

In re Products Liability

NEWSWIRE

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EVIDENCE

New York's High Court Requires Parties To Address Degree of Exposure In Toxic Tort Cases

See *Parker v. Mobil Oil Corp.*, 2006 WL 2945397 (N.Y. Oct. 17, 2006)

Under an eagerly awaited ruling by New York's highest court, plaintiffs and defendants in cases alleging injuries caused by chemical exposure will need carefully to assess the amount of the chemical to which the plaintiff was exposed. The Court of Appeals refused to require a plaintiff to prove the exact quantity of his exposure, but made clear that there must be a concrete scientific foundation for proof that the chemical caused his injuries. The

court held that expert opinions that are "subjective" or "conclusory" are not sufficient to prove that the chemical caused the claimed injuries.

In *Parker*, the plaintiff alleged that during his employment as a gas station attendant over 17 years, he was exposed to benzene through inhalation of gasoline fumes and dermal contact with gasoline, and that he contracted leukemia as a result. Defendants moved to preclude plaintiff's expert testimony that his leukemia was caused by benzene and for summary judgment dismissing plaintiff's claims. Plaintiff submitted reports from two experts in opposition to defendants' motions. One opined that the plaintiff's exposure to gasoline was "extensive" and that he had "abundant opportunity" for exposure to benzene. *Parker v. Mobil Oil Corp.*, 16 A.D.3d 648 (App. Div. 2d Dep't 2005). Plaintiff's other expert relied on a study purporting to show a link between leukemia and benzene exposure in refinery workers, and claimed that the plaintiff had "far more" exposure to benzene than refinery workers, but did not specify how the subjective exposure estimation was calculated.

The Court of Appeals held that plaintiff's claims should have been dismissed. It explained that it is necessary to assess the "specific reliability" of the procedures used by experts to arrive at their opinions and to determine whether the procedures establish a founda-

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Evidence

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tion for admission of their opinions at trial. This requirement was not met because plaintiff's experts did not quantify his exposure to benzene.

The Court was careful, however, to reject any notion that the plaintiff in a toxic tort case must prove the *exact* amount of his chemical exposure. The Court noted that it may be difficult, or impossible, to quantify a plaintiff's exposure "by pinpointing an exact numerical value," and stated that "it is not always necessary for a plaintiff to quantify exposure levels precisely . . ." Nevertheless, it made clear that a plaintiff must prove not only that he was exposed to a chemical and that the chemical is capable of causing the alleged injury, but "that [the] plaintiff was exposed to sufficient levels of the [chemical] to cause the illness."

The Court's decision will require the parties in New York toxic tort cases to address whether the degree of the plaintiff's alleged chemical exposure has been established with "specific reliability." ☉

Absence of Reliable Scientific Proof for General Causation Dooms Expert's Reliance on "Differential Diagnosis" Technique to Establish Specific Causation

See Bickel v. Pfizer, Inc., 431 F. Supp. 2d 918, 918-919 (N.D. Ind. 2006)

A federal district court in Indiana recently applied *Daubert* to reject an expert's use of the "differential diagnosis" technique to establish specific causation based on the lack of any underlying reliable scientific evidence of general causation in the first instance.

In *Bickel*, plaintiff alleged that "she suffered strokes of the optic nerves and partial vision impairment as a direct result of ingesting Lipitor, a cholesterol lowering statin drug." *Id.* at 919. Shortly after she started taking Lipitor, plaintiff "began experiencing body and joint pain and swelling of the eyes," and eventually suffered

"blurriness and partial vision loss in her right eye," which was later diagnosed as anterior ischemic optic neuropathy (AION). *Id.*

Attempted Linkage of Optic Stroke to Use of Lipitor

Plaintiff's neuro-ophthalmologist, Dr. Purvin, filed an expert report offering the opinion that Lipitor "most likely caused the Plaintiff's AION, commonly known as a stroke of the optic nerve." *Id.* at 921. This opinion was based upon a review of the scientific literature, and cited several reports where "a causal association [between ingestion of statin drugs and vasculitis — but not AION] had been proposed," as well as one report purporting to show an association between AION and patients taking atorvastatin — with the caveat that "further studies would be required to determine if in fact statin medications might promote rather than prevent vaso-occlusive events in some individuals." *Id.* at 921-922. Plaintiff's expert also cited clinical factors in support of her opinion, including the "unusual time course of [vision] loss in the two eyes and [plaintiff's] preceding symptoms that were temporally associated with taking Lipitor." *Id.* at 922.

The *Daubert* Challenge

Pfizer moved to exclude Dr. Purvin's testimony under *Daubert*, and also sought summary judgment dismissing the case on the basis that plaintiff "had no admissible evidence of causation." *Id.* at 920. The court agreed with Pfizer, noting that "Dr. Purvin did not rely upon any valid scientific methodology in forming her opinion," nor did she "conduct any scientific tests, experiments, or clinical studies to bolster her theory that statins can cause AION." *Id.* at 922. The court also observed that some of the scientific literature upon which Dr. Purvin's opinion rested "related only to statin drugs and vasculitis, not AION, and then only 'proposed' a connection." *Id.* at 924. While plaintiff's expert cited a study "not[ing] an association between statin drugs and AION," she admitted that validation of the causal connection she hypothesized required "further studies." *Id.* Finally, and ultimately fatally, Dr. Purvin admitted that plaintiff's case "was not strong enough by itself to publish a case report; it was 'suggestive, suspicious, intriguing, plausible, but not proven.'" *Id.*

Differential Diagnosis by Itself Cannot Prove Disease Causation

Arguing to save her case, plaintiff claimed that Dr. Purvin's

belief that Lipitor was the likely cause of her AION was nevertheless reliable because it was based upon a “differential diagnosis,” which she utilized for purposes of considering “all the possibilities that could cause the sequence of events and concluded that it was more likely than not that the plaintiff’s use of Lipitor cause her AION.” *Id.* at 923. Rejecting this argument, the court observed:

[D]ifferential diagnosis does not by itself prove the cause . . . Indeed, differential diagnosis assumes that general causation has been proven for the list of possible causes it eliminates . . . Differential diagnosis may be utilized by a clinician to determine what recognized disease or symptom the patient has, but it is incapable of determining whether exposure to a substance . . . caused disease in the legal sense. Simply put, an untested hypothesis cannot be a scientifically reliable basis for an opinion based on causation.

Id. at 923-924.

Put more simply, the court reasoned that without proof of general causation, an expert cannot use the “differential diagnosis” technique to “rule in” a suspected causal factor. *Id.* at 924. In the circumstances, plaintiff’s causation evidence was little more than an “untested hypothesis.” *Id.* at 924. ©

JURISDICTION

Citing “Interest of Justice,” New Jersey Court Dismisses British Vioxx Claimants on Grounds of *Forum Non Conveniens*

See *In re: Vioxx Litigation*, No. 619, 2006 WL 2950622 (N.J. Sup. Ct. Law Div. Oct. 2, 2006)

With increasing regularity, U.S. manufacturers find themselves faced with lawsuits brought in the U.S. on behalf of foreign plaintiffs for personal injuries supposedly caused by products purchased and consumed overseas.¹ In no small measure, these suits are driven by the glittering allure of punitive damages and contingency fee arrangements — two unique attributes of the U.S. legal system. (See “A Look Into The

Migratory Tort Phenomenon,” *supra*, at 4.) Recognizing that claims by foreign plaintiffs often bear little connection to the U.S., defendants and U.S. courts have come to rely heavily on the doctrine of *forum non conveniens* in disposing of these matters. One recent, high-profile example of this phenomenon is a suit against Merck and its U.K. subsidiary brought by U.K. citizens in New Jersey state court involving Vioxx.²

In this case, U.K. and U.S. plaintiffs brought suit against Merck claiming personal injuries arising from their use of Vioxx. Merck moved for dismissal of the U.K. plaintiffs on grounds of *forum non conveniens*, asserting that the United Kingdom, rather than New Jersey, was the most appropriate forum for their claims. *Id.*

Adequacy of U.K. As Alternative Forum

The court first addressed the threshold question of whether the United Kingdom was an adequate alternative forum for the litigation of the U.K. plaintiffs’ products liability claims. *Id.* at *2. In doing so, the Court noted that it “need only find that the [U.K.] is available and adequate” to address plaintiffs’ claims — not that the law of the U.K. was “more favorable, or even equally favorable” to that of New Jersey. *Id.*

Plaintiffs asserted that the U.K.’s “loser pays” rule and its prohibition of contingency fees constituted a *de facto* bar to running their claims in that jurisdiction. *Id.* at *3. They also contended that the U.K. could not provide an adequate remedy for their injuries, since U.K. law does not recognize claims for loss of consortium or punitive damages. *Id.* Merck argued that the U.K. was an adequate alternative forum not only because it permits pharmaceutical products liability claims and recognizes “wrongful death and survivor actions,” but also because both Merck and its U.K. subsidiary were amenable to suit in the U.K. *Id.* at *2-4.

The court rejected plaintiffs’ contentions, noting that U.K.

¹ This subject was recently discussed at length in an article by Chadbourne & Parke LLP attorney Phoebe A. Wilkinson. See “Should Foreign Plaintiffs’ Personal Injury Suits Be Litigated in U.S. Courts?,” *Law.com* (July 12, 2006) at <http://www.chadbourne.com/publications/index.html>.

² Similar claims were also advanced by French and Italian plaintiffs in the Vioxx federal multi-district litigation. See *In re: Vioxx Prods. Liab. Litig.*, MDL No. 1657, 2006 WL 2504353 (E.D. La. Aug. 30, 2006). An Eastern District of Louisiana Judge dismissed these claims on grounds of *forum non conveniens*. *Id.*

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“loser pays” rule was equally applicable to both parties, and more importantly that the U.K. litigation fee structure had no bearing on the adequacy of available remedies. *Id.* at *4. As for plaintiffs’ stated desire to pursue claims for loss of consortium and punitive damages, the court reasoned that the nature of the particular remedies available to plaintiffs was immaterial to the *forum non conveniens* analysis, provided that plaintiffs could maintain an action. *Id.* at *4-5. In concluding that the U.K. was an available and adequate alternative forum, the court relied, and expressly made its dismissal contingent upon, Merck’s (a) willingness to waive any jurisdictional defenses it might otherwise have to a U.K. action, and (b) agreement “to satisfy any final judgment rendered by the [U.K.] court.” *Id.* at *4.

Public Interest Factors Weighed in Favor of Dismissal

After establishing the availability of an adequate, alternative forum, the court next turned to the question of whether the constellation of public and private factors raised by the litigation weighed in favor of dismissal.

In assessing the private interests, the court recognized that critical documents and witnesses were located in both forums — with witnesses and evidence relating to liability centered principally in New Jersey, and the medical evidence (*e.g.*, doctors, medical records, etc.) centered in the U.K. *Id.* Concluding that the burdens of conducting the litigation in either venue were evenly balanced, the court turned to the question of whether the public interest favored retention of the U.K. plaintiffs’ claims.

In support of remaining in a U.S. court, plaintiffs asserted that New Jersey had a “strong[] interest in preventing its companies from marketing defective products,” and argued that the punitive damages remedy was necessary to effectuate this purpose. While accepting this argument as “absolutely true,” the court nevertheless concluded that this interest would be adequately protected by the remaining 15,000 or so Vioxx claims filed by U.S. plaintiffs in New Jersey, meaning that “the New Jersey court system will have plenty of opportunity to deter Defendant from future unsavory conduct if Defendant is found to be liable regarding the allegations against it.” *Id.*

Rejecting plaintiffs’ contention that New Jersey’s interest in

“preventing its companies from marketing defective products” was stronger than any interest the “U.K. might have in . . . protecting its citizens,” the Court held that the U.K. had a “significant interest in addressing the injuries of its citizens and adjudicating matters regarding products regulated and marketed within its borders,” which might well be undermined by “imposing an American view upon the judgment of a foreign country.” *Id.* More to the point, it found:

In the matter before this court it would be very difficult for a New Jersey jury to make adequate determinations regarding the appropriateness of warnings and the appropriate level of risk because medical practices, custom, usage, and other factors will differ in a foreign country. While the jury could be instructed on the practices of regulating drugs in the U.K., an American jury would likely still have difficulty evaluating whether a warning was reasonable and adequate in another country. Not only the regulations regarding medicines, but also the nature of the relationship between patient and doctor and pharmacist are all dependent on community cultural differences.

Id. at *8.

A final public interest factor weighing in favor of dismissal was the burden that litigation of the U.K. claims would place on the New Jersey court system, which the court deemed wholly “unnecessary . . . since a foreign country’s courts can do a better job of interpreting their own laws and protecting their citizens.” *Id.* at *10. ☉

INTERNATIONAL LAW

A Look Into The Migratory Tort Phenomenon

Why have some British claimants decided to seek redress against Merck and other claimed tort-feasors “across the pond” in the U.S., rather than in the U.K.? Apparently for the simple reason offered by claimants’ counsel that successfully pursuing claims against manufacturers in the U.K. is more difficult than pursuing those claims in the U.S.

The U.K. legal system differs from that in the U.S. in several important respects. According to British claimants’ counsel, these

differences result in a regime that not only makes it challenging for plaintiffs to commence and maintain products liability lawsuits (including mass tort claims), but significantly raises the stakes should they lose. As a consequence, U.K. claimants are seeking access to what they perceive is the generally more plaintiff-friendly U.S. legal system — where contingency fees, class actions, and uniquely large damage awards (including punitives) abound.

Lack of Funding and “Loser Pays” Rule

Importantly, public funding for a product liability action in the U.K. is not readily available. In recent years, amidst budgetary cutbacks and wide-ranging civil procedure reforms, legal aid for civil cases has been severely restricted. Many types of claims — such as those for personal injury (with the exception of medical malpractice) or property damage — are now excluded altogether from the public funding scheme. While traditional contingency fee arrangements do not exist in the U.K., lawyers there may represent clients on the more limited basis of Conditional Fee Agreements (CFAs). However, because a successful U.K. litigant is entitled to recover costs, including attorney fees, from the losing party (i.e., “loser pays”), an unsuccessful plaintiff remains liable for the opposing party’s costs even under a CFA.

Modest Damage Awards and Limited Class Action Regime

Another factor behind the flight of U.K. (and other overseas) plaintiffs to U.S. courts is the prospect of compensatory damage awards much larger than those generally dispensed by U.K. judges, as well as the availability of punitive damages. The absence of a jury system in most U.K. civil cases means that the court before whom the case is tried is less likely to be swayed by emotion or sympathy in setting damage awards that are typically rather modest. What is more, exemplary damages tend to be awarded only in rare circumstances.

England does not have a class action system akin to the U.S. model. Instead, more limited multi-party procedural devices, known as Group Litigation Orders (GLO) and representative actions, are favored. The GLO scheme, covering claims that raise “common or related issues of fact or law,” was introduced in 2000 after an extensive debate involving considerations of policy and fairness. One of the main differences between the U.S. class action system and U.K. GLOs is that the latter is an “opt-in,” rather

than “opt-out,” regime — meaning that litigants are named and must affirmatively choose to be a party to the proceedings by issuing an individual claim. Thereafter, all individual cases are stayed while one or more test cases proceed to trial, with the findings serving as collateral estoppel in the stayed cases.

The U.K.’s reservations about the “excesses” of the U.S.-style class action are, for the most part, shared by the majority of EU jurisdictions. Nevertheless, more recently there have been signs of change on the horizon. For example, in 2002, the Swedish legislature passed a measure permitting group actions in civil cases or matters relating to damages under the Environmental Code. Also, in January 2005, France’s President announced plans to introduce a U.S.-style class action system allowing consumer groups to obtain redress against wrongful market practices. A government task force was convened to analyze the subject and its proposed draft bill is currently under consideration.

Summary

Whether U.K. claimants will be permitted to forum shop in the U.S. or, indeed, in other European countries, remains to be seen, but clearly the present U.K. legal framework — where the risk of a large cost bill must be weighed against a potentially moderate damages award — is not as attractive a forum draw for some U.K. claimants as the U.S. ☺

WARNINGS

Michigan Supreme Court Rejects Plaintiff’s Effort to Subdivide Concept of “Obvious Material Risk” As End-Run of Tort Reform Law

See Greene v. A.P. Products, Inc., ___ N.W.2d ___, 2006 WL 2022254 (Mich. 2006)

A Michigan case involving the tragic death of a toddler after swallowing a bottle of his mother’s hair and body moisturizer demonstrates that the obviousness of a particular risk often lies in the eye of the beholder.

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Warnings

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Plaintiff Claims Need For Specific Warnings About All Material Risks

The warning label at issue in *Greene* cautioned users against spraying the hair oil near an open flame, but did not mention either that the product could be toxic if swallowed or that it should be kept from the reach of children. Following her son's death by "inflammatory respiratory failure" after drinking her moisturizer, plaintiff brought suit arguing that the product was defectively labeled because it did not specifically mention the risk of death associated with inhalation or ingestion of the moisturizer (which, plaintiff stressed, was actually promoted as containing "natural oils"). *Id.* at *1.

Finding that the risk of death was an obvious material risk, the trial court granted the manufacturer summary judgment under Michigan's tort reform statute. The intermediate appellate court reversed, finding that it could not conclude that "the risk of death" from ingesting the product, as distinct from "the risk of possibly becoming ill," was obvious as a matter of law; it held that the warning had to "indicate specific injuries a product user could incur." *Greene v. A.P. Products, Inc.*, 264 Mich. App. 391, 401 (2005).

Material Risks Associated with the Ingestion of Oils Are Obvious

The Michigan Supreme Court reversed and reinstated the trial court's summary judgment order. Turning to the language of Michigan's 1995 tort reform statute, which provides that a defendant "is not liable for failure to warn of a material risk that is or should be obvious to a reasonably prudent product user," the court held:

[D]efendants owed no duty to warn of specific injuries or losses, no matter how severe, if it is or should have been obvious to a reasonably prudent product user that ingesting or inhaling Wonder 8 Hair Oil involved a material risk. We conclude that it is obvious to a reasonably prudent user that a material risk is involved with ingesting and inhaling Wonder 8 Hair Oil.

Id. at *3. Dismissing plaintiff's claimed reliance on the fact that the product supposedly contained "natural oils," the court further reasoned:

Many, if not all, oils are natural. It should be obvious to a reasonably prudent user that many oils, although natural, pose a material risk if ingested or inhaled. For instance, the reasonably prudent person would know that breathing oil would be harmful [and] would also know that ingesting such things as crude oil or linseed oil poses a material risk although such oils are natural and pose no immediate danger from contact with hair or skin. *Id.*

A Rebuke of Judicial Activism

Chastising one of the dissenters (who charged the majority with "erroneously concluding that the obviousness of *one* risk means the obviousness of *all* risks") for mischaracterizing its holding, the court stressed that its ruling was "entirely consistent with the plain language of the statute," and, further, that "[t]he rule must and should be that a court applies the statute as written," not as a court would have itself written the statute. *Id.* at *4-*5 (emphasis in original). ☺

MEDICAL MONITORING

Oregon Appellate Court Rejects Medical Monitoring Claim

See Lowe v. Philip Morris USA, Inc., 142 P.3d 1079 (Or. App. 2006)

Since at least the mid-1980's, plaintiffs have been using medical monitoring claims to expand traditional principles of tort law by seeking recovery in product exposure cases even where the cornerstone elements of that law — namely, causation and injury — do not exist. To date, approximately 30 courts have weighed in on the "medical monitoring" issue, with cases almost evenly divided on whether medical monitoring claims are inconsistent with tort law's physical injury requirement. A recent appellate decision from Oregon provides a good general overview of the history of medical monitoring litigation before ultimately rejecting such a claim for lack of actual injury.

Risk of Future Disease Not a Cognizable Injury

In *Lowe v. Philip Morris USA, Inc.*, a putative class action plaintiff did not claim any current physical injury from her long-term

use of cigarettes. Instead, she alleged that her cumulative exposure to cigarette smoke had increased her risk of developing lung cancer in the future, and that this risk created a current need for medical monitoring (as well as smoking cessation treatment), which she claimed defendant cigarette manufacturers should fund. *Id.* at 1080. Finding that plaintiffs' lone negligence claim did not allege a cognizable present injury, as required by Oregon law, the trial court dismissed the complaint. *Id.* at 1081.

In a case of first impression, Oregon's Court of Appeals affirmed. The court began with a primer summarizing the line of cases recognizing medical monitoring claims as an exception to the physical injury requirement. *Id.* at 1082-84. In a nutshell, certain courts have concluded that the increased risk of harm itself constitutes an "injury" sufficient to establish liability, while most other courts recognizing such a claim have found that the need for treatment, occasioned by increased risk, is the "injury," although not a physical one, supporting liability for medical monitoring purposes. *Id.* at 1083 (citing cases). The *Lowe* court also noted that the viability of a medical monitoring claim in some cases has depended upon the extent of the increase in the alleged risk, in others on the "reasonably certain" need for medical monitoring, and in another group on the existence of medical tests making early detection and treatment possible. *Id.* at 1083-84 (citing cases).

Fundamental Negligence Principles Require Actual Injury

For its part, the Oregon court found the plaintiff's allegation of a mere increase in the possibility of future harm was irreconcilable with the fundamental premise of Oregon negligence law that a viable claim requires actual physical harm. *Id.* at 1089. Oregon does recognize tort claims that are, in effect, exceptions to the physical injury rule, such as claims for infliction of emotional distress and for purely economic loss. *Lowe's* claim, however, did not fall within these exceptions (and therefore failed as a matter of law), since she did not allege an "actual, present — even nonphysical — injury," grounding her claim instead on "only an allegation of the *possibility* of future harm." *Id.* at 1091 (emphasis in original). The court left "for another day," however, the question of whether a medical monitoring claim predicated upon different allegations might be cognizable under Oregon law. *Id.* at 1092-93. ©

DAMAGES

Seeing No Redundancy, Louisiana Supreme Court Endorses Recovery of Hedonic Damages In Addition to Pain and Suffering

See McGee v. A C & S, Inc., 933 So.2d 770, 772 (La. 2006)

In a split decision, the Louisiana Supreme Court has held that damages for loss of enjoyment of life — sometimes called hedonic damages — are recoverable as a distinct element of general damages, separate from pain and suffering, on a jury verdict form.

Plaintiffs in *McGee* filed a wrongful death and survival action for personal injuries against several defendants alleging that they had manufactured, or maintained workplaces containing, asbestos. *Id.* at 773. Defendants moved *in limine* to preclude any recovery for "loss of enjoyment of life" on the basis that it is "part of [a] general damage award" and not a "separate category of damages." *Id.* The trial court denied defendants' motion, the intermediate appellate court reversed, and the Louisiana Supreme Court reversed — reinstating the trial court's *in limine* ruling.

Majority Splits Hairs

The majority began by defining compensatory damages as "those damages designed to place the plaintiff in the position in which he would have been if the tort had not been committed." *Id.* at 774. It then divided compensatory damages into two parts, consisting of (a) special damages characterized by a readily determinable dollar value, such as hospital bills and lost wages; and (b) general damages, which "are inherently speculative and cannot be calculated with mathematical certainty," such as "mental and physical pain and suffering, inconvenience, *the loss of gratification of intellectual or physical enjoyment, and other losses of life or life-style* which cannot really be measured definitively in terms of money." *Id.* (emphasis added).

From this foundation, the majority reasoned that hedonic damages were "conceptually distinct from other components of general damages, including pain and suffering." *Id.* at 775. Illustrating the distinction, it described how the same injury

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Damages

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might adversely affect an athlete's enjoyment of life and lifestyle more so than it might an artist's if, for instance, the injury meant the athlete could no longer play her sport, whereas the artist could continue to pursue artistic endeavors (notwithstanding the injury). Under this scenario, the court reasoned that the athlete is damaged "well beyond the mental anguish . . . because now the athlete is forced to drastically alter his lifestyle as a result of his accident," meaning that "a separate award for loss of enjoyment of life is warranted and is not duplicative of the award of pain and suffering." *Id.* at 775-6.¹

Dissenters Warn of Double Recovery

McGee drew two dissenting opinions, both of which highlighted the danger of double recovery behind a rule allowing separate entries on verdict forms for pain and suffering as well as lost enjoyment of life.

Justice Victory began his dissent by noting that "hedonic damages" were of a relatively recent vintage, first appearing in the economic literature in the 1980s, and had not been analyzed as a separate element of damages by any Louisiana appellate court until 1987. *Id.* at 781 (noting that the "traditional Louisiana approach was to include such 'hedonic damages' within the broader scope of a unified damages award, which extends to such non-pecuniary issues as 'pain and suffering' and 'loss of gratification'"). He noted that "the majority of state courts have held that hedonic damages are included in general damages such as pain and suffering, mental anguish, and physical impairment, and may not be considered as a separate element of general damages." *Id.* at 781 & n.2 (citing cases, including California and New York).

Explaining the rationale behind the majority rule, Justice Victory wrote that the "delicate balance" between "making a victim whole" and "avoiding the inequitable outcome of the injured party securing a 'double recovery' for a single element of harm" would be upset if hedonic damages were listed as a

separate item on a jury form. *Id.* at 782-83. In his view, "[t]he inability to enjoy certain things that were once enjoyed is almost always part of mental pain and suffering, which is already routinely awarded by judges and juries as a separate item of general damages," and allowing a separate award for hedonic damages . . . sets a dangerous stage for double recovery of damages." *Id.* at 783-784.

Justice Weimer dissented on the basis of his belief that "'pain' and 'pleasure' are merely two sides of the same coin, making an award for pain the equivalent of an award for loss of pleasure." *Id.* at 785. While recognizing a theoretical distinction between these two forms of damages, Justice Weimer deemed it one that was "far too fine a distinction to observe practically," and would enable a plaintiff to be "potentially compensated for the same deprivation twice." *Id.*

His more "practical solution" was to allow jury verdict forms to "have a line for loss of enjoyment of life OR a line for mental pain and suffering, but not both. In the alternative, the jury verdict form could include a single line for loss of enjoyment of life AND mental pain and suffering, which would serve the purpose of allowing the jury to consider both components of general damages without having to draw a fine line distinguishing between the two." *Id.* at 785 (emphasis in original).

On balance, however, Justice Victory's approach seems preferable, since Justice Weimer's "alternative" approach arguably runs the same risk of double recovery inherent to the majority's decision — albeit on a single verdict line, as opposed to two. ©

PREEMPTION

Preemptive Effect Owed FDA Pharmaceutical Labeling Rule Generates Debate

See McNellis v. Pfizer, Inc., No. Civ. 05-1286, 2006 WL 2819046 (D.N.J. Sep. 29, 2006); *Ackerman v. Wyeth Pharm.*, No. 4:05 CV84, 2006 WL 2591078 (E.D. Tex. Sep. 8, 2006); *Levine v. Wyeth*, No. 2004-384, 2006 WL30 41078 (Vt. Oct. 27, 2006)

In July, we reported on recent case law developing around the preemptive effect of the Food and Drug Administration's

¹ The majority holding did limit a claim for loss of enjoyment of life to decedent's loss of enjoyment of life during his lifetime under the survival action, and precluded plaintiffs from asserting their own loss of enjoyment of life claims as a result of their reaction to decedent's illness, and eventual death. *Id.* at 780.

("FDA") 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"). See "FDA Approval of Pharmaceutical Labeling Preempts Warning Claims," *In Re Products Liability* at 8 (July 2006). Since then, additional courts have added divergent views to the mix on the preemptive effect of the FDA's labeling regulations, creating a split of authority. Three of those cases are addressed briefly here: *McNellis*, from the District of New Jersey; *Levine* from the Vermont Supreme Court; and *Ackerman* in the Eastern District of Texas.

McNellis and Levine Declare FDA Rulemaking a Floor, Not Ceiling

McNellis involved claims that Pfizer failed to warn decedent's physician of the risk of suicide associated with the use of its anti-depressant Zoloft, allegedly leading to decedent's suicide. *McNellis v. Pfizer, Inc.*, 2006 WL 2819046 at *1. The *McNellis* court initially denied Pfizer's summary judgment motion in December 2005, finding the warning claim not preempted because FDA regulations permitted pharmaceutical manufacturers to strengthen warning labels without regulatory pre-approval. *Id.* at *6 (citations omitted). Pfizer moved to vacate this ruling, citing the subsequently issued Preamble to the Final Rule, which provides that state laws "conflict with and stand as an obstacle to . . . Federal law when they purport to compel a firm to include in labeling or advertising a statement that the FDA has considered and found unsubstantiated." *Id.* at *4 (quoting 71 Fed. Reg. at 3935).

Notwithstanding this development, the court reaffirmed its reasoning that FDA regulations permit a manufacturer to "change the labeling of a drug in order to add or strengthen a contraindication, warning, precaution or adverse reaction." *Id.* at *7 (citations omitted). It explained that FDA regulations still place "an affirmative duty upon drug manufacturers to revise a drug's label to include a warning as soon as there is reasonable evidence or an association of serious hazard with a drug." *Id.* (internal quotation omitted). The court gave "less deference" to the FDA's interpretation of the Final Rule (as expressed in the Preamble) because it found that interpretation inconsistent with the FDA's position regarding the same regulations when they were initially proposed in December 2000, which "explicitly

stated that its regulations *do not* have preemptive effect." *Id.* at *8 (emphasis in original). An additional analytical consideration was the fact that the 2006 Preamble, which the court said "invert[ed]" the FDA's philosophy regarding preemption, was not subjected to prior public notice or comment. *Id.* at *9. However, acknowledging the "numerous conflicting opinions" regarding the Preamble's preemptive effect, the court certified its decision for interlocutory appeal to the Third Circuit. *Id.* at **11-12 (citing cases).

In *Levine v. Wyeth*, the Vermont Supreme Court rejected Wyeth's contention that the Final Rule preempted an inadequate warning claim regarding intravenous injection or "IV push" administration of Wyeth's Phenergan product. Similar to *McNellis*, the *Levine* court concluded that the Preamble merited no judicial deference, on the basis that it did not alter the underlying regulatory framework for prescription drug labeling that allows manufacturers to add to or strengthen a warning label without prior FDA approval. 2006 WL30 41078, ¶ at 32.

In reaching this conclusion, the *Levine* 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." *Id.* at ¶ 32. Because "federal labeling requirements create a floor, not a ceiling, for state regulation," *id.* at ¶ 6, and because, in the court's view, 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.

Ackerman Finds Preemptive Effect Necessary To Avoid Confusing Mosaic

Conversely, in *Ackerman v. Wyeth Pharm.*, a federal district judge in Texas concluded that plaintiff's failure to warn claims regarding Effexor, a serotonin re-uptake inhibitor, were preempted. 2006 WL 2591078 at *7 (Report and Recommendation). Though other courts within the Fifth Circuit previously found that state law warning claims were not preempted, they were, as the *Ackerman* court noted, without the benefit of the FDA's current "affirmative statements" regarding preemption as expressed in the Preamble. *Id.* at **6-7. Acknowledging that the issue is a "close question," the mag-

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Preemption

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istrate judge recommended that “absent some evidence that a drug manufacturer misled the FDA or failed to disclose critical information, preemption should apply in a failure-to-warn case.” *Id.* at *7. Otherwise, to permit different labeling standards in different states “promotes confusion not only for the manufacturers but also the consumers” and “offers the potential for far more harm than benefit to patients.” *Id.* ☉

Federal Doctrine of Conflict Preemption Bars Claim That Cigarettes Are “Unreasonably Dangerous Per Se”

See *Badon v. R.J. Reynolds Tobacco Co., et al.*, 934 So. 2d 927 (Ct. App. La., 3d Cir. 2006)

A Louisiana appellate court rejected — as impliedly preempted — a plaintiff’s effort to impose the equivalent of absolute or categorical liability on cigarette makers under Louisiana’s “unreasonably dangerous *per se*” rule, which was crafted by that state’s Supreme Court twenty years ago in *Halphen v. Johns-Manville Sales Corp.*, 484 So.2d 110, 118 (La. 1986).

Liability Claim Grounded on Product’s Intrinsic Characteristics

Alleging that her throat cancer was the result of her consumption of cigarettes manufactured by several cigarette manufacturers, plaintiff in *Badon* argued that defendants were liable for her injuries under the “unreasonably dangerous *per se*” theory of liability, based on the intrinsic characteristics of cigarettes. *Id.* at 932. As the trial court rather bluntly framed the issue, plaintiff’s argument was “they’re selling [cigarettes,] I smoked[,] and [I’m] dying.” *Id.* at 933.

Affirming the trial court’s dismissal of plaintiff’s claims on summary judgment, the intermediate appellate court held that an “unreasonably dangerous *per se*” theory of liability against cigarette manufacturers is impliedly preempted “because a ruling that cigarettes are unreasonably dangerous *per se* would have the effect of imposing a ban on the manu-

facture/sale of cigarettes where Congress has not enacted a ban.” *Id.* at 934. More specifically, it said, “[w]hat preempts [plaintiff’s] claim is Congress’s considered decision that the sale of cigarettes is not only not illegal but part of a market the government supports.” *Id.*

State Law Cannot Be Used to Ban Product

Cutting through plaintiff’s contention that “the fact that the defendants may be found liable for [the manufacture and sale of a cigarettes] does not equate to a ban on the marketing of their product,” the court explained:

Indeed, if Ms. Badon succeeds in proving the unreasonably dangerous *per se* character of cigarettes, she will have established a precedent for liability that cigarette manufacturers can avoid only by taking the product off the market. Thus, [plaintiff] will have effectively utilized Louisiana law to ban the sale of cigarettes in this state, in contravention of congressional policy foreclosing the removal of tobacco products from the market. Thus, the doctrine of federal conflict preemption applies. *Id.* at 934. ☉

EMERGING TRENDS

Uncharted Products Liability Waters: Nanotechnology

An emerging issue to watch on the products liability horizon relates to the appearance of nanotechnology-based food and other consumer products on the marketplace. Like “genetically modified,” the word “nanotechnology” is likely to become a buzzword for various public interest groups, not to mention the plaintiff’s bar. Already, the commercialization of nanotechnology is estimated to represent “a \$410 million sliver of the \$3 trillion global food market.” *See The New York Times*, at C-2 (Oct. 10, 2006). While manufacturers are generally proceeding somewhat cautiously, nanotechnology is already being employed in the areas of food processing, ingredients and additives, and packaging.

Nanotechnology in a Nutshell

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 one sheet

of paper being roughly 100,000 nanometers thick). Consumer goods, pharmaceuticals, cosmetics and food manufacturers are all expected in the coming years to increase dramatically their use of nanomaterials and nanotechnology in bringing products to market.

The widespread manufacture and distribution of goods containing such very small particles raises a host of possible health-related allegations. For example, since nanomaterials are similar in size to human cellular components and larger proteins, the smallest nanomaterials may be carried by inhalation into the human nervous system, ultimately lodging within intricate human brain structures. Scientists also theorize that nanomaterials in foodstuffs might diffuse through the gastrointestinal system, lodging throughout the human body, and that nanomaterials in cosmetics and lotions might penetrate various layers of the skin. Some researchers even theorize that these very small particles could eventually disrupt genetic processes and cause neurotoxicity.

Whether and to what extent the use of nanotechnology has the potential to produce physical injury is currently the subject of intense study and debate by various business, government and academic groups. On September 20, 2006, the National Nanotechnology Initiative (“NNI”), a program of the United States National Science and Technology Council involving 25 federal agencies published a 63-page report entitled *Environmental, Health and Safety Research Needs for Engineered Nanoscale Materials*.¹ Top priorities noted in the report include such basic prerequisites for meaningful research as reaching agreement on definitions, terminology and nomenclature as well as standards for future research of the possible health ramifications of nanotechnology. As noted in the recent NNI report, “novel properties exhibited by engineered nanoscale materials not only enable new benefits *but also may lead to unintended health and environmental risks.*”²

¹ See www.nano.gov/NNI_EHS_research_needs.pdf (accessed November 10, 2006).

² See www.nano.gov/NNI_EHS_research_needs.pdf (PDF page 17) (accessed November 10, 2006).

³ The FDA also permits its use as a colorant in foods. 21 CFR § 73.575(c).

⁴ See <http://www.fda.gov/nanotechnology/meetings/berube.html> (accessed November 10, 2006).

⁵ See <http://www.icta.org/doc/Nano%20FDA%20petition%20final.pdf>, p. 3. (accessed November 10, 2006).

The Example of Nanotechnology and Sunscreen

Titanium dioxide was perhaps the first nanotechnology-based product widely marketed to consumers. It had been used for decades as an essential pigment in white paint.³ When engineered into nanoparticles, however, it was discovered that titanium dioxide becomes transparent yet blocks ultraviolet light, eventually leading to its use as a main ingredient in popular sunscreens since the 1990s. Some of these sunscreens were marketed as alternatives for people who experienced irritation from traditional sunscreen ingredients.

So far, despite millions of individual applications for more than a decade, there have been no publicized reports of injuries possibly stemming from this commercial application of nanotechnology. Nonetheless, at the FDA’s Public Meeting on Nanotechnology Materials held on October 10, 2006, representatives of various interest groups — such as Friends of the Earth and the Cosmetic, Toiletry and Fragrance Association — vigorously debated whether nanoparticles of titanium dioxide used in sunscreen pose special health risks⁴. The meeting related to a petition filed by the International Center for Technology Assessment seeking, among other things, to have the FDA declare sunscreens containing nano-sized titanium dioxide “an imminent hazard to public health” and remove them from the market.⁵

A Caution

Growing use of nanotechnology in different products across many industries, together with still embryonic scientific and policy efforts aimed at reaching consensus on potential health risks, means that a regulatory framework in this area may take awhile to develop. This is hardly cause for relief, however.

As the breast implant litigation of the 1990s attests, mass tort claims are somewhat *sui generis*, and those who engineer and advocate such claims are often successful in convincing courts to lead science — notwithstanding the better view that the “[l]aw lags science; it does not lead it.” *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996). In the meantime, consumer products manufacturers expecting to utilize nanotechnology would do well to approach the issue cautiously, under the umbrella of an overarching strategy for minimizing products liability exposure as much as possible. ©

Et cetera

Speaking Engagements:

- On April 21, 2006, Gregory M. Loss spoke on the topic of “Challenges of World-Wide Pharmaceutical Law Suits,” at the Pharmaceutical Regulation and Product Liability Conference, sponsored by the British Institute of International and Comparative Law, held in London, England.
- On September 14, 2006, Mary T. Yelenick moderated a panel discussion entitled “Getting Up and Running When Trouble Hits,” — or, what to do when a company is confronted with mass product liability lawsuits, at the ABA Women in Products Liability Conference, held in Las Vegas, Nevada.
- On October 12, 2006, David L. Wallace and Philip A. Pfeffer delivered a presentation entitled “The RICO Racket: Plaintiffs Having ‘Fun with Fraud’ and Products,” regarding the expanded use of the RICO statute in products liability litigation, at the Annual Meeting of the Defense Research Institute (DRI), in San Francisco, CA.
- On October 12-13, 2006, Gregory M. Loss spoke on the topic of “U.S. Litigation Trends and Drug Liability Developments” at C5’s 7th Forum on Product Liability in the Pharmaceutical Industry, held in Munich, Germany.
- On October 27, 2006, Gretchen N. Werwaiss moderated a luncheon discussion on mass tort and medical monitoring class actions, at the 10th Annual National Institute on Class Actions, held at the Millennium Hotel in New York, NY.
- On November 16, 2006, Phoebe A. Wilkinson moderated a panel discussion on “The Increasing Attempts to Use U.S. Courts by Foreign Plaintiffs” at the ABA Section of Litigation Product Liability Committee Pharmaceutical Regional CLE workshop, held at Schering-Plough Corporation in Kenilworth, New Jersey.
- On January 30, 2007, Philip P. Pfeffer and Lawrence E. Savell will be presenting on “Transcript Management Technology for Competitive Edge,” at ALM’s Legal Technology Conference at the Hilton Hotel in New York, NY.
- On February 26-27, 2007, Gregory M. Loss and Phoebe A. Wilkinson will be presenting on “Hot Areas and Current Trends in U.S. Litigation,” at a C5 Conference regarding “Legal, Commercial and Regulatory Aspects of Medical Devices,” in Munich, Germany.

To find out more about these events, and register online, please visit Chadbourne’s News & Events online at <http://www.chadbourne.com/news/index.html>

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