

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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