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JUDGE RULES HUMAN FACTORS EXPERTS NO FACTOR IN FEMA TRAILER LITIGATION

***In re FEMA Trailer Formaldehyde Products Liability Litigation*, MDL No. 07-1873, 2009 WL 2169224 (E.D. La. July 15, 2009)**

In the aftermath of Hurricane Katrina, the Federal Emergency Management Agency ("FEMA") supplied trailers manufactured by various companies to hurricane victims for use as temporary housing. In 2007, individuals sued numerous trailer manufacturers, claiming that they were exposed to formaldehyde while living in the trailers. In the first upcoming bellwether trial, plaintiffs intended to use the testimony of Dr. Lila Laux, a human factors expert, regarding her evaluation of trailer warnings. The defendant, Gulf Stream Coach, Inc., ("Gulf Stream") sought to exclude the testimony of Laux, and argued, in part, that Laux's testimony would not assist jurors at trial.

On July 15, 2009, Judge Kurt D. Engelhardt of the Eastern District of Louisiana granted Gulf Stream's motion to exclude Laux's testimony. Judge Engelhardt held that Laux's proposed expert testimony would not assist the jurors at trial in understanding or determining factual issues about warnings, because the jury, using common experience and knowledge, could reach its own decision. Judge Engelhardt viewed the proposed testimony as advocacy, rather than expert testimony. Judge Engelhardt cited a description of human factor experts as "jack[s] of all trades" and "master[s] of none." In conclusion, he stated, "no party will be permitted to introduce a human factors expert; no expert will be allowed to directly instruct the jury on how it should dispose of a factual issue in this case."

—*Eric M. Liddick*

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CLAIMS AGAINST CONTRACTORS WHO INSTALLED FEMA TRAILERS SURVIVE MOTION TO DISMISS

***In re FEMA Trailer Formaldehyde Products Liability Litigation*, MDL 07-1873, 2009 WL 1683289 (E.D. La. June 15, 2009)**

In January 2009, a number of plaintiffs brought a lawsuit against various contractors that managed the hauling and installation of emergency housing trailers used in the wake of Hurricanes Katrina and Rita. The contractors moved to dismiss the suit on the grounds that not all plaintiffs' claims were matched to a specific defendant, the plaintiffs' claims had prescribed, and the plaintiffs failed to plead claims under the Louisiana Products Liability Act ("LPLA") because the contractors were not "manufacturers."

Judge Kurt D. Engelhardt of the Eastern District of Louisiana dismissed claims made by all plaintiffs whose claims were not linked to a specific contractor. Judge Engelhardt rejected the contractors' prescription argument, however, because he found that it was not evident on the face of the pleadings that the plaintiffs knew about their alleged injuries for more than a year before filing the lawsuit. Finally, Judge Engelhardt rejected the contractors' argument that as a matter of law the contractors were not "manufacturers" with the meaning of the LPLA. He reserved the question of whether the contractors were manufacturers for determination at a later time.

—*Tarak Anada*

CART MAKER NOT RESPONSIBLE FOR ELECTRICAL CORD IT DID NOT MANUFACTURE

***Crocket v. Wal-Mart Louisiana, et al.*, 2:06-cv-1019, 2009 WL 1787681 (W.D. La. 6/16/09)**

Plaintiff Nancy Crocket ("Crocket") filed suit on behalf of the estate of Francis Crocket following an accident that occurred in a store. While attempting to get out of a motorized handicap shopping cart, Francis Crocket tripped over a power cord attached to the cart and suffered injuries as a result. Crocket first sued the store, and later amended her complaint to add Assembled Products, the manufacturer of the cart. In her amendment, Crocket claimed that the accident was caused by Assembled Products' failure to properly design, manufacture, and test the cart, and by its failure to properly warn against the tripping hazard due to what she alleged was a supposedly unsafe, non-retractable electrical cord.

Assembled Products admitted that it was the manufacturer of electric carts, and sold the cart at issue to the store. The electric carts manufactured and sold by Assembled Products were charged by plugging a connected cord into a power source. The carts were manufactured with three cord options—retractable, curly, or straight. The cart at issue in this case was sold to the store with a curly cord, and, on the order form, the store rejected the retractable cord option for the cart by

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noting that "a retractable cord is not acceptable." At some point after receiving the cart, the store replaced the curly cord with a straight cord that was not provided by Assembled Products. During discovery, the plaintiff's expert, Dr. Gary Nelson, testified that in his opinion the accident would not have occurred had the original curly cord been used.

Assembled Products filed a motion for summary judgment requesting the dismissal of all claims against them, arguing that the straight cord had been substituted for the curly cord they provided, and that, according to plaintiff's expert, the accident would not have occurred if the curly cord had not been replaced. Crocket filed an opposition but did not dispute any of the facts alleged in Assembled Products' motion. The store did not oppose the manufacturer's motion.

Because Crocket alleged in her suit that the straight cord caused the accident, the court agreed that the case could not proceed against Assembled Products. Under Louisiana law, the plaintiff must prove that the damages were proximately caused by a characteristic of the product that renders it unreasonably dangerous, and that this characteristic was the most probable cause of the damages. Further, the damages must result from a reasonably anticipated use of the product. The court held that the replacement of the curly cord with a straight cord—if indeed the plaintiff could prove her allegations at all—was not a reasonably anticipated use of the product.

Next, the court turned to the failure to warn claim. The court noted that an essential element in a failure to warn claim is that there be some reasonable connection between the omission of the manufacturer and the damages suffered by a plaintiff. The court concluded that Assembled Products had no duty to warn against a danger that might have resulted from the replacement of the original cord provided, if the plaintiff could ultimately prove that the replacement caused such a danger. As such, the court granted the motion for summary judgment of Assembled Products, and dismissed it with prejudice.

Crocket's claims against the store were not at issue in this motion and the court made no ruling as to whether the store was at fault.

—*Sara C. Valentine*

CHRISTMAS TREE LIGHTS RETAILER NOT LIABLE FOR FIRE

***Maryland Cas. Co. v. Wal-Mart Stores, Inc.*, No. 05-1399, 2009 WL 1766856 (M.D. La. 6/19/09)**

Robert and Judy Southard owned a business that suffered extensive damage from a fire allegedly caused by defective Christmas tree lights purchased at Wal-Mart. The Southards filed suit against Wal-Mart in state court under the Louisiana Products Liability Act ("LPLA"), and Wal-Mart removed to the Middle District of Louisiana based on diversity jurisdiction. The Southards argued that Wal-Mart was liable under the LPLA as the manufacturer of the Christmas tree lights. Wal-Mart initially filed a motion for summary judgment on the basis that Wal-Mart was not the manufacturer of

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the lights. Magistrate Judge Docia L. Dalby denied that motion, finding that there was an issue of fact as to whether Wal-Mart labeled the lights as its own or otherwise held itself out as the manufacturer.

Wal-Mart filed a second motion for summary judgment, contending that the Southards could not prove the lights were unreasonably dangerous. The Southards, who at this point were representing themselves, failed to oppose the motion. Magistrate Dalby assumed for purposes of the motion that Wal-Mart was the manufacturer of the lights.

Magistrate Dalby considered the four ways in which a product may be unreasonably dangerous under the LPLA: composition, design, warning, or failure to conform to an express warranty. Because the Southards did not file an opposition, there was no evidence that the lights were defective in construction or composition. In fact, the Southards admitted to purchasing identical lights from Wal-Mart after the fire and could identify no differences between the lights that allegedly caused the fire and the manufacturer's specifications or performance standards, or identical lights purchased later. Likewise, the Southards stated they had no knowledge of any alternative designs, a requirement for proof of a design defect. Wal-Mart introduced evidence showing that every light set sold contained a warning about fire risks and detailed instructions about proper use of the lights. The Southards failed to show that their lights did not contain the same warning; therefore, the lights could not be unreasonably dangerous because of an inadequate warning. Lastly, the plaintiffs failed to identify any express warranty and thus could not demonstrate that the lights failed to conform to an express warranty.

Magistrate Dalby concluded that the mere occurrence of an accident is insufficient to establish that a product is defective or unreasonably dangerous under established Louisiana law. The Southards' inability to prove the lights were defective in composition, design, warning or warranty resulted in summary judgment in favor of Wal-Mart.

—*Sarah S. Brehm*

WARNING ON EMBOLI-TRAPPING MEDICAL DEVICE NOT SUBJECT TO ATTACK UNDER STATE LAW

***Bencomo v. Guidant Corp.*, No. 06-2473, 2009 WL 1951821 (E.D. La. June 30, 2009)**

Raul Bencomo filed an action against a medical device manufacturer under the Louisiana Products Liability Act ("LPLA") to recover for injuries he sustained during a carotid stent procedure. During the procedure, Bencomo's physician used ACCULINK and ACCUNET systems manufactured by Abbott Laboratories. These devices were designed to "capture emboli that might escape during the procedure and travel to other parts of the body causing stroke." Bencomo, who had considered and rejected a different procedure due to a risk of injury to his vocal cords, consented to carotid stent procedure using the Abbott devices after reviewing pertinent information in Abbott's Patient Guide, which, according to Bencomo, confirmed that the device would capture *any* emboli, *i.e.*, plaque or particles that could travel into the smaller

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vessels in the brain. Bencomo interpreted this to mean that the devices would catch *all* such plaque or particles. During Bencomo's procedure, an emboli did escape and traveled to the brain, resulting in stroke and loss of vision in one eye.

Bencomo filed suit against Abbott, alleging that the device was unreasonably dangerous because it did not conform to an express warranty in the Patient Guide regarding the ability of the devices to capture all emboli. Bencomo claimed that he relied upon this express warranty, which served as the basis for his consent to the carotid stent procedure.

Abbott filed a motion for summary judgment, asserting that Bencomo's claims were preempted by the Food, Drug and Cosmetic Act and specifically the Medical Device Amendment ("MDA") which provides the FDA the authority to regulate medical devices. Abbott argued that the devices were Class III medical devices, the most heavily regulated devices falling under the FDA's authority, meaning that Abbott presented "reasonable assurances" to the FDA that the device was safe and effective during the premarket approval process. During this extensive process, the FDA approved the language in the warnings and instructions pertaining to the devices, including the Patient Guide reviewed by Bencomo.

Bencomo opposed Abbott's motion on the basis that the Patient Guide contained warnings that were inconsistent with the Instructions for Use ("IFU") published by Abbott for physicians. According to Bencomo, this contradiction meant that the warnings in the Patient Guide were factually false. Bencomo also argued that his claim was not preempted because it was a "parallel" claim, intending to enforce the provisions of the MDA that the device was safe and effective.

Judge Carl Barbier examined Bencomo's claims in light of the MDA regulations and recent jurisprudence interpreting the MDA's preemptive scope. The MDA contains an express preemption provision that requires preemption of state laws that impose requirements different from or in addition to any requirement imposed pursuant to the MDA that relates to the safety or effectiveness of the device. Judge Barbier noted that Abbott's devices were Class III devices and subject to the most rigorous approval process set forth in the MDA, specifically the premarket approval process. Under this process, the manufacturer submits extensive information to the FDA to establish the safety and effectiveness of the device and proposes labeling and instructions regarding the indications, uses, and risks of the device. The FDA not only approves the device, but also approves the language in all informational documents to be published by the manufacturer for consumers, including physicians and patients. Under the MDA, this language cannot be changed without the express prior approval from the FDA. Judge Barbier found that the devices were approved by the FDA and that the very IFUs and Patient Guide criticized by Bencomo were submitted to and approved by the FDA during the premarket approval process.

Following a recent U.S. Supreme Court case, *Riegel v. Medtronic*, Judge Barbier found that Bencomo's claims were preempted. Under *Riegel*, a state law claim is preempted by the MDA if the FDA has established a requirement applicable to the device and state law imposes a requirement different from or in addition to federal requirements. *Riegel* held that the premarket approval process itself establishes federal requirements under the MDA. Furthermore, state common law claims for negligence and strict liability constitute state requirements. Judge Barbier also applied the reasoning of a recent Fifth Circuit Case, *Gomez v. St. Jude Medical Diag. Division, Inc.*, that described an express warranty claim under state law as a state requirement to describe the warnings or risks of a device in a particular manner. Because these state requirements are potentially inconsistent with the warnings required by the FDA, under *Gomez*, state express warranty claims are preempted by the MDA.

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Judge Barbier concluded that Bencomo's state express warranty claim was preempted by the MDA. The FDA approved the precise language contained in both the Patient Guide and the IFU. Even assuming these publications contained inconsistent statements, Judge Barbier found both the Patient Guide and the IFU to be in compliance with federal requirements. Judge Barbier also rejected Bencomo's argument that he was asserting a "parallel" claim to enforce the MDA requirements. To the contrary, Bencomo's claims that the Patient Guide warnings were untrue and contradictory to the IFU conflicted with the FDA's finding that the approved language constituted accurate representations of the device's indications for use and an appropriate statement of risks.

—*Amy M. Winters*

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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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