

In re Products Liability

NEWSWIRE

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PREEMPTION

The Federalist Papers: Medical Equipment Makers Take Dispositive Preemption Question to U.S. Supreme Court

See *Riegel v. Medtronic, Inc.*, 2006 WL 2849233 (S. Ct. June 25, 2007)

Introduction

In a classic federalism battle pitting the makers of medical devices against the plaintiff's bar deploying state law based tort claims, the U.S. Supreme Court will hear *Riegel v. Medtronic* (No. 06-179) in the fall. In doing so, it will resolve judicial conflict over the preemptive effect of the medical device amendments of 1976 to the Food, Drug and Cosmetic Act.

Defendant manufacturers argue that pre-market FDA approval of medical devices trumps and precludes most state law tort claims. At the same time, a similar issue is percolating through federal and state courts in the context of FDA prescription drug labeling regulations, and recently spawned a *certiorari* petition that went to conference on May 17, causing the Supreme Court to invite the Solicitor General to present the "the views of the United States" on the subject. See *Wyeth v. Levine* (No. 06-1249), 2007 WL 1461080 (May 21, 2007).

At bottom, these disputes center on the Bush administration's effort to federalize product safety standards (among others) in the interest of uniform regulation nationally. It has been sixteen years since the Court's seminal preemption ruling in *Cipollone*, which essentially protected tobacco companies from post-1969 failure-to-warn liability based on the preemptive effect of the Federal Cigarette Labeling and Advertising Act. Now, medical device makers are raising similar arguments that the Food, Drug and Cosmetic Act's prohibition against any state law device requirement "which is different

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PREEMPTION

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from, or in addition to, any requirement” in federal law precludes tort claims under state law.

Recent pro-business decisions from the court — dealing with antitrust law and shareholder class action litigation (by Justice Ginsburg) — may be reason for commercial optimism. Plainly Supreme Court guidance is much needed. According to the New York Times (June 26, 2007 at C3):

[t]he issue has so confounded the courts that three appeals courts reviewing the same medical device made by the same company have reached two different conclusions about whether the patients could bring a lawsuit.

Below we frame the *Riegel* preemption issue.

Background

Plaintiff Charles Riegel underwent an angioplasty, during which his doctor used a balloon catheter manufactured by Medtronic. *Riegel v. Medtronic*, 451 F.3d 104, 107 (2d Cir. 2006). The catheter burst, causing Plaintiff to lose consciousness and to be placed on life support. *Id.* Plaintiff survived emergency bypass surgery, but alleged that he suffered “severe and permanent personal injuries and disabilities” as a result of the defective nature of Medtronic’s catheter. *Id.*

Riegel and his wife sued Medtronic alleging multiple New York state common law causes of action challenging the design, testing, manufacturing, distribution, labeling and marketing of Medtronic’s “Evergreen Balloon Catheter.” *Id.* Medtronic moved for summary judgment, arguing that plaintiffs’ claims were barred by the doctrine of federal preemption. *Id.* The district court granted summary judgment dismissal of all of plaintiffs’ claims, except those for negligent manufacturing and breach of express warranty. *Id.*¹

FDA Pre-Market Device Approval and Preemption

The Second Circuit, in a 2-1 decision, affirmed. After describing the “lengthy and rigorous” process of obtaining pre-market approval (“PMA”) from the FDA of certain so-called “Class III” medical devices² — like the balloon catheter manufactured by Medtronic — the court concluded that the catheter was “subject to the federal device-specific requirement of complying with the particular standards set forth in its approved PMA application.” *Id.* at 119; *see also id.* at 118 (court noting agreement with the “majority of circuits that have held that . . . PMA-approved devices . . . are subject to federal device-specific requirements”). The majority held that because the Riegels’ state-law claims

“would, if successful, impose state requirements that differed from, or added to, PMA-approved standards,” those claims were preempted by federal law. *Id.* at 121-22.

The dissent argued that while the PMA process did “focus[] on safety and effectiveness,” it did not impose “*specific*” requirements on the device seeking pre-market approval. *Id.* at 131-32 (emphasis added). It reasoned that “although the PMA process involves a rigorous and intensive review of a device, neither that review nor eventual approval imposes any ascertainable requirement upon the device that could be compared to any state requirement” to determine whether the state requirement is in fact preempted. *Id.* at 132. Put differently, the PMA approval process merely establishes that a product “has met the FDA’s minimum requirements” (setting basically a floor) — it “does not represent a reasoned consideration and rejection by the agency of possible alternative, safer designs.” *Id.* On this basis, the dissent held that the PMA approval process, without more, does not preempt state law tort claims like those asserted by the Riegels: because PMA does not itself mandate “device-specific requirements.”

Certiorari Briefs Paint Starkly Different Pictures of the Current State of Law

The Riegels’ petition highlighted the purported:

division among the federal and state appellate courts [on the issue of] whether the FDA’s grant of PMA for a medical device triggers preemption of state-law damages claims alleging that a manufacturer did not properly design the device and failed to warn of the device’s risks.

Petitioner’s Brief, 2006 WL 2252499, at *14 (Aug. 3, 2006). As one example of this alleged split of authority, Petitioner noted that in states such as Illinois, Kentucky and Iowa, federal courts find preemption of such claims, while state courts do not. *Id.*

In opposition, by contrast, Medtronic downplayed the magnitude of any circuit split, emphasizing instead a “clear and growing consensus” of courts throughout the country that pre-market approval of medical devices preempts conflicting state law claims based on the design, manufacture and labeling of these FDA-approved products. Respondent’s Brief, 2006 WL

¹ These surviving claims were subsequently dismissed on other grounds. *Id.* at 108.

² The Court noted that the “majority of Class III medical devices” do not go through this rigorous PMA process inasmuch as pre-1976 devices and new devices that are “substantially equivalent” to pre-1976 devices can be marketed without FDA approval as long as they comply with “premarket notification,” which is a far less rigorous process. *Id.* at 111.

2849233, at *1 (Oct. 5, 2006). Medtronic maintained that:

[e]very court of appeals to have considered the issue in the past seven years has concluded, as did the Second Circuit below, that the FDA's vigorous PMA process established device-specific federal requirements that . . . preempt state common law damages claims that would effectively create state requirements 'different from' or 'in addition to' the federal requirements.

Id. It characterized the few aberrant decisions finding no preemption as mere "vestigial inconsistenc[ies]" rooted in an earlier misinterpretation of a landmark Supreme Court decision on federal preemption, *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). According to Medtronic, these early outlier decisions are inconsistent with subsequent Supreme Court case law that clarified and crystallized the holding in *Lohr*, and were therefore "unlikely to survive even absent [the Supreme] Court's intervention" in the instant case. *Id.* at *14.

Finally, the United States Government filed an *amicus* brief arguing against *certiorari*. In its brief, the Government argued that the Second Circuit had "correctly held . . . that the FDA's pre-market approval of a Class III medical device imposes federal 'requirements' that preclude the imposition of state-law tort liability based on a respondent's alleged failure to satisfy inconsistent or additional state-law requirements." Government Amicus Brief, 2007 WL 1511526, at *7-8 (May 23, 2007). The Government also observed that the only federal circuit decisions (from the Eleventh Circuit) and state supreme court decision (from the Kentucky supreme court) to the contrary "predate most of the other cases addressing the question, and were issued without the FDA's current judgment" on the issue. *Id.* at *8. After recognizing that the Government's position in a 1998 *amicus* brief filed with the Court was that PMA "did not itself establish" federal requirements that would be preemptive, the Government conceded that it "has since reexamined the issue and determined that the position it announced" in 1998 "was erroneous." *Id.* at *16.

Having previously denied several *certiorari* petitions raising this exact issue, the U.S. Supreme Court has set the stage for clarification.³ ©

³ See Respondent's Brief, 2006 WL 2849233, at *1 (listing five denials of *certiorari* review by the Court on this precise issue).

MEDICAL MONITORING

Eleventh Circuit Holds That Beryllium Sensitization May Be Cognizable "Injury"

See *Parker v. Brush Wellman*, 2007 WL 1149982 (11th Cir. April 18, 2007), *vacating in part* 420 F. Supp. 2d 1355 (N.D. Ga. 2006)

As previously reported, see *In Re Products Liability* at 13 (July 2006), a federal trial judge in Georgia ruled in March of last year that beryllium sensitivity is not a compensable injury under Georgia law. On April 18, 2007, the Eleventh Circuit Court of Appeals vacated that determination, finding that a genuine dispute of material fact existed on whether beryllium sensitization constitutes "a current disease or impairment and on the probability that the condition will later develop into" chronic beryllium disease.

Proceedings in the District Court

The named plaintiffs commenced this putative class action on behalf of otherwise asymptomatic individuals seeking recovery for "sub-clinical, cellular, and sub-cellular damages" supposedly caused by exposure to respirable beryllium associated with the manufacture or use of products containing beryllium in the course of work at a Lockheed Martin Corporation facility in Georgia. *Id.* at *1. Plaintiffs also claimed that they had "been placed at substantially increased risk of catastrophic latent disease, such as chronic beryllium disease ["CBD"] and cancer," and "have suffered and will suffer in the future from fear, anxiety and emotional upset" due to their increased risk of injury. *Id.* Plaintiffs' complaint included claims for medical monitoring, strict liability, negligence, negligent infliction of emotional distress, fraudulent concealment, and civil conspiracy. *Id.*

In March 2005, on defendants' motion to dismiss and for judgment on the pleadings, the district court ruled that Georgia law did not recognize sub-clinical, cellular, or sub-cellular injuries as actionable, holding that it only allowed tort recovery for injuries with "manifest physiological injuries." *Id.* The district court also granted defendants' motion to dismiss plaintiffs' claims for increased risk, negligent infliction of emotional distress and medical monitoring. As a consequence, the district court ordered plaintiffs to provide a more definite statement of their claims by segregating out those plaintiffs who actually sustained actionable tort injuries. *Id.*

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Dueling Experts on Summary Judgment

Plaintiffs instead filed an amended complaint reiterating their belief that the former effects constituted legally cognizable injuries, and identified five individuals with “injuries . . . detected by physical examination and/or laboratory test.” *Id.* at *2. Defendants responded with a motion to enforce the district court’s prior order and also argued that “the five specified plaintiffs alleged only beryllium sensitization, which is not an actionable injury even when detected by clinical tests.” *Id.*

In support, defendants submitted the affidavit of a Dr. Repsher, a pulmonary physician specializing in environmental and occupational lung diseases, who opined that beryllium sensitization is similar to an allergy and is “part of a normally functioning and healthy immune system” that does not involve in any “structural or functional changes” in the body. *Id.* at *4. Instead, a sensitized person is merely “capable of having a harmful, allergic-type reaction to beryllium in the future.” *Id.* Dr. Repsher also opined that the condition “cause[s] no impairment or harm of any kind” and that a sensitized person may never develop CBD. He also stated that sensitization appears to be reversible, as some people who test positively for the condition later test negative. *Id.*

Plaintiffs responded with an affidavit from a Dr. Maier, an expert on beryllium medicine, who opined that beryllium sensitization is “an abnormal immune response” that is “comparable to an allergy” and “an important precursor to [CBD].” *Id.* Dr. Maier stated that approximately six to eight percent of sensitized persons per year develop CBD and further opined that “[i]t is likely that the majority of individuals with sensitization will eventually develop CBD.” *Id.* Dr. Maier compared beryllium sensitization with HIV (as a “precursor” to AIDS) and asbestos-related pleural plaques, both immunological conditions with a “high risk” of developing into more serious diseases. *Id.* Dr. Maier concluded that “it is clear that beryllium sensitization is a marker of injury to beryllium.” *Id.*

Because both parties submitted expert affidavits, the district court, with the parties’ consent, treated defendants’ motion as a motion for summary judgment. The court granted defendants’ motion and dismissed the case, concluding that, even accepting plaintiffs’ expert’s opinion, “beryllium sensitization constituted no actionable injury under Georgia law.” *Id.* at *2. Plaintiffs’ appeal followed.

The Eleventh Circuit’s Analysis

On appeal, plaintiffs argued that the district court committed

two errors of law — *first*, by dismissing plaintiffs’ claims grounded on alleged sub-clinical injuries and *second*, by dismissing plaintiffs’ claims based on beryllium sensitization.

Sub-clinical Injuries Not Cognizable. The Eleventh Circuit affirmed the district court’s dismissal of plaintiffs’ claims based on sub-clinical injuries and the alleged emotional harm flowing therefrom, stating that “under Georgia law, a plaintiff must show that he has suffered injury to life, limb or damage to other property” and that damages for emotional distress can only be awarded “upon a showing of . . . [a] physical injury to the plaintiff [that] caused the plaintiff’s mental suffering or emotional distress.” *Id.* at *3 (internal citations omitted). Noting that “a personal injury plaintiff must present evidence of ‘actual disease, pain or impairment of some kind,’” *id.* (quoting *Boyd v. Orkin Exterminating Co. Inc.*, 381 S.E.2d 295, 298 (Ga. Ct. App. 1989)), and that plaintiffs failed to allege “an identifiable physical disease, illness or impairing symptoms,” the court ruled that “plaintiffs’ claims for personal injury and emotional distress must fail.” *Id.* It also affirmed the district court’s dismissal of plaintiffs’ claim for medical monitoring because “plaintiffs . . . failed to point . . . to any Georgia authority that allows recovery for medical monitoring costs in the absence of a current physical injury.” *Id.* at *4.

Beryllium Sensitization May Be Cognizable. Plaintiffs also argued that the district court improperly granted summary judgment to defendants based on the district court’s conclusion that “beryllium sensitization — a clinically-manifest condition — constituted no actionable injury under Georgia law.” *Id.* Specifically, plaintiffs argued that the medical expert affidavits submitted by Drs. Repsher and Maier established the existence of a material issue of fact on the question of “whether beryllium sensitization is a current ‘disease, pain or impairment.’” *Id.* Noting that the parties’ experts disagreed on whether beryllium sensitization is a current disease or impairment as well as on the probability that the condition will later develop into CBD, the court remanded, holding:

These issues are questions of fact that should be answered by a jury, and summary judgment was therefore improper . . . on the claims of the five plaintiffs identified as being sensitized.

Id. at *5. ☉

Illinois Appeals Court Disallows Medical Monitoring Claim Based on Absence of Present Physical Injury

See *Jensen v. Bayer AG*, 862 N.E.2d 1091 (Ill. App. Ct. 2007)

An intermediate appeals court in Illinois reached a result contrary to *Parker v. Brush Wellman* on summary judgment in a medical monitoring claim in *Jensen*, where plaintiff pressed (among other things) a claim for medical testing based on Bayer AG's decision to recall "Baycol" in August 2001, which plaintiff said exposed him and others to "an increased risk of developing rhabdomyolysis." *Id.* at 1100.

Background

In *Jensen*, plaintiff was prescribed Baycol to lower his cholesterol after suffering a heart attack. *Id.* at 1094. Shortly thereafter, defendant announced that it was removing Baycol from the market due to the risk of developing rhabdomyolysis, a breakdown of muscle that may release myoglobin into the bloodstream, which is toxic to certain organs. *Id.* at 1094-95. Plaintiff filed a class action complaint against defendant asserting claims for consumer fraud, breach of implied warranty and medical monitoring. After the trial court denied class certification on predominance grounds, defendant moved for summary judgment, which the court granted. *Id.* at 1096. Plaintiff appealed.

Medical Monitoring Claim Requires Present Injury

On a question of first impression in Illinois, the *Jensen* court held that the lack of any present personal injury — coupled with plaintiff's failure to prove to a reasonable degree of medical certainty that medical testing was necessary "to detect a *present* physical injury" — doomed plaintiff's putative class action for medical monitoring. *Id.* at 1101 (emphasis added).

Here, plaintiff offers nothing in support of his medical monitoring claim other than his own allegation that Baycol caused him leg cramps. . . . Indeed, the evidence in the record seems to invite a different conclusion. Plaintiff's own doctors testified that no future medical monitoring would be necessary for plaintiff.

Id.

Distinguishing an earlier Illinois appellate decision that allowed a medical monitoring to proceed in a case against lead-based paint manufacturers — where "plaintiff sought compensation for medical testing to detect a *present* physical injury," *id.*

(emphasis in original) — the *Jensen* court said it "did not address the question posed by plaintiff here; namely, whether a plaintiff may bring a claim for medical monitoring for potential *future* harm, where no present injury is shown." *Id.* (emphasis in original). Unable to prove that medical testing was necessary to detect a present injury, plaintiff's medical monitoring claim failed.

Consumer Fraud Claim Fails, Too

Plaintiff's statutory consumer fraud claim — alleging that defendant had concealed Baycol's safety risks from the public, *id.* at 1097-98 — fared no better. Obligated to prove defendant's intent to conceal, plaintiff argued that defendant's "announcement that it intended to remove Baycol from the market" (*i.e.*, the recall) established the requisite *scienter*. *Id.* at 1098. Unpersuaded, the court held:

The most natural and unstrained interpretation of defendant's [recall] statement, in our view, indicates that defendant's ongoing monitoring of Baycol revealed that Baycol may no longer be safe to the public. This is not an admission, either implicitly or explicitly, that defendant *concealed* the safety of its product from the public. * * * Furthermore, it is well-established principle of law that a recall announcement is not an admission of fault. . . . Under plaintiff's interpretation of [the Illinois Consumer Fraud Act], any recall announcement, such as in the present case, would provide a *prima facie* case for concealment. This result, in our view, constitutes an unsupported and unreasonable extension of the Act. We therefore decline to adopt it.

Id. at 1098 (emphasis in original). This claim also failed for plaintiff's inability to prove proximate causation — that "he was actually deceived by any omission made by Bayer," as required by the Illinois consumer fraud law. *Id.* at 1099.

Having reached the conclusion that plaintiff was without a "valid cause of action," the court denied plaintiff's motion for class certification on the basis that he was "an inadequate [class] representative." *Id.* ☉

TOBACCO

U.S. Supreme Court Rejects Novel Application of Federal-Officer Removal Statute

See *Watson v. Philip Morris Companies, Inc.*, 551 U.S. ___, 2007 WL 1660910 (June 11, 2007)

Introduction

The federal-officer removal statute allows a defendant sued in state court to remove a case to federal court in an action brought against

[the] United States, or any agency thereof or any officer (or any person acting under that officer) of the United States or of any agency thereof, sued in an official or individual capacity for any act under color of such office . . .

28 U.S.C. § 1442 (emphasis added). Philip Morris used this statute to remove an Arkansas consumer fraud class action relating to its sale of “light” cigarettes to federal court, on the theory that plaintiffs were attacking the use by Philip Morris of a government-mandated methodology for testing and reporting the tar and nicotine levels of its products.

The question presented to the Supreme Court in *Watson* was whether the “fact that a federal regulatory agency directs, supervises, and monitors a company’s activities in considerable detail brings that company within” the scope of the statute, thereby permitting removal. Slip op. at 1. The Court held that mere compliance with federal regulation does not bring a private person within the scope of the federal-officer removal statute.

The Road to the Supreme Court

Plaintiffs filed a class action in Arkansas state court alleging that Philip Morris violated Arkansas’s unfair business practice laws. Plaintiffs’ claim, in a nutshell, was that Philip Morris fraudulently advertised and packaged certain cigarettes as “lights,”¹ while intentionally manipulating the design of these cigarettes to register lower levels of tar and nicotine on FTC-approved machine-testing methods than they actually deliver to consumers. *Id.* at 1-2.

Philip Morris removed the case to Arkansas federal district court under the federal-officer removal statute. The district court upheld federal jurisdiction on this basis since the complaint “attacked Philip Morris’s use of the Government’s [machine] method of testing cigarettes,” which meant that plaintiffs had

sued the company for “acts” the company took “under” the authority of the FTC, which was a “federal agency” staffed with “federal officers.” *Id.* at 2.

The Eight Circuit affirmed, reiterating “the FTC’s detailed supervision of the cigarette testing process,” and drawing an analogy to a string of prior cases that had permitted removal “by heavily supervised Government contractors.” *Id.* at 2-3.

High Court Says Complying with the Law is not “Acting Under” Federal Authority for Removal Purposes

The Court began its analysis by examining the legislative history of 19th century removal statutes which were precursors to the modern-day federal-officer removal statute. The first federal-officer removal statute was enacted in 1812 to allow federal customs officers — and “any other person aiding or assisting them” in enforcing a trade embargo with England — to remove cases filed in state courts, many of which were filed by shipowners in New England adversely affected by the embargo. *Id.* at 3 (emphasis in original). In the 1830s, and again after the Civil War, Congress enacted two other federal-officer removal statutes, both in response to claims brought in state courts against federal officers trying to collect federal tax revenue. *Id.* at 4. In 1948, Congress enacted the modern federal-officer removal statute, expanding its coverage to *all* federal officers, not simply custom officials or revenue collectors. The amendment did not, however, indicate “an intent to change the scope of words, such as ‘acting under,’ that described the triggering relationship between a private entity and a federal officer.” *Id.* at 4-5.

After reciting this legislative history, the Court next examined early cases involving lawsuits brought in state courts against federal officers accused of murder, all in the context of federal officers raiding illegal alcohol distilleries. These cases demonstrated that “the removal statute’s ‘basic’ purpose” was “to protect the Federal Government from the interference with its ‘operations’ that would ensue were states able to bring to trial ‘officers and agents’ of the Federal government acting ‘within the scope of their authority’ as federal officers.” *Id.* at 6. Put differently, federal-officer removal jurisdiction is predicated on the perceived need to protect federal officers, and those acting under their authority, from being sued in state courts for acts undertaken within the scope of their authority as federal officers enforcing federal laws.

After analyzing the statutory history and early case law, the Court concluded that “the help or assistance necessary to bring

¹ “Lights” is a term “indicating lower tar and nicotine levels than those present in other cigarettes.” *Id.* at 2.

a private person within the scope of the statute does *not* include simply *complying* with the law.” *Id.* at 8 (emphasis in original). “The upshot is that a highly regulated firm cannot find a statutory basis for removal” based solely on its compliance with federal regulation. *Id.* at 9. Ultimately, the Court distinguished Philip Morris’s situation from federal contractors who have successfully invoked federal officer jurisdiction on the basis that federal contractors are “helping the Government to produce an item that it needs” by contractual agreement. *Id.*

No Proof of “Delegated Authority” or “Special Relationship”

The Court was unmoved by Philip Morris’s argument that it was not merely complying with federal regulation, but rather, the FTC had “delegated authority” to the cigarette manufacturers, including Philip Morris, to test cigarettes for tar and nicotine yields. *Id.* at 10. Assuming the facts in a light most favorable to Philip Morris, the Court found a “fatal flaw . . . of omission” with this delegation argument: the absence of “evidence of a delegation of legal authority from the FTC to the industry . . . to undertake testing on” the FTC’s behalf. *Id.* at 12.

Indeed, the Court noted that there was not “any contract, any payment, any employee/employer relationship, or any principal/agent arrangement” that would demonstrate “the type of formal delegation that might authorize Philip Morris to remove the case.” *Id.* In the end, the absence of any clear indication of delegation of federal lawmaking authority to a private person separated Philip Morris from government contractors who generally enjoy a “special relationship” with the federal government. ☉

PHARMACEUTICALS

N.J. Supreme Court Sees Legislative Intent to Limit Liability in Product Liability Statute, Not Encouragement of Tort Recoveries Divined by Appellate Division

See *Rowe v. Hoffman-La Roche*, 917 A.2d 767 (N.J. 2007), reversing *Rowe v. Hoffman-La Roche*, 892 A.2d 694 (N.J. Super. Ct. App. Div. 2006)

Last July, we commented on a seemingly result-oriented decision by the New Jersey Appellate Division in *Rowe v. Hoffman-*

LaRoche, 892 A.2d 694 (N.J. Super. Ct. App. Div. 2006), which reinstated a products liability action against a New Jersey pharmaceutical company by a Michigan man — whose domicile law immunized defendant from liability on the claims asserted — that had been dismissed by the trial court on application of Michigan law under choice of law principles. See *In re Products Liability* at 9 (July 2006).

REVIEW

More specifically, we said:

“In light of the recent holding in *International Union v. Merck*, 894 A.D.2d 1136 (N.J. Super. Ct. App. Div. 2006) . . . one has to wonder what New Jersey pharmaceutical companies (and similarly situated others) make of their chosen corporate home. *Rowe*, in effect an open invitation to forum shopping for non-residents against New Jersey-based companies, can only add to the worry and wonder.

Defendant Immunized from Liability Under Michigan Law

In *Rowe*, New Jersey’s Appellate Division reversed a trial court’s rather sensible choice-of-law analysis and dismissal of a Michigan man’s action for damages based on claims that “he became severely depressed and attempted suicide several times” after taking Accutane (a drug used in the treatment of severe acne) years earlier. *Rowe*, 892 A.2d at 698. Michigan products liability law — which the trial court applied in granting summary judgment — provides that drug warnings approved by the FDA, like those issued by defendant in respect of Accutane, are adequate as a matter of law, and as such immunize drug manufacturers against failure-to-warn claims like the one filed by Mr. Rowe. *Id.* at 700. New Jersey law, on the other hand, provided that FDA approval created “only a rebuttable presumption” of warning adequacy. *Id.* at 698.

On the basis that New Jersey was defendant’s principal place of business (and place of incorporation), and that the state was the “exclusive location” for defendant’s “domestic operations” pertaining to the manufacture, sale, distribution, and labeling of Accutane, the Appellate Division reversed the trial court’s choice of Michigan law, holding “that New Jersey products liability law respecting the effect of prior FDA approval applies to plaintiff’s claim.” *Id.* at 698-699.

New Jersey’s Governmental Interest Trumps Michigan’s

Writing for the majority, Judge Wecker held that the New Jersey Supreme Court had adopted a “flexible, government

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PHARMACEUTICALS

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interest analysis” for choice-of-law questions. While conceding that the alleged consequences of plaintiff’s Accutane use were visited upon him in Michigan, the court ultimately gave greater weight to the fact that all the relevant testing and manufacturing of Accutane had taken place in New Jersey, tipping the balance in favor of New Jersey law — notwithstanding the lack of available relief under the law of plaintiff’s home state.

Citing *Gantes v. Kason Corp.*, 145 N.J. 478 (1996), the court “rejected the argument that New Jersey did not have an interest in exposing its domestic manufacturers to liability when the law of the state of injury would not hold them liable,” noting that New Jersey’s highest court had “described New Jersey’s strong policy interest in deterring the manufacture of unsafe products within its borders as neither discriminatory nor unnecessarily burdensome.” *Rowe*, 891 A.2d at 704. Turning to Michigan’s interests in applying its immunity law, the court inferred that the Michigan law was likely intended “to protect Michigan businesses,” and finding “no reason to think it was concerned about the business climate in New Jersey or elsewhere,” *id.* at 705-706, the majority concluded that application of “Michigan’s immunity statute would be contrary to New Jersey’s interest.” *Id.* at 707. In effect blinding itself to reality, *Rowe* declared:

We see [no] danger that applying New Jersey law in this case will lead to an influx of drug failure-to-warn cases brought by non-residents of New Jersey.

Id. at 708.

The Dissent

In a stinging dissent, Judge Welfing noted (tongue firmly in cheek) that “New Jersey courts are, for whatever reason, the site of much mass-tort litigation,” adding:

I am unable to perceive what governmental interest New Jersey has in seeking to assure compensation for a Michigan resident when the Michigan Legislature has determined that compensation is not available . . . New Jersey should not become the asylum for claims asserted by citizens of another state whose legislature has made a policy choice to immunize a particular defendant from such litigation.

Id. at 711.”

Defendant appealed.

UPDATE

N.J.’s Rebuttable Presumption Limits Rather Than Expands Liability

The New Jersey Supreme Court recently adopted Judge Welfing’s “stinging dissent,” rejecting the notion that New Jersey had any serious “governmental interest” in “assur[ing] compensation” for anyone in N.J. courts, much less Michigan residents — especially “when the Michigan Legislature has determined that compensation is not available” in the circumstances. *See In re Products Liability* at 10.

Concluding that the Appellate Division improperly — and too broadly — discerned New Jersey’s governmental interests in applying its products liability law regarding rebuttable presumptions of warning adequacy in light of FDA labeling regulations applicable to defendant’s pharmaceutical product, New Jersey’s Supreme Court said:

The predominant object of the law is not to encourage tort recoveries by plaintiffs, whether New Jersey citizens or not, in order to deter this State’s drug manufacturers. On the contrary the law limits the liability of manufacturers of FDA-approved products by reducing the burden placed on them by product liability litigation. The Legislature carefully balanced the need to protect individuals against the need to protect an industry with a significant relationship to our economy and public health. New Jersey’s interest in applying its law to Rowe’s failure-to-warn issue, when properly discerned, is not antithetical to Michigan’s interest but substantially congruent.

Rowe, 917 A.2d at 774 (emphasis added).

New Jersey’s Interest Must Yield to Michigan’s

In finding a different balance between the competing governmental interests than the one reached by the Appellate Division, New Jersey’s high court reasoned that New Jersey’s rebuttable presumption “cede[d] to FDA regulation some of this State’s interest in policing local pharmaceutical manufacturers, thereby reducing New Jersey’s interest in applying its law to this case.” *Id.* In remanding the case for reinstatement of the trial court’s dismissal order, it concluded:

To allow a life-long Michigan resident who received an FDA-approved drug in Michigan and alleges injuries sustained in Michigan to by-pass his own state’s law and obtain compensation for his injuries in this State’s courts completely undercuts Michigan’s interests, while overvaluing our true interest in this litigation.

In this instance, where the challenged drug was approved by the FDA and suit was brought by an out-of-state plaintiff who has no cause of action in his home state, this State's interest in ensuring that our corporations are deterred from producing unsafe products . . . is not paramount. *Our interest in deterring local manufacturing corporations from providing inadequate product warnings, within the context of an FDA approved drug, must yield to Michigan's interest.*

Id. at 775-76 (emphasis added). ©

LEAD PAINT

Missouri High Court Affirms Dismissal of Public Nuisance Suit Against Lead Paint Makers for Lack of Product Identification

See *City of St. Louis v. Benjamin Moore & Co., et al.* No. SC88230, 2007 WL 1693582 (Mo. June 12, 2007)

It has been almost thirty years since the inception of market share liability, and courts still have not reached a consensus regarding its application. A recent decision by the Missouri Supreme Court rejecting this liability theory in a lead-based paint public nuisance action brought by the City of St. Louis illustrates the continuing controversy. (Last year in these pages, we reported on two other lead paint cases involving public nuisance theories of liability. See *In re Products Liability* at 10 (July 2006).)

City's Lead Paint Abatement Program Leads to Public Nuisance Claim

Some years ago, the City of St. Louis instituted a program to assess, abate and remediate lead paint because it can be harmful when ingested by children. *Id.* at *1. Thereafter, the city filed a public nuisance action against the defendant paint manufacturers, alleging that they “produced, manufactured, processed, distributed, and marketed” lead paint and pigment with knowledge that it was highly toxic and posed a serious health threat for children. *Id.* Specifically, the city claimed that the “presence of lead paint in the [c]ity's housing built before February 27, 1978¹ . . . unreasonably interferes with the public's health, safety, welfare, and comfort.” *Id.* The city sought compensatory damages for assessing, abating, and remediating the nuisance from

those “companies that put lead paint into the stream of commerce.” *Id.* While the city was able to identify the residences where it had incurred costs abating or remediating lead paint, “it could not identify the manufacturer of any lead paint that was allegedly present at or abated from the properties at issue.” *Id.*

The Trial Court's Dismissal Order

Defendants moved for summary judgment, arguing that Missouri law requires a plaintiff to identify a specific defendant as the manufacturer, distributor or seller of a product, and also prove that a product made or sold by the defendant actually caused the plaintiff's injury. Defendants argued “that product identification was necessary to hold them liable under [public nuisance] or any tort theory.” *Id.* (citing *Zafft v. Eli Lilly & Co.*, 676 S.W.2d 241 (Mo. 1984)). The city responded that product identification was not a requirement in the context of a public nuisance claim and that it needed only to adduce “market share evidence,” which established that the defendants “substantially contributed to the lead paint problem in the city.” *Id.*

The trial court granted defendants' motion, holding that Missouri tort law did not permit the city to rely solely on market share evidence to prove actual causation.

Missouri's Prior Rejection of Market Share Liability

On appeal,² the city argued that the trial court's reliance on *Zafft* — a product liability case in which the Missouri Supreme Court rejected the market share theory of liability — was misplaced. In *Zafft*, plaintiffs sued various manufacturers and distributors of diethylstilbestrol (DES), alleging that DES when taken during pregnancy caused cancer in female offspring. The plaintiffs in *Zafft* claimed, among other things, that DES was defective and sought to hold the defendants responsible for failing to adequately warn pregnant mothers about the risks associated with the drug. While the *Zafft* plaintiffs claimed that “the defendants represented all the known makers, sellers or distributors of DES in Missouri at the relevant time,” they “were unable to identify which defendant made or sold the particular product th[at plaintiffs'] mothers had ingested.” The plaintiffs urged the court to adopt an “alternative theory of liability with a more relaxed standard of causation or none at all.” *Zafft*, 676 S.W.2d at 243-44.

The *Zafft* court rejected the market share theory of liability,

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¹ The federal government banned lead paint on February 27, 1978. See 16 CFR § 1303.

² The Missouri Court of Appeals, Eastern District, transferred the case directly to the Supreme Court of Missouri. *Id.*

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characterizing it as “unfair, unworkable, and contrary to Missouri law, as well as unsound public policy.” *Id.* at 246. The court justified its rejection of the market share theory on the basis that it “continues the risk that the actual wrongdoer is not among the named defendants, and exposes those joined to liability greater than their responsibility.”³ *Id.*

“Substantial Participation” Not Enough

Turning to the case before it, the Missouri Supreme Court began its analysis with the black letter principle that “[i]n all tort cases, the plaintiff must prove that each defendant’s conduct was an actual cause, also known as cause-in-fact, of the plaintiff’s injury.” *City of St. Louis*, 2007 WL 1693582 at *1. The Court made quick work of the city’s argument that the *Restatement (Second) of Torts* only required proof that a defendant in a nuisance action substantially participated in or contributed to the nuisance-producing activity. *Id.* at *2.

Referencing the commentary to the *Restatement*, and citing other Missouri public nuisance cases, *see City of St. Louis v. Varahi, Inc.*, 39 S.W.3d 531, 535-38 (Mo. App. 2001), the Court explained that “substantial participation” refers to legal (or proximate) cause and does not supplant the element of factual causation. *City of St. Louis*, 2007 WL 1693582 at *2.

Product Identification Needed to Establish Actual Causation

The Missouri Supreme Court affirmed the trial court’s dismissal order, stating that “[w]ithout product identification, the city can do no more than show that the defendants’ lead paint may have been present in the properties where the city claims to have incurred abatement costs. That risks exposing these defendants to liability greater than their responsibility and may allow the actual wrongdoer to escape liability entirely.” *Id.* at *3. The Court noted that the trial court’s dismissal order was correct even if:

the city could prove — via marketing evidence or something else short of product identification — that a particular defendant held a certain share of the lead paint market in the city at the relevant time or even if it could prove that because of that defendant’s market share

there was a statistical probability that its paint was in a certain percentage of the properties at issue.

Id. at *4. Concluding its analysis, the Court held that “[a]bsent product identification evidence, the city simply cannot prove actual causation.” *Id.*

Damages Sought Not Common to General Public

Finally, the city also argued that its status as a governmental entity — and the “public nature of the injury” alleged — meant that its public nuisance claim was subject to “lesser causation standards” because “the damage is not an individual injury, but a widespread health hazard that is ‘uniquely public — the monumental task of cleaning up [d]efendants’ toxic products falls upon the city and its taxpayers.” *Id.* This argument was given great weight in the dissent lodged by Chief Justice Wolff, who wrote that *Zafft* and traditional principles of tort law were irrelevant to the city’s suit because:

[t]his public nuisance case has nothing to do with identifying a particular paint and linking it to a particular injured victim. It has everything to do with identifying the sources of a poison and making those sources pay their fair share of the cost of the cleanup of a direct hazard to the public health.

Id. at *7.

The majority, however, rejected the city’s effort to characterize its suit “as one for an injury to the public health.” *Id.* at *4. Noting that the city sought damages “for the costs the city allegedly incurred abating and remediating lead paint in certain, albeit numerous properties” — that is, harm “not shared with the general public” — the Court reasoned that its claims were “like those of any plaintiff seeking particularized damages allegedly resulting from a public nuisance.” *Id.* (emphasis added). As such, the city was required to prove actual causation through product identification. ☉

³ The market share theory of liability has been accepted in other jurisdictions in the context of DES litigation. *See Sindell v. Abbott Laboratories*, 607 P.2d 924 (Ca. 1980); *Hymowitz v. Eli Lilly & Co.*, 73 N.Y.2d 487 (N.Y. 1989).

TRADEMARKS

Trademark Licensor Liability for Defective Products Under U.S. Law¹

Trademark licensing in all its forms — promotional, collateral and classical — has become an increasingly large and dynamic part of the global economy. It has been reported that in the U.S. alone manufacturers paid nearly \$6 billion in licensing royalties in 2003. Although nearly one third of all global commerce in trademark licensing is generated outside the U.S., many of those licensed goods are eventually floated into the U.S. stream of commerce.

While the majority of trademark licensing agreements involve “mere” or “pure” licensing, under which the trademark owner does little more than give another (usually a manufacturer) permission to use its trademark, in other instances the trademark owner will involve itself to some degree in the design and manufacture of the licensed product. In both instances, trademark licensors who do not actually manufacture the licensed product need to consider the various theories of products liability that U.S. plaintiffs might use to hold them liable when claimed defects in licensed goods give rise to personal injury litigation.

Preliminarily, trademarks registered in the U.S. enjoy legally enforceable protection against infringement under the Lanham Act. The consideration for this protection — on pain of trademark abandonment — is the licensor’s assumption of a legal duty to exercise control over the quality of goods sold under its mark, which the Lanham Act unfortunately does not otherwise define. Although this statutory “quality control” obligation does not itself give rise to products liability, it has befuddled some courts, leading them to subject trademark licensors to questionable liability for product defects.

In brief, trademark licensors are subject to products liability in the U.S. legal system under either (a) the “enterprise” theory of liability, or (b) the “apparent manufacturer” doctrine.

The “Enterprise” Theory

Under the “enterprise” theory of liability, the analytical approach adopted by a majority of U.S. courts, non-manufacturing trademark licensors who exercise “substantial control” over the manufacture or sale of licensed goods are deemed the “functional equivalent” of the manufacturer and subjected to strict liability — that is, liability without fault — for any design, manufacturing or warning defects that render the product

“defective” and “unreasonably dangerous” under Section 402A of the Restatement (Second) of Torts. With “substantial control” — sometimes called “participatory connection” — as its predicate, the “enterprise” theory implicitly presumes non-liability for minimally involved trademark licensors.

While the intensely fact-specific nature of the “control” inquiry makes it difficult to divine predictive rules or tests from the case law, as a general matter this much can be said with confidence about the reach of the “enterprise” theory: trademark licensors who provide licensees with detailed specifications and standards for the manufacture, design or distribution of the licensed product are commonly subjected to products liability by U.S. courts under the “enterprise” theory.

The “Apparent Manufacturer” Doctrine

Trademark licensors also face negligence-based products liability under the “apparent manufacturer” doctrine of the Restatement (Second) of Torts § 400, which provides that “one who puts out as his own product a [good] manufactured by another is subject to the same liability as though he were its manufacturer.”

Although a small number of U.S. courts used this doctrine in the 1970s to subject trademark licensors to products liability for no more than “mere” licensing, most courts since then have — consistent with the doctrine’s original purpose — limited its application to trademark licensors who actually sell or distribute the licensed goods, generally making the “apparent manufacturer” doctrine a less viable theory of liability against trademark licensors. This in fact is the approach taken by the new Restatement (Third) of Torts § 14, which expressly limits the doctrine to product sellers and distributors, and by terms specifically exempts “mere” or “pure” trademark licensors from its operation.

Unfortunately, the traditional restriction on this doctrine’s application — to those who “put out” a good as their own by sale, lease, gift or loan — is sometimes still overlooked by courts.

Summary

On the whole, a trademark licensor’s products liability exposure in the U.S. under a “mere” or “pure” licensing agreement is real but generally low, provided it does not sell or distribute the licensed product. Thereafter, the risk rises in proportion to the amount and nature of any control the trademark owner exercises over the design, manufacture or distribution of the licensed product or the licensee’s operations (when, for instance, the licensee is the licensor’s wholly owned subsidiary).

Summing up, a good rule of thumb for a trademark licensor to follow in walking the tightrope of U.S. products liability risk is to

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¹ This article was originally published in *Law.com* on May 16, 2007.

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make the licensee as autonomous as possible, consonant with the licensor's obligation under the Lanham Act to exercise "quality control" over its mark. While less control is better from a risk management perspective, almost any type of control can be a slippery slope to products liability in U.S. courts. ☺

NANOLAW

Nanotechnology Law & Commerce: Doing Business at One-Billionth of a Meter

As things have developed, nanoscience itself — basically, manipulating and engineering matter at the molecular level — may be the easy part of commercializing nanotechnology. The rub, it seems, may be in the law.

In the case of nanotechnology,¹ there is currently no clear regulatory framework notwithstanding the potential health risks of nanoparticles, such as carbon nanotubes. From beginning to end of applied nanoscience — product development all the way through sale, use, disposal and recycling — there are a host of legal implications, from occupational to environmental to venture capital to intellectual property to corporate finance and products liability, among other disciplines.

Nanotechnology — projected to account for some \$1 to \$3 trillion in global commerce in the next decade — is a veritable frontier for both science and law. The legal issues are seemingly boundless, beginning with the need for and nature of legislation and regulation — if for no reason other than to secure economic leadership and advantage for the U.S. economy in future nanotechnology-related trade.

For now, the future of nanotechnology regulation and understanding is mired in the identification, understanding and debate of its associated health risks at the level of fundamental science, and great uncertainty. Some say that current regulatory schemes — from the FDA, EPA, OSHA, NIOSH and beyond — are sufficient to regulate nanotechnology, while others say not. A

¹ Nanotechnology refers to the science of engineering and manipulating matter at the scale of 1 to 100 nanometers, with a nanometer equaling one-billionth of a meter (and a single sheet of paper being roughly 100,000 nanometers thick). *See In re Products Liability* at 11 (Nov. 2006).

Canadian organization advocates a moratorium on nanotechnology as a threat to human and environmental health and safety. Complicating matters is the fact that nanotechnology is not a single industry; it is multi-disciplinary, reaching across a broad stretch of the global economy. What is more, the vast majority of the public has no familiarity with or understanding of nanoscience or nanotechnology.

In the meantime, nanotechnology companies must weigh the promise of innovation against the backdrop of a largely uncertain legal landscape. This breach was recently rushed by DuPont and Environmental Defense (with EPA funding), who collaborated to produce voluntary guidelines — or best practices — for evaluating the safety and environmental risks of nanotechnology. There is concern, however, about the ability of smaller companies to handle the expense of such processes.

The asbestos model, which by the time its course is run will likely have consumed some \$200 billion and bankrupted countless corporations, will hopefully not be the template for nanotechnology. Instead, liability caps, immunity and mandated insurance coverage might be used to support responsible investment in and commercialization of nanotechnology through its infancy — free of potentially ruinous litigation exposure.

In the 1960s, at the dawn of today's highly commercialized, mass consumption and Internet-driven society, the California Supreme Court began the modernization of American tort law with the invention of strict liability. Half a century on, one wonders whether nanotechnology will produce any significant developments in products liability law to accommodate the reality of doing business at one-billionth of a meter. ☺

EVIDENCE

Sixth Circuit Panel Applies *Daubert* Factors More Rigorously With “Quintessential Expert for Hire”

See Johnson v. Manitowoc, 484 F.3d 426 (6th Cir. 2007)

Introduction

In *Johnson*, a Tennessee magistrate judge excluded the testimony of a plaintiff's engineering expert under three of the four *Daubert/Kumho* factors and grafted a fourth one not mentioned by the Supreme Court in *Daubert* or *Kumho*: “the extent to which [the expert's] opinions were prepared in the context of litigation”

tion,” as opposed to independently in the laboratory or field. *Id.* at 430. On appeal, the Sixth Circuit upheld the magistrate judge’s exclusion of the expert witness, resulting in summary judgment for the defendant manufacturer. *Id.* at 436.

This case demonstrates the willingness of courts to apply the *Daubert* reliability factors with greater rigor when the expert witness’s testimony is manufactured solely for litigation, rather than flowing naturally from the expert’s prior or current research.

Background

Plaintiff in *Johnson* was injured when a truck-mounted crane manufactured by the defendant fell over when a stabilizer for the crane was temporarily retracted by a co-worker. *Id.* at 427. To support his claim that the defendant’s crane was defective, the plaintiff introduced the expert testimony of a registered professional engineer, who had been employed exclusively as an engineering “consultant” for the prior twenty years. In this capacity, he had testified “in a wide range of design defect cases” over those years — rendering

opinions on the design of ‘almost any machine,’ including a ‘wheelchair, a deep fat fryer, a passenger elevator, an antique replica shotgun, a hay baler, a meat tenderizer, a forklift, a manure spreader, a lawn mower, a seat belt assembly, a log skidder, a concrete saw, a trampoline, and a tree stand.’

Id.

Based solely on document review, including discovery documents and operators’ manuals for various truck cranes, and without conducting any empirical research whatsoever, plaintiff’s expert testified by deposition that the truck crane was defective due to the lack of an “interlocking” system that he asserted would have prevented the plaintiff’s accident. *Id.* at 428. Thereafter, defendant moved to exclude plaintiff’s sole design expert testimony as unreliable, and for summary judgment given that “expert testimony is absolutely required for a products liability action to proceed” under Tennessee law. *Id.* at 428.

Daubert/Kumho Factors: Testing and General Acceptance

Finding the expert’s testimony to be “clearly relevant,” the magistrate judge applied three *Daubert/Kumho* factors to assess its reliability: (1) “the extent to which the opinions of [the expert] had been tested”; (2) “the extent to which his opinions had been subjected to peer review or publication”; and (3) “the extent to

which his theory regarding the [interlocking system] had gained general acceptance within the engineering/manufacturing community.” *Id.* at 430.¹ Under these factors, the magistrate judge found the expert witness’s testimony to be unreliable, granted defendant’s motion to exclude and entered summary judgment for defendant. *Id.* Plaintiff appealed.

The Sixth Circuit focused on two of the *Daubert/Kumho* reliability factors chosen by the magistrate judge — namely, the testing factor and the general acceptance factor. *Id.* As to the former, the court found that it was reasonable for the magistrate judge “to have shut the gate on [the expert] because he had made no attempt whatsoever to test the interlock system” in a similar truck-mounted crane — relying instead on a “one-page diagram that is nothing more than an engineer’s version of a cut-and-paste” to support his proposed design. *Id.* at 432-33. Siding with the lower court, the Sixth Circuit agreed that “at least a modicum of empirical testing should have been performed in order to determine how easily an interlocking outrigger system could be installed” onto the machine in question, as well as whether its use would have entailed any safety or performance downsides. *Id.* at 431. More to the point, it added:

We can imagine innumerable tests that could have been conducted by [plaintiff’s expert] — all well short of building a full-fledged prototype . . . , but all well beyond drawing a one-page diagram — that would have demonstrated the practicality of his proposed design. And yet [he] failed to conduct any testing at all.

Id. at 433.

At the same time, the Sixth Circuit cautioned that testing is not always an “absolute prerequisite” to establishing the reliability of expert opinion, since the “reliability inquiry is a flexible one and may ‘focus upon personal knowledge and experience.’” *Id.* at 432 (quoting *Kumho*). One way around the testing requirement, for instance, is to show that the expert has “significant technical expertise in the specific area in which he is suggesting an alternative design.” *Id.* at 431. In the end, however, the court found that plaintiff’s expert’s “self-serving testimony that he is qualified to render an opinion on the design of ‘almost any machine’ undercuts any claims of *specific* expertise he might hope to make.” *Id.* at 432 (emphasis in original).

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¹ The second factor (peer review essentially) was deemed “largely insignificant” based on the parties’ concession that “there is little in the way of published or peer-reviewed information — at least in the sense contemplated by *Daubert* or *Kumho* — on interlocking outrigger systems for truck cranes.” *Id.* at 430.

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Plaintiff likewise could not demonstrate his expert's reliability through the general acceptance factor, because although he could show that similar truck-mounted cranes *currently* utilize the "interlocking" system advocated by his expert, he could not show that the absence of the "interlocking" system rendered the truck-mounted crane defective at the time it left the control of the defendant years earlier in 1999. *Id.* at 433. As the Sixth Circuit observed, "[i]f we were to bless a rule to the contrary, we would pave the way for retroactive imposition of liability in products liability cases such as this one," running afoul of long-standing Tennessee state law. *Id.* at 434.

"Quintessential Expert For Hire"

The magistrate judge used a fourth factor not mentioned by the Supreme Court in *Daubert* or *Kumho* in determining the reliability of plaintiff's expert, but fashioned by the Ninth Circuit on remand of *Daubert* in 1995 (see *Daubert v. Merrell Dow Pharmaceuticals*, 43 F.3d 1311, 1317-18): "the extent to which [the expert's] opinions were prepared in the context of litigation," or "prepared-solely-for-litigation." *Johnson*, 484 F.3d at 430. The magistrate judge considered this factor to be a "very important one," and along with the testing factor, was the factor primarily responsible for her decision to exclude the expert's testimony. *Id.* at 435. She labeled plaintiff's expert as the "quintessential expert for hire" who had "spent the last twenty plus years of his life testifying as an expert in a wide variety of design defect cases" and invented his opinions "solely in the context of this litigation," without offering "a proposed design that would necessarily make th[e] crane safer." *Id.*

Characterizing the magistrate judge's analysis and application of this factor as "quite lucid and quite correct," the Sixth Circuit went on to describe a sliding scale of rigor for assessing the reliability of expert opinion under *Daubert*, explaining:

If it is clear that a proposed expert's testimony flows naturally from his own current or prior research (or field work), then it may be appropriate for a trial judge to apply the *Daubert* factors in somewhat more lenient fashion. . . . However, if a proposed expert is a 'quintessential expert for hire,' then it seems well within a trial judge's discretion to apply the *Daubert* factors with greater rigor, as the magistrate judge seem to have done in this case.

Id.

Under this standard, the "quintessential expert for hire" is not subjected to a presumption of unreliability, but instead "must

show some objective proof" of reliability, such as "familiarity with the particular type of machine in question." *Id.* Plaintiff's expert, by contrast, supported his opinions with little more than his "say-so." *Id.* at 431. ©

PHARMACEUTICAL LABELING

FDA Pharmaceutical Labeling Preemption Update

See *Wyeth v. Levine*, 2007 WL 1461080 (S. Ct. May 21, 2007); *Deutsch v. Wyeth, Inc.*, Docket No. MID-L-0998-06 MT, Case No. 266 (N.J. Super. Ct. June 22, 2007)

Background

The Food and Drug Administration's Preamble to its final rule on the "Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products," 71 Fed. Reg. 3922 (Jan 24, 2006) ("Final Rule") — now 18 months old — continues to generate litigation and conflicting results regarding its preemptive effect on failure-to-warn claims in pharmaceutical litigation. See *In Re Products Liability* at 8 (July 2006); *In Re Products Liability* at 8 (Nov. 2006); see also Chadbourne Client Alert, "Recent Federal Court Decision Dismissing as Preempted Pharmaceutical Failure-to-Warn Claims" (June 7, 2006); Chadbourne Client Alert, "New FDA Rule on Prescription Drug Package Inserts" (Feb. 14, 2006).

More recently, at its conference on May 17, 2007, the U.S. Supreme Court invited the Solicitor General to express "the views of the United States" on the subject in connection with *Wyeth's certiorari* petition in *Wyeth v. Levine* (No. 06-1249), 2007 WL 1461080 (May 21, 2007).

Lower Court Split Headed for Supreme Court Resolution?

As previously reported, in *Levine* the Vermont Supreme Court rejected *Wyeth's* contention that the FDA's Final Rule preempted a plaintiff's failure-to-warn claim regarding "IV-push" administration of Phenergan. *Levine v. Wyeth*, No. 2004-384, 2006 WL 3041078 (Vt. Oct. 27, 2006). It held that the Final Rule was not preemptive because it did not alter existing regulations permitting manufacturers to add or strengthen a warning label without prior FDA approval. In reaching this conclusion, Vermont's

high court reasoned that: "Congress intended the [Food, Drug and Cosmetic Act] to preempt only those state laws that would make it impossible for manufacturers to comply with both federal and state requirements." 2006 WL 3041078, at ¶ 32. In the court's view, because "federal labeling requirements create a floor, not a ceiling, for state regulation," *id.* at ¶ 6, and because it was possible for Wyeth to comply with FDA regulations and the duties imposed by Vermont law by issuing a stronger warning against "IV push" administration, there was no conflict between federal and state law that warranted preemption. *Id.* at ¶¶ 32-34. This view is directly opposite that of the FDA itself. See 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006).

On March 12, 2007, Wyeth petitioned the U.S. Supreme Court for *certiorari*, with The Products Liability Advisory Council and the U.S. Chamber of Commerce filing amicus briefs. Potentially teeing up the burgeoning lower court split over the meaning of the FDA's recently expressed judgments about the deference owed its comprehensive prescription drug labeling regulations, the question presented is:

Whether the prescription drug labeling judgments imposed on manufacturers by the Food and Drug Administration ("FDA") pursuant to FDA's comprehensive safety and efficacy authority under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., preempt state law product liability claims premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use.

See Wyeth's Petition for a Writ of Certiorari at *i* (Mar. 12, 2007).

Plaintiff, awarded \$6.4 million following a jury trial, argues that this case is not an appropriate test of the Final Rule's preemptive effect since it was published years after FDA approval of the Phenergan label; the Vermont Supreme Court found that plaintiff's recovery was based on a labeling judgment different from those addressed by the FDA; and because the FDA never specifically considered whether Wyeth should have warned against the risks of the IV-push method of Phenergan administration. See Respondent's Brief in Opposition, 2007 WL 1223762 (April 20, 2007).

A similar result was reached recently in hormone replacement litigation in New Jersey, where in late June state court Judge Garruto denied Wyeth's motion for partial summary judgment dismissal of plaintiff's inadequate warning claim as barred by federal preemption. *Deutsch v. Wyeth, Inc.* No. MID-L-0998-06 MT, Case No. 266 (N.J. Super. Ct. June 22, 2007). In concluding that the Food, Drug and Cosmetic Act does not preempt state law tort claims for failure to warn, Judge Garruto adopted the rea-

soning and findings of U.S. District Judge Weinstein in *In re: Zyprexa Products Liability Litigation*, No. 04-MD-1596, 06-CV-1729 (E.D.N.Y. June 11, 2007), and New Jersey Superior court Judge Higbee in *Cona/McDarby v. Merck*, Nos. ATL-L-3553-05 MT, ATL-L-1296-05 MT (N.J. Super. Ct. June 8, 2007).

Litigants and clients on both sides of the pharmaceutical tort bar wait to see whether the Supreme Court will address and resolve this critical question. ☉

Et cetera

Publications

- David Wallace and Allison Alcasabas published “Trademark Licensor Liability for Defective Products Under U.S. Law,” on *Law.com* (May 16, 2007).
- David Wallace and Ellen Black published “Overview of Trademark Licensor Liability for Defective Products,” which appeared as the featured article in *Bloomberg’s IP Law Reports: Intellectual Property* (June 25, 2007).
- Lawrence Savell published “Electronic Transcript Management Technology for Litigators,” on *Law.com* (March 14, 2007).
- In May 2007, Gretchen Werwaiss and Cassandre Charles coauthored the “Chapter on Minnesota Law” in *Update on Punitive Damages Claims: A 50 State Survey: A Report of the Pharmaceuticals Subcommittee of the Products Liability Committee*, Section of Litigation, American Bar Association.
- In May 2007, Gretchen Werwaiss and Doroilo Nixon coauthored the “Chapter on New York Law” in *Update on Punitive Damages Claims: A 50 State Survey: A Report of the Pharmaceuticals Subcommittee of the Products Liability Committee*, Section of Litigation, American Bar Association.

Speaking Engagements

- On July 18-19, 2007, Phoebe Wilkinson will be presenting on cross-examining a plaintiff’s regulatory/FDA expert at “*Drug and Medical Device on Trial, An Interactive Mock Trial of a Medical Products Company*,” in New York City.
- On October 4, 2007, Gretchen Werwaiss will moderate a panel discussion on litigating products liability cases under the new FRCP e-discovery rules at the ABA Women in Products Liability 2007 Conference in New Orleans, LA.
- On June 7, 2007, Allison Alcasabas served on a panel discussing “US Techniques: a Solution to Access to Justice in Europe?” at the Product Liability and Mass Torts in the Global Market Place Conference in London, which was sponsored by the British Institute of International and Comparative Law Conference.

Press Coverage

- David Wallace offered commentary on the U.S. Supreme Court’s recent decision in *Watson v. Philip Morris Cos., Inc., et al.* (No. 05-1284) — and the topic of federal-officer removal jurisdiction — in an interview with the host of *Bloomberg Law* that aired June 17, 2007, on Bloomberg Radio nationally.

To view the full articles visit Chadbourne’s online publications at www.chadbourne.com/publications

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