



GOLDBERG SEGALLA ^{LLP}

PRODUCT LIABILITY LEGAL UPDATE

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Goldberg Segalla LLP is proud to present its inaugural issue of *Product Liability Legal Update*, a monthly newsletter covering significant developments and evolving trends in product liability litigation across the country. As a Best Practices law firm we understand the importance of being ahead of the curve on cutting edge legal issues, especially in the product liability area. Through this newsletter, we hope to keep our clients and friends informed and to provide insight into the practical effect of recent decisions and legislation. Each month, we will publish two feature articles highlighting one of our signature practice areas, along with notable case summaries on topics that affect the clients we represent.

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NEWS AND UPCOMING EVENTS

Federal Preemption– Different Rules For Medical Devices and Pharmaceuticals

While many defense strategies in medical device and pharmaceutical product liability litigation overlap, in the area of federal preemption the emerging law could not be more different.

In *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), the United States Supreme Court held that state law requirements are federally preempted by the Medical Device Amendments (“MDA”) to the Federal Food, Drug and Cosmetic Act. The Court held that premarket approval of a Class III medical device by the Food and Drug Administration (“FDA”) imposed federal requirements on medical device manufacturers and federal law preempts state law action that seeks to impose requirements different from or in addition to those federal requirements. The *Riegel* decision was significant to manufacturers of medical devices that had obtained pre-market approval for those devices from the FDA since, in general, most courts have been reluctant to entertain state law claims in light of the MDA’s express preemption provision unless the plaintiff can establish that the manufacturer violated federal regulations.

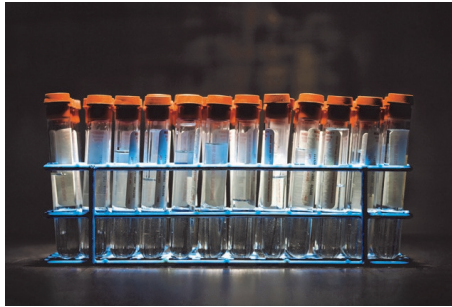
In contrast, on March 4, 2009, the United States Supreme Court decided *Wyeth v. Levine*, 129 S.Ct. 1187 (2009), which limited federal preemption in pharmaceutical cases. In *Levine*, the Court held that state law claims against pharmaceutical companies alleging personal injuries from use of a drug or a failure-to-warn about the drug’s potential side effects are not preempted even if the drug has been approved by the FDA. The Court noted that plaintiff’s claims involved the 1938 Federal Food, Drug and Cosmetic Act (FDCA), which did not have an express preemption provision, as did the MDA in *Riegel*.

Since the decisions in *Riegel* and *Wyeth* it is clear that a defendant/manufacture in cases involving Class III medical devices that obtained pre-market approval will likely be successful on a motion to dismiss on the basis of federal preemption, while the same motion in cases involving a pharmaceutical will be denied. The following summaries of recent cases involving both medical device and pharmaceuticals demonstrate that the doctrine of federal preemption provides much more shelter to the manufacturers of medical devices than to prescription drug manufacturers.

MEDICAL DEVICE CASES

***Illaraza v. Medtronic, Inc.*, 677 F. Supp.2d 582 (E.D.N.Y. 2009)**

Plaintiff underwent surgery to implant a medication pump manufactured by Med-



tronic, Inc. in February 2003. In 2008, a CT scan showed that the plaintiff’s issues were a result of a break in the pump’s catheter that allegedly occurred in July 2008. Plaintiff’s amended complaint alleged only one cause of action, “Negligence Per Se (A Parallel Action).” The Complaint alleged that the defendant failed to manufacture the pump in a reasonable and prudent manner in accordance with federal regulations. Defendant brought a motion to dismiss on the basis that the Complaint failed to state a cause of action and on the basis of federal preemption. The Court held that Plaintiff failed to raise a parallel claim since none of the federal regulations relied upon referred specifically to the device at issue, but noted that a plaintiff could maintain a cause of action if it was alleged that a particular federal specification that referred to the device at issue had been violated.

NINTH CIRCUIT COURT OF APPEALS

***Carson v. Depuy Spine, Inc.*, 365 Fed. Appx. 812 (9th Cir. 2008)**

The Ninth Circuit Court of Appeals affirmed summary judgment in favor of the defendant, the manufacturer of a Charite Artificial Disk. The Court held that the plaintiff had failed to create a genuine issue regarding violation of federal law and causation. Plaintiff had claimed, in part, that the device was negligently manufactured. The Court held that plaintiff failed to controvert the defendant’s expert testimony that the disk did not have any visible problems when implanted and that plaintiff had failed to identify any federal standard that the defendant had violated. The Court also noted that the FDCA expressly protected off-label use of medical devices by health care practitioners and that manufacturers are not liable merely for the sale of a device with knowledge that the prescribing doctor may intend an off-label use. However, the Court also noted that while a doctor may use a drug or device off-label, marketing or promoting the device or drug for an unapproved use would violate section 331 of the FDCA.

***Williams v. Cyberonics, Inc.*, 2010 U.S. App.**

LEXIS 16060 (3rd Cir. 2010)

The Third Circuit Court of Appeals affirmed summary judgment in favor of the defendant on the basis of federal preemption. The case involved the alleged malfunction of the Cyberonics Vagus Nerve Stimulation (VNS) Therapy System, a medical device that treats depression by electronically stimulating a nerve in the neck. The VNS is a Class III medical device that was given pre-market approval by the FDA. The Court held that plaintiff’s manufacturing defense and breach of warranty claims were preempted by the MDA. It also held that plaintiff’s strict products liability claim based upon a malfunction theory was preempted because plaintiff failed to show how the device deviated from the FDA requirements.

PHARMACEUTICAL CASES

***Wimbush v. Wyeth*, 2010 U.S. App. Lexis 17184 (6th Cir. 2010)**

The Sixth Circuit Court of Appeals reversed a trial court decision that had granted summary judgment to the defendants, manufacturers and sellers of a diet pill, Redux. Plaintiff claimed that Redux had allegedly caused her primary pulmonary hypertension (“PPH”) and subsequent death. Wyeth marketed and sold Redux after its approval by the FDA in 1996 and subsequently sent warning letters to physicians regarding the risk of PPH. The district court had granted Wyeth’s motions for summary judgment on the basis that the plaintiff’s strict products liability claim and negligence claims were preempted by the FDA’s approval of Redux and all other claims that were not preempted by their merits. The Sixth Circuit cited *Wyeth v. Levine* and noted that the FDCA did not contain an express preemption provision for drugs as the MDA did for medical devices in *Riegel v. Medtronics*. Accordingly, the Court reversed the district court’s decision and held that FDA approval does not automatically preempt state law tort claims for negligence.

***Demahy v. Actavis, Inc.*, 593 F.3d 428 (5th Cir. 2010)**

The Fifth Circuit Court of Appeals affirmed the denial of the defendant’s motion to dismiss the plaintiff’s failure-to-warn claims on conflict preemption grounds. Plaintiff claimed that he sustained personal injuries due to the defendant’s failure-to-warn of the risks of neurological disorders after long term use of metoclopramide. The sole issue on appeal was whether the federal regulations governing pharmaceuticals preempted state law failure-to-warn claims

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The Learned Intermediary Doctrine– What Is It and How Does It Apply?

I. What is the Learned Intermediary Doctrine?

Cutting out the “middle man” is a good idea in many areas of business. The reasons are varied: costs are lowered; direct contact between the seller and the buyer is established; greater profit margin is possible. However, when litigating a failure to warn claim in the realm of medical products liability litigation, the “middle man,” a clinician who recommends the subject device or prescribes the subject medication, is a valued asset, as the presence of such an individual makes available the defense of the “learned intermediary.”

Pharmaceutical and medical device manufacturers are required by the FDA to provide instructions with an approved drug or medical device regarding use, and information relating to identified risks, complications or warnings. These instructions and warnings are not intended educate the patient, but rather to provide relevant information about the drug or medical device to the clinician who ultimately will prescribe the drug or device for a patient. Because the treating clinician is in the best position to evaluate a patient’s medical condition, provide diagnoses and prescribe treatments, it follows that the clinician is also in the best position to convey the benefits, risks and complications of a specific therapy to the patient. In so doing, the clinician assumes the role of the “learned intermediary,” educating the patient about the benefits, risks and complications associated with a particular therapy, including drugs and/or medical devices.

Thus, the Learned Intermediary Doctrine is a valuable defense to pharmaceutical and medical device manufacturers involved in products liability actions.

II. What Exceptions Exist to the Learned Intermediary Doctrine?

To date, there are three recognized exceptions to the Learned Intermediary Doctrine defense: Direct to Consumer Advertising; Overpromotion and Mass Immunization.

Seen with the least frequency is the Mass Immunization Exception, in large part because there has been no national push to immunize individuals against a specific ailment. In *Davis v. Wyeth Laboratories* (399 F.2d 121 (9th Cir.Idaho; Jan 22, 1968) the plaintiff developed Polio after receiving an immunization to protect against contracting this disease. Because the plaintiff did not consult with a physician before receiving the

immunization, nor did a physician administer the immunization, the court concluded that the Learned Intermediary Doctrine did not apply.

III. Direct to Consumer Advertising

More and more, medical product companies are marketing their products directly to consumers via the available media outlets (e.g., television, publications, internet, tweets and blogs). Some courts have held in the DTC context that manufacturers may have duty to provide adequate warnings to users even when a physician prescribes the medication at issue. See, e.g., *Perez v Wyeth Laboratories, Inc.*, 161 N.J. 1, 734 A2d 1245 (1999). In *Perez*, the plaintiff sued for injuries sustained as a result of an implanted contraceptive device (Norplant). Because plaintiff acquired information about Norplant from reading materials in addition to learning about the device from her physician, the Court held that the drug company was not protected by the learned intermediary doctrine.

Until recently, New Jersey stood alone on DTC and learned intermediary. In *Centocor, Inc. v Hamilton* (No. 13-07-00301-CV, 2010 WL 744212, March 2010), however, plaintiff received a prescription to treat Crohn’s disease, and was advised by the treating physician that lupus-like symptoms might arise from ingestion of the drug. Because no such warning was contained in the manufacturer’s video shown to the plaintiff, the Texas Court of Appeals held that the DTC exception trumped the Learned Intermediary Doctrine, thus shifting liability from the treating physician to the drug company.

IV. Overpromotion

Some plaintiff’s lawyers argue that the marketing methods of a drug company effectively obviate the warnings provided in conjunction with a prescribed drug. In *Stevens v. Parke, Davis & Company*, 9 Cal.3d 51, 65, 107 Cal.Rptr. 45, 53, 507 P.2d 653, 661 (1973) the court concluded that a manufacturer or supplier of a prescription drug has a duty to adequately warn the medical profession of its dangerous properties, and that adequate warning(s) to the profession may be “eroded or even nullified by over promotion of the drug through a vigorous sales program which may have the effect of persuading the prescribing doctor to disregard the warnings given.” In *Nobles v. Astrazeneca Pharmaceuticals* (48 Conn.Supp. 134, 832 A.2d 1241, 1242-1243 (Conn.Super. 2003), the court held that there was a triable issue of fact as to whether the manufacturing company over



promoted the prescription nasal spray that allegedly caused plaintiff’s injuries.

Recently, the Second Circuit Court of Appeals in *Dean v. Eli Lilly & Co.*, 2010 U.S. App. LEXIS 14581 (2d Cir. 2010) was not persuaded by plaintiff’s argument that Overpromotion trumped the Learned Intermediary Doctrine. Although evidence showed that a vigorous campaign to sell Zyprexa was undertaken by Eli Lilly, there was no evidence to substantiate that the physician who prescribed the medication to plaintiff disregarded the warnings that accompanied the medication.

V. Recent Decision Involving the Learned Intermediary Doctrine

Applying Florida law, the Second Circuit Court of Appeals recently upheld summary judgment for a pharmaceutical company based on the learned intermediary defense. In *Dean v. Eli Lilly & Co.*, the plaintiff received a prescription for Zyprexa, an anti-psychotic medication manufactured by Eli Lilly. Dean took Zyprexa in 1998, and again between June 2002 and October 2006, until he was diagnosed with diabetes. Commencing an action against Eli Lilly, Dean claimed that Zyprexa caused his diabetes. Also, he claimed that had he been properly warned of this potential complication, he would not have taken the medication. [*Dean v. Eli Lilly*, 09-3723; 2nd Cir. 2010]

Under Florida law, to succeed on a failure to warn claim, plaintiff must establish that the defendant failed to provide an adequate warning of the inherent dangers of the product (*Zanzuri & G.D. Searle & Co.*, 748 F. Supp 1511, 1514 (S.D. Fla. 1990), and that such omission was the cause of his injury (*Christopher v. Cutter Labs*, 53 F.3d 1184,

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The Learned Intermediary Doctrine cont.

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1191 (11 Cir. 1995). In *Dean*, defendant Eli Lilly introduced the testimony of the physician who prescribed Zyprexa to the plaintiff in 2002 who testified that he was aware of the link between Zyprexa and diabetes, and that nothing he learned after 2002 prompted him to change his decision about prescribing this drug to Dean.

The Second Circuit found this testimony sufficient to establish that Dr. Rousseau understood the warnings associated with the use of Zyprexa before prescribing the

drug to his patient. (See *Beale v. Biomet*, 492 F.Supp.2d at 1371, (“clinician had actual knowledge of the substance of the alleged warning and would have taken the same course of action even with the information the plaintiff contends should have been provided.”))

The Court was not persuaded by plaintiff’s agreement that Lilly overpromoted Zyprexa. Evidence establishing that Lilly salespeople undertook a vigorous sales campaign for Zyprexa was introduced, but there was no evidence to support that Eli Lilly’s employees misled Dr. Rousseau about the link

between Zyprexa and diabetes, or that they induced Dr. Rousseau to prescribe this drug to Dean.

Dean v. Eli Lilly & Co. highlights the value of the Learned Intermediary Doctrine to pharmaceutical and medical device manufacturers. It also serves as a reminder of the balance that must be struck between the substance of written information disclosed with a product and the verbal information conveyed by marketing personnel.

CASE SUMMARIES

ASBESTOS LITIGATION

Texas High Court Holds Successor Statute Unconstitutional As Applied to Pending Cases

John Robinson died from mesothelioma as a result of his occupational exposure to asbestos. Plaintiff claimed that Crown Cork & Seal Company Inc. was liable for Mr. Robinson’s death because during Mr. Robinson’s service in the United States Navy from 1956 until 1976, he worked with asbestos insulation manufactured by Mundet Cork Corporation. Crown Cork & Seal purchased Mundet Cork in 1966, when the company had a dormant asbestos insulation division, which Crown Cork & Seal Company Inc. sold three months later.

Either New York or Pennsylvania law applied to the case and under either, Crown Cork & Seal would be liable as a successor. The Texas Legislature enacted a statute, however, the sole beneficiary of which was Crown Cork & Seal Company, limiting the liability of corporations that became successors prior to May 13, 1968. Defendant argued that choice of law rules are procedural and subject to change, the Legislature’s intent in enacting the statute was to extinguish all plaintiffs’ claims, including Mrs. Robinson’s, against Crown Cork & Seal in Texas.

The court held that an interest in main-

taining an established common-law cause of action is greater than an interest in choice of law rules. It found that plaintiff’s right to assert her claim for damages relating to Mr. Robinson’s mesothelioma, “a uniquely asbestos-related disease,” was real, important, and firmly vested.

The court held that this statute, as applied to pending cases, violated the Texas Constitution’s prohibition on retroactive laws. It rejected defendant’s argument that plaintiff could not have expected Mundet Cork Corp. to merge with a larger corporation with deeper pockets. The court held that these were not the expectations that the rule against retroactive application was meant to protect. Plaintiff could well have expected that a rule of law that permitted their recovery, and many others’ before them, would not be changed after they filed suit. The court would not speculate about what additional recovery plaintiff would be entitled to under joint and several liability. The statute’s shielding of an otherwise liable defendant either would reduce the recovery plaintiff could expect to receive or force other defendants to pay the shielded defendant’s share. In either circumstance,

the court held that the statute disturbs settled expectations.

The court considered whether the statute served the public interest. In this regard, the court noted that, even though the Texas Legislature acknowledged the severity of the asbestos litigation crisis, the statute was enacted solely to help Crown Cork & Seal. Defendant did not justify the statute by how many asbestos lawsuits it faced or by pointing to another company it would shield. The court held that although Texas would benefit from defendant’s reduced liability, nothing suggested the public interest rose to the level required to permit retroactive application of the statute, and other states’ perception of the public interest served by such retroactive legislation was at best ambiguous.

Accordingly, the court reversed summary judgment in favor of Crown Cork & Seal and remanded the case to the lower court for further proceedings

Robinson v. Crown Cork & Seal Company Inc. (Tex. October 22, 2010).

Mississippi High Court Addresses Widow's Standing and Statute of Limitations

Lonnie Pittman died nearly two years before an asbestos lawsuit was filed, listing him as a plaintiff. Later, Mr. Pittman's widow, Mary Pittman, attempted to substitute herself as a plaintiff.

In August 2004, several defendants moved to dismiss or sever Mr. Pittman's claim. His claim was severed, and in August 2005 plaintiff's widow filed an amended complaint as the executrix of Mr. Pittman's estate. The court granted the motion to substitute and defendants answered, asserting a statute of limitations defense. Several defendants moved to dismiss, arguing that the widow's substitution was improper. Defendants' motion was denied. Defendants then moved to dismiss on the basis that the court lacked subject matter jurisdiction and that plaintiff was not the duly appointed executrix for Mr. Pittman. The court denied these motions, and defendants appealed.

The Mississippi Supreme Court held that the lawsuit was null and void because Mr. Pittman died nearly two years before his

action was filed. The court noted that "a dead person cannot institute a suit." Additionally, the court held that the Mississippi Rules of Civil Procedure governing substitution presuppose a valid action. The rules governing substitution require that a suit legally exists. Because the Pittman action could never actually have existed, there was no action in which Mr. Pittman's widow could be substituted as plaintiff.

The court held, however, that Mr. Pittman's widow's status as a listed relative under Mississippi's wrongful death law overcame defendants' argument that Mrs. Pittman lacked standing to file her amended complaint because she was not the executrix of Mr. Pittman's estate at that time. The court held that any survival action was subsumed into one for wrongful death under Mississippi law once Mr. Pittman died. "Consequently, the wrongful-death statute conferred on Mary standing to bring the 2005 amended complaint regardless of whether she had been formally appointed as executrix of Lonnie's estate when the 2005 amended complaint was filed." Ac-

cordingly, the court held that defendants' argument relating to plaintiff's standing lacked merit.

With respect to defendants' statute of limitations defense, the court held that, because the three-year statute of limitations began to run at the time of Mr. Pittman's death on March 11, 2001, plaintiff's 2005 claim was untimely unless the defendants waived the issue by not raising it sooner. The court noted that defendants raised the defenses at various times and that each waited nearly two years or more to pursue the defense. The court held that a two-year delay generally does not constitute waiver of an issue. Additionally, during the delay, little action was taken in the case and what little action was taken did not constitute waiver.

Accordingly, the court reversed the lower court's decision and granted summary judgment to defendants.

Garlock Sealing Technologies v. Pittman
(Miss. October 14, 2010).

AUTOMOTIVE LITIGATION

Evidence of Prior Complaints: Louisiana Appellate Court Upholds Jury Verdict in Unintended Powered Reverse Motion Case

The Fourth Circuit Court of Appeals in Louisiana upheld a jury verdict that awarded \$5.4 million to a couple who lost their prematurely born son and sustained injuries after their 1999 Jeep Grand Cherokee unintentionally shifted into reverse. The Court also found that the testimony of plaintiffs' experts and evidence regarding similar incidents were properly admitted at trial.

One of plaintiff's experts, despite not being an engineer, had been qualified as an expert with respect to the transmission at issue on over 120 occasions, and his methodology was similar to that used by the NHTSA. The court found that the expert established that prior incidents introduced at trial were substantially similar because the transmission in the prior incidents was identical to the one at issue despite the

prior fact that accidents involved different models or model years. Notably, the court rejected defendant's argument that this expert had intentionally situated the gear shift selector in such a way as to reproduce the unintended power reverse problem during his tests, citing the expert's testimony that attempting to produce the result would have taken him several days.

Further the appellate court found that the trial court properly permitted plaintiff's other expert to testify about 22 customer park-to-reverse complaints (out of 200 received) where Chrysler investigators were able to successfully achieve the unintended power reverse problem. It also found that Chrysler's denial letters in response to the complaints were properly admitted. The court felt that the denial letters were rele-

vant to the defense theory that the plaintiff-husband-driver was at fault.

IMPACT: This case is interesting in that the court not only upheld the trial court's decision to admit the 22 complaints and denials into evidence, but felt that, even if the complaints were hearsay, to admit them it would not have been reversible error because there was ample other evidence on which the jury could have based its findings. Thus, this decision can be interpreted to mean that a manufacturer's investigative findings may be presented at trial without proper evidentiary foundation if a plaintiff can independently establish a design defect.

South Carolina Supreme Court Reverses \$18 Million Trial Verdict in Unintended Acceleration Case

In *Watson v. Ford Motor Co.*, plaintiff claimed that after she set the cruise control in her 1999 Ford Explorer, the vehicle began to suddenly accelerate. Plaintiff lost control of her vehicle, which veered off the road and rolled over several times leaving plaintiff a quadriplegic and a passenger dead. Plaintiff's theory was that the Explorer's cruise control system was defective because it allowed electromagnetic radiation to interfere with it. The jury awarded \$15 million to the plaintiff driver and \$3 million to the decedent's estate.

The South Carolina Supreme Court found that the trial court had erroneously qualified two of plaintiff's witnesses as experts. One expert, an automotive consultant and soft-

ware developer, had no professional experience working on cruise control systems and had never taught or published papers on cruise control systems. The other expert, an electrical engineer from Britain, testified that Ford should have used an alternative design in the Explorer's cruise control system. However, the second expert had no experience in the automobile industry, never studied a cruise control system and offered no evidence to support his conclusion about his alternative design theory.

Additionally, plaintiff failed to show that the prior incidents presented at trial were substantially similar. Most of the Explorers in the prior incidents were made in different years and were different models with

driver's seats on the right side of the vehicle.

Finding that the evidence submitted at trial was insufficient to support the verdict, the court granted Ford judgment as a matter of law.

IMPACT: The South Carolina Supreme Court decision is consistent with other decisions that hold an expert must be properly qualified and that prior incidents must be substantially similar to support a theory for alternative design.

Engine Fire Caused By Faulty Wiring Not Proof of Manufacturing Defect At Time of Sale

Plaintiff, the owner of a seven year old BMW 528i, sued defendant BMW alleging theories of strict products liability as a result of a fire which originated in the engine compartment of the subject vehicle while parked in plaintiff's garage. The fire destroyed the BMW and adjacent minivan, as well as caused structural damage to plaintiff's home.

Plaintiff's expert fire investigator testified that the likely cause of the fire was faulty wiring. Defendant BMW moved to preclude the expert from testifying as to causation of the fire as speculative and beyond his area of expertise.

The court explained that, to present a *prima facie* claim of strict liability in the manufacturer and/or sale of the product, the plaintiff must prove three elements: 1) the injury resulted from a condition of the product; 2) the condition was an unreasonably dangerous one; and 3) the condition existed at the time the product left the defendant's control. The court further explained that "proving the existence of a manufacturing defect while under the control of the manufacturer is particularly difficult where the product has been used for a substantial period of time," highlighting that the BMW was seven years old at the time of the fire with over 53,000 miles on the odometer and with a significant service history. The court concluded that "although plaintiffs have shown the origin of the fire was in the BMW, they have failed to demon-

strate a factual basis to support a reasonable inference that the cause of the fire existed when the BMW left the possession or control of the defendant seven years earlier."

This matter highlights the court's refusal to infer the necessary elements of a strict product liability claim where the defense is able to successfully attack plaintiff's expert in accordance with *Daubert v. Merrell Dow Pharmaceuticals, Inc.* Daubert requires a showing that: 1) the testimony is based upon sufficient facts or data; 2) the testimony is based on reliable principles and methods; and 3) the witness has applied the principles and methods reliably to the facts of the case. As it relates to a product liability claim, particularly one involving the cause and origin of fire, courts will pay particularly close attention to number 3, questioning whether "the witness has applied the principles and methods reliably to the facts of the case." In *Dorn*, the court found that by plaintiff's expert's own admission he was not capable of determining the precise cause of the fire due to the limits of his particular area of expertise and the nature and extent of the damage caused by fire. As a result, the court was unwilling to find a factual basis to support a reasonable inference that the cause of the fire existed when it left BMW's possession.

Thus, the case supports the principle that plaintiff must be able to show that an al-

leged defect existed when the product left the manufacturer.



CATASTROPHIC INJURY

Comparative Fault: Pennsylvania Appellate Court Reverses Defendant's Verdict in Severe Burn Product Liability Case

The plaintiff alleged he suffered severe burns and scarring while cleaning a product designed by the defendant. He filed a product liability claim sounding in theories of design defect and failure to warn. The jury applied New Jersey law and determined the product was not designed defectively. On appeal the plaintiff alleged: 1) the trial court improperly instructed the jury on the principles of contributory and comparative negligence and assumption of risk and, 2) the trial court failed to instruct the jury not to consider his use of the product when determining whether the product was defective under the risk-utility analysis.

The appellate court found that the trial

court improperly instructed the jury on the doctrines of contributory and comparative negligence in addition to assumption of the risk. Under New Jersey law, these principles do not apply in a strict product liability action where a plaintiff is injured by a defective product while performing a job assignment at his or her workplace. An employee engaged in his assigned task at a factory or plant has no "meaningful choice" and may unreasonably encounter a known risk.

However, the appellate court did agree that the trial court erred in failing to limit the jury's consideration of plaintiff's conduct in determining whether the product was designed defectively. The appellate court em-

phasized that a plaintiff's conduct may be considered relevant to the issue of causation. However, a limited instruction must be given, which indicates the focus is on an "average user," and not the particular plaintiff. Without this limiting instruction, a jury may find the product, although designed improperly, is not defective because the plaintiff could have avoided the danger through the exercise of due care. Thus, the trial court's abuse of discretion was found to be prejudicial and the case was remanded for a new trial.

Sterling Lewis v. CRC Industries, Inc., 2010 Pa.Super. 179 (September 27, 2010).

FIRE LITIGATION

Summary Judgment: Res Ipsa Loquitur and Circumstantial Evidence of Manufacturing Defect Permitted

Plaintiff, as subrogee of its insured, sued defendant under the Louisiana Product Liability Act ("LPLA") for damages sustained by the subrogor as a result of a fire which allegedly originated from a stove manufactured by the defendant.

Defendant moved for summary judgment arguing that, *inter alia*, plaintiff presented insufficient evidence to succeed in its manufacturing defect claim. Under the LPLA, in order to prove manufacturing defect, plaintiff must show that at the time the product left the manufacturer's control, the product deviated in a material way from the manufacturer's specifications or performance standards for the product. Defendant argued that plaintiff offered no evidence of the specifications or performance standards for the stove, and because, the evidence was destroyed in the fire, plaintiff could not show how the stove or its wiring deviated in a material way from these specifications or standards. Plaintiff countered that the doctrine of *res ipsa loquitur* can be applied to provide the evidentiary foundation for a

permissive inference of liability sufficient to survive summary judgment.

The court ruled that plaintiff is indeed permitted to prove a product defect using circumstantial evidence, and that the doctrine of *res ipsa loquitur* could be used in product liability matters to shift the burden of proof back to the defendant. The court added that *res ipsa loquitur* is especially applicable in matters where, as here, the product was purchased directly from the manufacturer with no evidence of any third-party involvement, and there is no evidence of product misuse by the plaintiff. Taking into consideration that the parties' experts determined that the fire originated from the stove, that the stove was off at the time of the fire, and that defendant had previously issued a recall for the same model stove due to faulty circuits, the court determined that plaintiff had presented sufficient circumstantial evidence to invoke *res ipsa loquitur*, shifting the burden back to defendant to prove that the stove was not defectively manufactured when it left defendant's

control. As such, the court held that plaintiff's manufacturing defect claim would survive summary judgment.

IMPACT: Under Louisiana law, circumstantial evidence may be employed to infer manufacturing defect in circumstances where, as is common in fire-related accidents, physical evidence is unavailable. Depending on the facts of the case, the doctrine of *res ipsa loquitur* can be used to shift the burden back to the product manufacturer to prove that the product did not leave its control in a defective state. The court made clear, however, that the doctrine of *res ipsa loquitur* will not be applied in matters where the facts dictate the consideration of an inference of negligence by the plaintiff or a third-party.

Louisiana Citizens Property Insurance Co. v. General Electric Co., 2010 U.S. Dist. Lexis 38348 (M.D. La. April 19, 2010).

Summary Judgment/Punitive Damages Factors

Plaintiffs sued under strict liability, negligence, and failure to warn against an electric blanket manufacturer for injuries sustained as a result of a fire allegedly caused by a faulty circuit in the blanket. Defendant moved for partial summary judgment seeking, *inter alia*, a ruling that plaintiffs were not entitled to punitive damages.

Under Missouri law, factors relevant to the consideration of punitive damages include the frequency of prior similar accidents (sufficient to call a defendant's attention to a dangerous condition and lead to further precautions) and whether the product manufacturer knowingly violated any statute, regulation or industry standard. Conversely, the court noted that evidence of compliance with statute, regulations or industry standards is not, by itself, dispositive in eliminating the prospect of a punitive damages award. In considering previous

similar accidents, the court will not only consider accidents involving the identical product model, but also accidents involving other models containing a substantially similar design. In the instant matter, plaintiff sought to introduce evidence of failures in blankets containing Circuit 104 (present in the subject blanket) as well as evidence of failures in blankets containing Circuit 100, which plaintiff contended was substantially similar to Circuit 104. Defendant argued that the two circuits were not substantially similar and, as such, any instances of failure in blankets containing Circuit 100 did not provide notice for taking further precautions with regard to blankets containing Circuit 104. Because a question of fact existed as to whether Circuit 100 and Circuit 104 products were substantially similar, the court denied defendant's summary judgment motion on the issue of punitive damages.

IMPACT: While evidence of a product manufacturer's compliance with applicable statutes, regulations and industry standard will be considered in making punitive damages determinations, the more heavily weighted factor seems to be prior instances of failure in substantially similar products. In addition to expert opinion as to whether two designs are substantially similar, another indication of design similarity employed the court for purposes of punitive damages consideration includes the determination of whether failures in one model will sufficiently call a manufacturer's attention to potential problems in another model, thus warranting precautions.

Kay v. Sunbeam Products, Inc., 2010 U.S. Dist. Lexis 52209 (W.D. Mo. May 27, 2010).

MEDICAL DEVICE AND PHARMACEUTICAL LITIGATION

Pain Pump Manufacturer Obtains Dismissal For Lack of Specific Causation Judgment Granted to Medical Device Company

An important recent decision, the 11th Circuit affirmed the dismissal of a products liability and negligence case against the manufacturer of a pain pump that plaintiff claimed caused permanent damage to his shoulder. At issue was whether the pain pump, used to control pain before and after surgery through administration of an anesthetic, caused a condition known as glenohumeral chondrolysis, a breakdown of cartilage. The plaintiff proffered only one expert witness to argue general and specific causation.

Plaintiff's expert relied on the medical literature and differential diagnoses to formulate his opinion. The literature, lacking any epidemiological studies, consisted of five main articles, none of which offered a mechanism by which the damage might be caused or an ultimate conclusion on general causation. One article that reviewed a small number of pain pump patients was flawed by its failure to include statistical analysis, to explain cases without the condition, to

offer alternative causes, and to make a conclusion on general causation. The Court found another case report with two subjects flawed for similarly not including any statistical analysis and not drawing any medically valid conclusions. An animal study was dismissed as the authors specifically did not extrapolate their findings to humans, and plaintiff's expert could not explain the possible differences between dose-responses in humans versus rabbits. Additionally, neither the articles nor the expert took into account the background risk for the condition without exposure to the product or anesthetic.

As to specific causation, the Court found that the expert's reliance on the temporal relationship between the use of the product and injury was inherently unreliable. Additionally, the expert failed to consider and eliminate a comprehensive list of differential diagnoses, and could not explain away idiopathic causes. The Court affirmed the lower court's finding that the method used by the expert to formulate his opinion was

unreliable and his testimony was inadmissible.

Practical lessons:

1. Case reports by themselves are the weakest form of evidence, and although they may provide a hypothesis, do not establish causation. Product manufacturers, however, should pay close attention to the medical literature and monitor the science in order to be prepared for potential litigation issues.
2. The review of an expert's testimony in federal court is rigorous. Manufacturers should expect their counsel to extensively prepare their own experts to deal with this difficult challenge. An expert cannot be fully prepared without the proper time, research, testing and other preparation necessary to pass muster. There are no shortcuts when it comes to preparation.

Kilpatrick V. Breg, 11th Cir. Ct. App., August 12, 2010.

New Jersey Supreme Court Reverses Diet Supplement Class Action

In *Lee v. Carter-Reed Co., L.L.C.*, 203 N.J. 496 (2010), plaintiffs brought a class action for economic damages for *inter alia* fraudulent mass-marketing in violation of the New Jersey Consumer Fraud Act (“CFA”). The putative class consisted of consumers who purchased Relacore, an herbal dietary supplement. Defendant had marketed Relacore primarily as a weight-reduction product with the additional benefits of lessening anxiety and elevating mood. Allegedly, Relacore is not effective for weight loss, and after using the product as directed for approximately four months, plaintiff actually gained weight. Plaintiff moved for class certification alleging that Relacore was marketed in a deceptive manner, and that there is no evidence that Relacore provides any weight-loss benefits. The trial court denied plaintiff’s motion for class certification on the grounds that prosecution of thousands of claims was dependent on many individualized factors including whether the advertising was seen by individual plaintiffs, whether they bought the product for purposes other than weight loss, and whether they received any benefit from the product. Such individualized issues made the putative class unmanageable. The Appellate Division affirmed, but for different reasons, finding that the individual issues of fact and law predominated over common issues.

The New Jersey Supreme Court unanimously reversed the appellate court and determined that it was an abuse of discre-

tion for the lower courts to deny class certification. It found that neither the trial court nor the Appellate Division accepted as true plaintiff’s allegations that *all* of Relacore’s advertisements were false, thus the individualized issues of causation were based on a distorted view of the facts.

Goldberg Segalla LLP, on behalf of Product Liability Advisory Council, Inc. (“PLAC”), appeared as *amicus curiae* and pointed out to the Court that defendant offered a full money-back guarantee and provided refunds to all dissatisfied consumers who asked for a refund. PLAC urged the court to find that a class-action lawsuit is not the superior method of resolving the dispute. Rather, the superior method of resolution would be for the consumer to request and receive a refund. Further, under the CFA, a plaintiff must prove he/she has suffered an “ascertainable loss” that is a loss that is not hypothetical or illusory. Had plaintiff merely requested the refund freely available to her, she would have been made whole and would not have sustained an ascertainable loss under the CFA.

PLAC argued that allowing lawsuits to proceed where refunds are readily available is not in the public interest because it undermines the efficacy of warranties and discourages companies from offering money-back guarantees. In urging the court to adopt this position, PLAC asked that the Court narrowly construe its earlier decision

in *Bosland v. Warnock Dodge, Inc.*, 197 N.J. 543 (2009), which held that a consumer need not first request a refund as a precondition to filing suit. PLAC distinguished *Bosland* based on the fact that it involved “hidden fees” tacked onto an automobile purchase agreement, while the Relacore refund offer appeared in the company’s advertising and was freely and obviously available to any dissatisfied consumer. The Court rejected this argument and held that requiring a consumer to demand a refund before filing suit would provide a “safe harbor for an offending merchant” which would be at odds with the purposes of the CFA. The Court noted that it did not believe that the CFA was intended to provide relief only to consumers who are alert enough to ask for a refund. Therefore, it had “little difficulty” in concluding that a class action is the superior means of vindicating the rights of consumers who claim to have been wronged.

IMPACT: By holding that the trial court must accept all allegations in the complaint as true when electing the class certifications issue, the Supreme Court virtually guarantees certification of any class when the plaintiff pleads that the product has no benefit. Prior class action law concerning “rigorous analysis” of the plaintiff’s allegations appears to be in jeopardy.

MULTIDISTRICT LITIGATION

MDL Established for iPhone Litigation

Following the June 26, 2010, release of the iPhone 4, it did not take long for consumers across the country to sue Apple and AT&T for alleged problems with signal degradation and data unavailability. At least fourteen actions were begun in California, Texas, Massachusetts, Maryland and Tennessee. In October 2010, the Judicial Panel on Multidistrict Litigation considered an application to consolidate these actions into an MDL to be venued in the Northern District of California. Pursuant to 28 U.S.C. § 1407, when the actions involve “one or more common questions of fact” the JPML may consolidate these proceedings “upon its determination that transfers for such

proceedings will be for the convenience of parties and witnesses and will promote the just and efficient conduct of such action.” Here, the JPML noted “the actions share allegations that Apple’s iPhone 4 experiences signal degradation during normal use, which causes connectivity problems and results in dropped calls and data unavailability. Plaintiffs also allege that Apple and AT&T Mobility made misrepresentations regarding the performance of the iPhone 4.” In terms of venue selection, the JPML stated: “The Northern District of California stands out as an appropriate transferee forum. The headquarters, witnesses and documents of the common defendant, Ap-

ple, are located within the Northern District of California, and over two-thirds of the pending actions are already in this district before a single judge.”

In Re: Apple iPhone 4 Products Liability Litigation, 2010 U.S. Dist. LEXIS 108627 (J.P.M.L. October 8, 2010).



MDL Court Dismisses Failure to Warn Claim Under Learned Intermediary Doctrine

The United States District Court for the Eastern District of New York has been overseeing “a massive and highly complex multi-district litigation” involving Zyprexa, a drug used to treat symptoms for psychotic conditions such as schizophrenia and bipolar disorder. Over 30,000 cases have been brought against Eli Lilly & Company alleging that Zyprexa caused deleterious side effects of excessive weight gain, hyperglycemia, and diabetes. In its latest decision, the MDL

Court, applying North Carolina law, ruled that the learned intermediary doctrine bars claims by plaintiffs whose treating physicians were made aware of the product’s warnings before prescribing it. In North Carolina, “[a] pharmaceutical company’s duty to warn runs to the prescribing physician rather than to the patient taking a prescription drug.” In this case, the plaintiff’s treating physician received a “Dear Doctor” letter concerning the metabolic risks and

had been aware of the diabetes-related risks of Zyprexa. The Court concluded: “Because the treating physician had received full disclosure of Zyprexa’s risks prior to prescribing the drug to plaintiff, her failure-to-warn claim must fail.”

In Re: Zyprexa Products Liability Litigation, 2010 U.S. Dist. LEXIS 109520 (E.D.N.Y. October 14, 2010).

Bellwether Trial Expert Precluded Under Daubert Based on Lack of Specific Causation

As the parties prepared for trial in the first bellwether trial in the Fosamax MDL litigation, the district court dealt a blow to the plaintiff’s claims by precluding her specific causation expert. The focus of this MDL is the drug alendronate sodium sold by Merck & Co., Inc. under the brand name Fosamax. Fosamax is used for treatment of osteoporosis. Plaintiff’s claim is that Merck should have warned about the link between the extended use of Fosamax and the development of osteonecrosis of the jaw, a destructive bone disease. In this particular case, a 66-year old woman began taking Fosamax for treatment of severe rheumatoid arthritis. She claimed that Fosamax

suppressed her immune system and inhibited the ability of her bones to heal. When she had a tooth extracted, she suffered from exposed bone and extensive infection in the extraction area.

In support of her claim, plaintiff offered expert testimony that of a specific causal link between Fosamax and her injuries. Merck argued under Daubert v. Merrell Dow Pharms., 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469(1993), that plaintiff’s expert “was not qualified to give testimony on the issue of specific causation where a plaintiff has been using Fosamax for less than three years,” noting that [i]n Septem-

ber 2009, this Court ruled that Dr. Marx’s opinion that Fosamax could cause ONJ was ‘not sufficiently reliable’ to be admitted ‘in cases involving less than three years of use.’” The MDL Court agreed, stating that plaintiff’s expert “has opined in the past that Fosamax causes ONJ when used for a period of time greater than three years, and the Court has deemed Dr. Marx’s recent attempts to shorten this time-frame not sufficiently reliable to accept under Daubert.”

In Re: Fosamax Products Liability Litigation, 2010 U.S. Dist. LEXIS 113260 (S.D.N.Y. 2010).

SPORTING GOODS

Bicycle Expert’s Opinions Based Solely On Experience Precluded

Plaintiff was riding a bicycle manufactured by defendant when the bicycle frame failed at the junction of the head tube, top tube, and down tube, causing him to be thrown from the bicycle and suffer severe injuries. Plaintiff retained an engineering expert to determine the condition of the bicycle, as well as the cause of the failure of the frame. The expert opined that the accident resulted from metal fatigue at the junction, and that separation of the down tube and top tube where they attach to the head tube would have been a wiser design choice. He further opined that these high-stress junction areas could also have been reinforced with the use of “doubblers” and/or use of thicker tubes to prevent metal fatigue. Finally, the expert referenced a drawing prepared by plaintiff’s counsel to visually

demonstrate his alternative design opinions. The theories offered by plaintiff’s expert were not generated via any reproducible or peer reviewed technique. None of the theories offered were formally analyzed, tested, or modeled. Further, there was no indication that doing testing, calculations, or modeling was an impossible undertaking. Instead, the theories were wholly the product of the expert’s “experience.” Therefore, on the defendant manufacturer’s *Daubert* motion, the Court found that while it may be true that the expert’s design suggestions would have prevented the frame failure in this case, it was equally true that those design theories could lead to the opposite result, since there was no empirical evidence to show otherwise. Because there was no way to guarantee the reliability of

the alternative design theories, the court excluded the expert from testifying about alternative bicycle frame design theories at trial.

Borel v. Trek Bicycle Corp., 2010 U.S. Dist. LEXIS 76663 (Dist. Colo. 2010).



Football Helmet Manufacturer's Offering Of Evidence Of Industry Standards Is Relevant To Rebut Plaintiff's Attempt To Prove That A Safer Design Was Feasible

Jeremy Green was a football player at Levelland High School. During a summer scrimmage, Green tackled a player and suffered an injury to one of his neck vertebra that resulted in quadriplegia. Green sued Schutt, the manufacturer of the helmet he was wearing at the time of his injury, asserting various theories of liability. At trial, the only liability theory submitted to the jury was whether the helmet was defectively designed. Schutt's defense had two main components: that no helmet could be designed to prevent neck and spine injuries, as distinguished from head injuries; and that the cause of Green's catastrophic injury was the

manner in which he executed the tackle, with his head bent or down rather than up. Schutt obtained a no cause verdict. On appeal, Green argued that the district court erred by permitting Schutt to introduce evidence that it complied with industry standards set by the National Operating Committee on Standards for Athletic Equipment (NOCSAE) and that NOCSAE is of the view that no football helmet is capable of protecting against neck injuries. This evidence was inadmissible, Green asserted, because compliance with industry custom is not a defense in a products liability design defect case. The Fifth Circuit found that because a

manufacturer's level of care is irrelevant in a products liability action, evidence that a manufacturer complied with industry standards is also irrelevant if it is introduced for the purpose of showing that the manufacturer took reasonable care in the design of its product. The Court noted that evidence of industry standards is relevant if offered to rebut a plaintiff's attempt to prove that a safer design was technologically possible and economically feasible.

***Green v. Schutt Sports Manufacturing Co.*, 369 Fed. Appx. 630; 2010 U.S. App. LEXIS 5482 (5th Cir. 2010).**

Federal Preemption– Medical Devices and Pharmaceuticals cont.

(Continued from page 2)

against manufacturers of generic drugs. The Court noted that, although Congress had expressly preempted state failure-to-warn cases for medical devices, it chose not to do so for other FDA-regulated products, such as pharmaceuticals. The court affirmed the district court's denial of the defendant's motion to dismiss since the state's imposition of duties to warn on generic drug manufacturers did not make compliance with federal regulations impossi-

ble or obstruct the goals of that regulation.

***Foxamax Productions Liability Litigation*, 2010 U.S. Dist. LEXIS (S.D.N.Y. 2010)**

This case involved a multi-district litigation involving Defendant Merck Sharpe & Dohme Corp.'s prescription drug Fosamax. After trial, the jury could not reach a unanimous verdict and a mistrial was declared. A second trial ended in an \$8 million verdict for plaintiff. Merck contended in a post-trial motion that plaintiff's tort law claims were

preempted by federal law since the FDA had determined that Fosamax could be on the market and used for its intended purposes and it was safe and effective. The United States District Court for the Southern District of New York cited *Wyeth v. Levine* and noted that the same analysis was applicable in this case, the state tort law was not an obstacle to FDA regulation, but serves a complementary role. Accordingly, the state law claims were not preempted.

News and Upcoming Events

Robert Hanlon, Jr. served on the faculty of the American Board of Trial Attorney's inaugural Trial College at Princeton University this past summer and he will serve as Associate Dean of the College in 2012.

Matthew McDermott published an article in the New York Law Journal, titled "Not So Simple: Manufacturer's Liability for an Altered." The article was published in the September 7, 2010 issue and provides an acute analysis on noteworthy product liability cases.

Cheryl Possenti will be a featured presenter at the American Conference Institute's (ACI) Summit on Drug and Device Product Recalls in March 2011. The presentation will focus on product recalls and the impact on product liability actions.

Michael Shalhoub will present on FDA, social media and medical product liability companies at the Federation of Defense and Corporate Counsel (FDCC) Winter Meeting in February 2011, and also at the June 2011 Medmarc meeting.

Robert Hanlon, Jr. and Bonnie Hanlon will be featured speakers at the DRI Strictly Automotive seminar in Dearborn, Michigan in September 2011. They will present on unexpected acceleration cases.

Goldberg Segalla, a Best Practices firm, has an international product liability trial, defense and prevention practice. Goldberg Segalla's Product Liability Group consists of the following attorneys:

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