

In re Products Liability

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PUNITIVE DAMAGES

U.S. Supreme Court Says Jurors May Not Use “Reprehensibility” To Punish Defendants For Harm To Non-Parties

— Leaves Procedural Safeguards To Laboratory of Lower Courts

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See *Philip Morris U.S.A. v. Williams*, ___ U.S. ___, 2007 WL 505781 (Feb. 20, 2007)

ANALYSIS

In a 5-4 decision, the *Williams* court held that a punitive damages award based “in part upon the desire to punish the defendant for harming persons who are not before the court (*e.g.*, victims whom the parties do not represent)” constitutes “an unconstitutional taking of ‘property’ from the defendant without due process.”¹ It remanded to the Oregon Supreme Court with instructions that it develop and impose the procedural safeguards necessary to avoid “an unreasonable and unnecessary risk” of juries asking themselves “the wrong question” and using the “reprehensibility” analysis to punish defendants for injuries to non-parties.

Background

An Oregon jury found Philip Morris responsible for the death of a smoker named Jesse Williams, and

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¹ Page citations are not yet available for this opinion.

Punitive Damages

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awarded his wife \$79.5 million in punitive damages, and \$821,000 in compensatory damages, for the company's alleged deceit in marketing cigarettes. The trial court declared the punitive damages award excessive and reduced it to \$32 million. After the Oregon Court of Appeals restored the \$79.5 million award, Philip Morris unsuccessfully sought review by the Oregon Supreme Court, and then won review in the U.S. Supreme Court, which remanded for reconsideration in light of *State Farm Mut. Automobile Ins. Co. v. Campbell*, 538 U.S. 408 (2003). On remand, the Oregon Court of Appeals refused to budge, finding the original punitive verdict of \$79.5 million constitutionally permissible notwithstanding *State Farm*.

Thereafter, in the Oregon Supreme Court, Philip Morris argued that: (i) the trial court erred by failing to instruct the jury that they "could not seek to punish Philip Morris for injury to other persons not before the court," and (ii) the roughly 100-to-1 ratio between punitive and compensatory damages was "grossly excessive" and not "reasonably related to the plaintiff's harm." The Oregon Supreme Court rejected both arguments, and the U.S. Supreme Court again granted *certiorari*.

The Majority Holding

In a majority opinion authored by Justice Breyer, the Court recognized that "the Constitution imposes certain limits, in respect both to procedures for awarding punitive damages and to amounts forbidden as 'grossly excessive.'" It declined to decide whether the award in *Williams* was "grossly excessive," however. Instead, the Court addressed only the procedural due process question of whether the failure to instruct the jury that it could not punish Philip Morris for "the impact of its alleged misconduct on other persons" was error. In brief, the Court answered in the affirmative.

More particularly, the Court expressed concern that absent adequate procedural safeguards (*e.g.*, jury instructions, but presumably evidentiary rulings as well), punishment for "potential harm" to non-parties could be imposed under the head of "reprehensibility" despite the fact that a defendant "has no opportunity to defend against the charge."² The Court worried that permitting a jury to punish a defendant "for injuring a nonparty victim . . . would add a near standardless dimension to the punitive damages equation," forcing juries to

"speculate" about issues such as the number of other victims, the seriousness of their injuries, and the circumstances in which they were injured. Referring to its discussion in *State Farm*, 538 U.S. at 424, of the "potential harm" relevant to the reprehensibility guidepost, the Court said "we have made clear that the potential harm at issue [is] harm potentially caused *the plaintiff*." (Emphasis is original.)

While holding that harm to non-parties could not be used to "punish" a defendant, the Court said that "[e]vidence of actual harm to nonparties [nevertheless] can help to show that the conduct that harmed the plaintiff also posed a substantial risk of harm to the general public, and so was particularly reprehensible" — that is, to support the "reprehensibility" part of the constitutional calculus applicable to punitive damages.³ It cautioned, however, that juries should not "go further than this and use a punitive damages verdict to punish a defendant *directly* on account of harms it is alleged to have visited on nonparties." (Emphasis added.)

Ultimately, it was the possibility that the jury in *Williams* asked itself "the wrong question" and punished Philip Morris for injuries to Oregonians other than Jesse Williams that warranted remand of the case to the Oregon Supreme Court for the determination of "some form of protection" and legal guidance against the "unreasonable and unnecessary risk" of juries "taking account of harm caused others under the rubric of reprehensibility." *Id.* (emphasis in original.)

Justice Stevens' Dissent

The *Williams* decision drew three separate dissenting opinions, but Justice Stevens' dissent may have the most impact.⁴

² Philip Morris, for instance, could not show "that the other victim was not entitled to damages because he or she knew that smoking was dangerous or did not rely upon the defendant's statements to the contrary."

³ This seems contrary to the statement in *State Farm* that the only "potential harm" at issue is the "harm potentially caused the plaintiff."

⁴ A dissent authored by Justice Thomas — echoing his (and Justice Scalia's) state's rights views — reiterated his belief that "the Constitution does not constrain the size of punitive damages awards." See Thomas Dissent (quoting *State Farm*, 538 U.S. at 429-30). Justice Ginsburg's dissent, joined by Justice Scalia and Justice Thomas, focused on how the Oregon courts complied with what the majority was mandating: a charge to the jury that it could consider evidence of harm to other Oregonians for reprehensibility purposes. In addition, Justice Ginsburg's dissent criticized Philip Morris's proposed charge for "confus[ing]" rather than "enlighten[ing]" the questions of how a jury could (and could not) consider evidence of harms to non-parties when assessing punitive damages.

He identified conceptual difficulties with the majority's approach, namely its reliance:

on a distinction between taking third-party harm into account in order to assess the reprehensibility of the defendant's conduct — which is permitted — from doing so in order to punish the defendant — which is forbidden. . . . This nuance eludes me. *When a jury increases a punitive damages award because injuries to third parties enhanced the reprehensibility of the defendant's conduct, the jury is by definition punishing the defendant's conduct — directly — for third-party harm.* (Emphasis added.)

In Justice Stevens' view (and the dissenters generally), a jury that considers harm to non-parties, and then decides a defendant should pay more in punitive damages than otherwise might have been the case — because such harm demonstrates greater reprehensibility — is unavoidably “punishing” a defendant for injuries to non-parties.

The Likely Impact Of the *Williams* Decision

How lower courts will ensure that their procedures do not “create an unreasonable and unnecessary risk” that juries will “punish” for harm to non-parties remains to be seen. *Williams* only requires that “some” procedural safeguards prevent this outcome; it did not mandate exactly what “kind” of procedures would do the job. Plus, even if juries are instructed in ways that satisfy procedural due process, it remains to be seen whether these instructions will ultimately lead to lower punitive damages.

Only time, and yet more “reprehensibility” litigation, will tell.

COMMENT

Is It Time Yet For An Alternative Approach to Punitive Damages?

While bench and bar were looking to *Williams* for a clear-cut legal rule — something to cling to in the storm — the Court instead opted for an incremental approach to the hazard of the “reprehensibility” guidepost, somewhat in deference to principles of federalism.

In the end, *Williams* fails to provide any bright-line rule.

Regarding the “reprehensibility” inquiry, it basically directs the Oregon Supreme Court to provide “some form of protection in appropriate cases,” but not to “authorize procedures that create an unreasonable and unnecessary risk of any [jury] confusion” — essentially to “make sure [jurors] ask the right question.” A beacon has been illuminated, but it's down to the state courts to chart a course through the constitutional shoals.

It may be that the continuing confusion wrought by the “reprehensibility” guidepost regarding potential harm to “others” requires its abandonment. All the more so given the *State Farm* quote dug out by Justice Breyer for the majority opinion in *Williams* to the effect that the only constitutionally relevant “potential harm” falling for jury consideration on punitive damages under the “reprehensibility” standard is the “harm potentially caused *the plaintiff*.” *Williams* Majority Op. (citing *State Farm*, 549 U.S. at 424) (emphasis in original).

In short, if the only relevant “potential harm” for “reprehensibility” purposes is that to which plaintiff was subjected, why bother with the plainly confusing business of “others” at all? No matter the instructions ultimately given “to provide assurance that juries are not asking the wrong question, *i.e.*, seeking not simply to determine reprehensibility, but also to punish for harm caused strangers,” principle and practice suggest that looking at potential harm to “others” cannot but lead in some cases (probably most) not only to higher punitive damage awards requiring subsequent judicial review, but also to application of the complex, often vexing, constitutional mechanics of punitive damages: calibration and adjustment for “reprehensibility,” “reasonable relationships,” and “excessiveness” (filtering what “shocks the conscience”).

Perhaps the law of punitive damages might be generally simplified and reformed by borrowing the example of the antitrust and RICO statutes, among others. Give plaintiffs the right to recover trebled damages on proof of certain aggravating factors (*i.e.*, egregiousness) by clear and convincing proof. Such an approach would also seem a more direct way of arriving at already agreed constitutionally permissive punitive/compensatory damage ratios of single digits (by simply tripling compensatory damages in certain circumstances, rather than analyzing ratios for reasonableness and the like). [DLW] ©

Ninth Circuit Announces Discovery of “Realms” Around BMW v. Gore “Reprehensibility” Guidepost

See *In re Exxon Valdez*, 472 F.3d 600 (9th Cir. Dec. 22, 2006)

On its third review of the punitive damages award against Exxon Mobil Corporation arising from the spilling of 11 million gallons of crude oil by the supertanker Exxon Valdez off the coast of Alaska in 1989, the Ninth Circuit held that a 5:1 punitive/compensatory damages ratio comported with constitutional due process requirements. As in *Williams, supra*, reprehensibility was the sticking point.

“Reprehensibility” Analysis

On *de novo* review of the jury’s \$4.5 billion punitive award, against \$513 million in actual harm, the court said “that the ratio of punitive damages to actual economic harm . . . exceeds by a material factor a ratio that would be appropriate.” *Id.* at 602. It then ordered reduction of punitive damages to \$2.5 billion — a roughly 5:1 ratio, reasoning that Exxon’s misconduct was “in the higher realm of reprehensibility, but not in the highest realm,” thereby unveiling yet another constitutional wrinkle to punitive damages: “reprehensibility” has “realms.” *Id.* at 618.

The Ninth Circuit held that Exxon’s decision to “[p]lace a relapsed alcoholic in control of a supertanker” meant that it knew it was “imposing a tremendous risk on a tremendous number of people” and, therefore, could not “be regarded as merely accidental.” *Id.* at 617-18. “Exxon acted with no intentional malice towards the plaintiffs, or anyone else,” however, and its postgrounding efforts to mitigate the environmental effects of the spill, including the “institut[ion] of a system of voluntary payments to plaintiffs” and “prompt cleanup efforts,” made its misconduct less reprehensible. *Id.*

The Mathematics of Mitigation

After weighing the reprehensibility of Exxon’s conduct, the Ninth Circuit next did the damage math. It rejected Exxon’s arguments that \$493 million of the \$513.1 million in compensatory harm assessed by the district court for ratio purposes should have been deducted because it “represented amounts paid to plaintiffs through Exxon’s voluntary claims program and other settlements.” *Id.* at 619. In an about-face from an earlier decision by the Ninth Circuit in this case, where it said that “[t]he amount that a defendant voluntarily pays before judgment should generally not be used as part of the numerator, because that would generally deter settlements prior to judgment,”¹ the court rejected Exxon’s argument. It justified its change of position by noting that the “general” rule it announced in 2001 does not permit defendants like Exxon to “buy full immunity from punitive damages by paying the likely amount of compensatory damages before judgment.” *Id.* at 621.

5:1 Ratio Passes Constitutional Master

The court then evaluated the reasonableness of the damages ratio. While recognizing it “is not possible to ‘draw a mathematical bright line between the constitutionally acceptable and the constitutionally unacceptable that would fit every case’” (*id.* at 619, quoting *BMW North America, Inc. v. Gore*, 517 U.S. 559, 576 (1996)), the Ninth Circuit applied the “rough framework” it developed for ratio analysis in *Planned Parenthood v. American Coalition of Life Activists*, 422 F.3d 949, 962 (9th Cir. 2005) concluding:

Exxon’s reckless decision to risk the livelihood of thousands by placing a relapsed alcoholic in command of a supertanker, while mollified by its prompt settlement and clean up policies, was ‘particularly egregious.’ Moreover, the \$500 million of loss is well within the range of ‘significant economic damages.’ Thus, under *Planned Parenthood*, an appropriate ratio would be above 4 to 1.

¹ See *In re Exxon Valdez*, 270 F.3d 1215, 1244 (9th Cir. 2001).

Our review of the reprehensibility and mitigation . . . however, compels us to conclude the award should be toward the lower end of that range. Our cases have generally reserved high single-digit ratios for the most egregious forms of intentional misconduct, such as threats of violence and intentional racial discrimination.

Id. at 623.²

Summary

“Realms” aside, the Ninth Circuit has at least moved toward a single-digit ratio rule — a “cap” of sorts — by which high single digit ratios are reserved for defendants acting with the equivalence of malice, and lower single digit ratios (*e.g.*, 5:1 and 4:1) apply to conduct that is “reprehensible” and even “particularly egregious,” but nevertheless falls short of the “highest realm of reprehensibility.” ©

² Under the *Planned Parenthood* framework, where economic damages are “significant,” but behavior is “not particularly egregious, a ratio of up to 4 to 1 serves as a good proxy for the limits of constitutionality.” *Id.* at 623 (citations and quotations omitted). In cases where economic damages are significant, but there is “more egregious behavior,” a higher single digit ratio “might be constitutional.” *Id.* (citations and quotations omitted). Finally, in cases where economic damages are “insignificant,” and the behavior is “particularly egregious,” “the single digit ratio may not be a good proxy for constitutionality.” *Id.* (citations and quotations omitted).

MEDICAL MONITORING

In a prior issue, we reported on developments in medical-monitoring litigation against the backdrop of an Oregon appellate court’s holding that such suits are inconsistent with traditional negligence principles of causation and injury. See “Oregon Appellate Court Rejects Medical Monitoring Claim,” *In re Products Liability*, at 6 (Nov. 2006). Here we discuss three other recent medical-monitoring cases — one *Scott* with a twist, in that while the medical-monitoring claim was rejected, defendant manufacturers were ultimately ordered to fund a multi-year program (at a cost of nearly \$300 million) to get Louisiana residents to stop using their otherwise legal products.

Louisiana Appeals Court Cuts Class Action Award, But Otherwise Affirms “Damages” To Fund Court-Supervised Smoking Cessation Program

See *Scott v. American Tobacco Co.*, ___ So.2d ___, 2007 WL 495259 (La. App. Feb. 7, 2007)

In an appeal involving a smokers’ class action, a Louisiana court recently affirmed the jury’s award of a court-supervised fund for the establishment of a smoking cessation program, holding that the same considerations justifying medical monitoring claims in that state applied to the requested remedy. *Id.* at *13-15.

Introduction

Briefly, *Scott* involved a broad class of Louisiana smokers who sought, among other things, direct damages for personal injuries under theories of fraud and product liability.

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A more limited class, restricted to claims for court-supervised medical monitoring and smoking cessation programs, proceeded to trial. Although the jury found for defendants on the medical monitoring claims, it awarded damages of \$591 million to establish a statewide smoking cessation program. The Louisiana Court of Appeals largely affirmed, but reduced the damages by a significant amount as improperly awarded.

“Common Unitary Claim” Justified Class Certification

Defendants challenged class certification on the grounds that individual issues, such as injury and reliance (critical liability components), actually predominated but were essentially eliminated by the class-wide trial. Rejecting these arguments, the appeals court distinguished class actions that merely “aggregated” distinct and individualized claims from those that certified “a common unitary claim” by the class as a whole, finding along the way that the *Scott* class fit the latter category best. *Id.* at *15. The court, in a result-oriented analysis, reasoned that because the individual claims of class members were not seeking “individual damage claims,” but rather “a single court-supervised fund for the payment of class-wide cessation costs,” common proof of causation and reliance was proper. *Id.* at *16. Having created this commonality with largely conclusory reasoning, the court went on to affirm class certification as the superior vehicle for adjudication of plaintiffs’ claims. *Id.*

The court similarly rejected defendants’ argument that the finding of class-wide liability, when the jury did not determine factual or legal causation, violated due process. It held that individualized determinations of “addiction” were not necessary “since smoking cessation is desirable regardless of addiction” — basically, “an end justifies the means” approach. *Id.* at *6. The court also specifically rejected the notion that individual trials were required to determine class member eligibility for participation in the court-supervised cessation program. Instead, it held that “‘individualized’ eligibility determinations should be made administratively,” by those managing the fund, “not by a jury.” *Id.* at *16.

Only “Medically Necessary” Costs Recoverable — Proposed Funding of “Multi-Tentacled Bureaucracy” Rejected

Finally, and not insignificantly for defendants, the court ruled that over \$312 million (some 60%) of the approximately \$591 million awarded (plaintiffs asked for approximately \$1.2 billion) for the establishment of a court-supervised smoking cessation program was not legally recoverable. Plaintiffs’ proposed cessation program, developed by their expert, earmarked \$312 million “for the creation of a statewide ministry of health, including ‘infrastructure,’ ‘centers of excellence,’ a multi-tentacled bureaucracy and marketing campaigns,” with the balance going to fund “traditional cessation aids, such as nicotine gum, patches, and telephone counseling.” *Id.* at *18.

Finding plaintiffs’ remedy at law limited to “the medically necessary costs of cessation treatment,” the court only allowed some \$280 million in “damages” — rejecting the rest of the award as “speculative, unsubstantiated, and unrelated to the actual treatment of nicotine addiction . . . utilization rates, class size, or any other facts.” *Id.* at *19.¹ ©

¹ Among other things, plaintiffs’ expert proposed a grant program for \$10 million, community outreach through hospitals and health clinics for \$30 million, a marketing campaign valued at \$130 million, research projects for \$62 million, \$30 million for training local doctors and their staff, and \$40 million for building so-called “centers for excellence” in Louisiana. *Id.* at *18-19.

Claimed Beryllium Exposure Alone — Without Actual Physical or Mental Injury — Cannot Support Medical Monitoring Suit Under Mississippi Law

See Paz v. Brush Engineered Materials, Inc., 2007 WL 14891 (Miss. Jan. 7, 2007); *Sinclair v. Merck & Co.*, 2007 WL 91446 (N.J. Super. Ct. App. Div. Jan. 16, 2007)

In pushing aggregate claims generally, plaintiffs continue efforts to leap-frog one of the fundamental underpinnings of tort law: that liability requires proof of a cognizable injury in the first instance.

As previously reported, *see In Re Products Liability* at 12 (July 2006), a federal district judge facing this very issue last year ruled that beryllium sensitivity, without more, is not a compensable injury under Georgia law because it is not an injury in and of itself — even though it can lead to a beryllium-related injury *in the future*.¹ The Mississippi Supreme Court recently reached a similar result in answering a certified question from the United States Court of Appeals for the Fifth Circuit. An intermediate New Jersey appellate court, however, reached the opposite result on a similar question.

Background

In *Paz*, employees of the John C. Stennis Space Center in Mississippi sought medical monitoring costs against several entities, including the distributor of the beryllium products used at the Space Center, claiming that defendants' negligence caused plaintiffs' exposure to beryllium. Plaintiffs maintained that this exposure put them at risk of eventually developing "Chronic Beryllium Disease, typically a latent disease which impairs the lungs and often causes death," justifying medical

monitoring at defendants' expense. *Id.* at *1. It was common ground between the parties that "[n]one of the plaintiffs ha[d] suffered physical injury from the alleged exposure." *Id.*

The federal district court in Mississippi granted defendants' motion to dismiss, finding failure to state a claim in plaintiffs' medical monitoring allegations. *Id.* On plaintiffs' appeal, upon "finding that Mississippi law was silent as to the recognition of medical monitoring actions," the Fifth Circuit certified the following question to the Supreme Court of Mississippi: whether "a plaintiff can recover medical monitoring costs for exposure to a harmful substance without proving current physical injuries from that exposure." *Id.*

No Liability Without "Identifiable Injury"

In response, the Mississippi Supreme Court held that "[c]reating a medical monitoring action would be contrary to Mississippi common law, which does not allow recovery for negligence without showing an *identifiable injury*." *Id.* at *2 (emphasis added). Relying on *Leaf River Forest Products, Inc. v. Ferguson*, 662 So. 2d 648 (Miss. 1995), an emotional distress case, plaintiffs argued that because Mississippi had already recognized a tort-based theory of liability in the absence of physical injury, they could recover "damages in the form of medical monitoring costs solely on the basis that they have been exposed to harmful levels of beryllium and are in danger of suffering from latent diseases." *Id.* at *2.

The court rejected this argument, holding that while *Leaf River* did not require proof of a physical injury, it still required proof of a "medically cognizable" psychological or mental injury necessitating treatment. *Id.* at *3.

Fear of "Potential Illness" Not Cognizable

Concluding that plaintiffs had not alleged any medically recognized psychiatric conditions requiring professional treatment, the court characterized plaintiffs' medical monitoring claim as one simply for fear of contracting a disease in the future. *Id.* Relying on its prior rejection of such claims,² the

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¹ *See Parker v. Brush Wellman*, 420 F. Supp. 2d 1355 (N.D. Ga. 2006).

² *See Brewton v. Reichhold Chemicals, Inc.*, 707 So.2d 618, 620 (Miss. 1998).

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court then declared that “[t]here is no tort cause of action in Mississippi without some identifiable injury, either physical or emotional.” *Id.* at *4, citing *Metro-North Commuter R.R. v. Buckley*, 521 U.S. 424, 432 (1997) (“[a]n exposed plaintiff can recover related reasonable medical monitoring costs if and when he develops symptoms”). Closing the point, the Mississippi Supreme Court found:

[C]onsidering Mississippi law, this Court finds that as Mississippi requires the traditional elements of proof in a tort action, *it has refused to recognize a category of potential illness actions, which would include medical monitoring actions.* Therefore, this Court preserves the requirement of each of the traditional tort elements and declines to recognize medical monitoring as a cause of action.

Id. at *5 (emphasis added).

Split of Authority Continues to Widen

In reaching this result, the court recognized the “existence of a conflict among jurisdictions over” the viability of and prerequisites for medical monitoring claims. It found itself, however, “at perfect liberty to disregard” the decisions of other courts recognizing the viability medical monitoring claims in the absence of physical injury. *Id.*³

Interestingly, less than two weeks after *Paz* was decided, a New Jersey intermediate appellate court extended medical monitoring claims to the Vioxx litigation, holding that plaintiffs may recover medical monitoring expenses even in the absence of a present injury. See *Sinclair v. Merck & Co.*, 2007 WL 91446 (N.J. Sup. Ct. App. Div. Jan. 16, 2007). The *Sinclair* court refused to adopt a bright-line rule requiring the existence of a manifested disease before a medical monitoring claim could be pursued. *Id.* at *8. Instead, it held that trial courts must allow plaintiffs the opportunity to develop a fac-

³ See *Id.* at f. 3 & 4 (surveying 12 jurisdictions allowing medical monitoring claims without requiring physical injury) and *id.* at f. 5 (listing 17 jurisdictions refusing to recognize medical monitoring claims absent a present injury).

tual record regarding their exposure, and then analyze the following factors to determine plaintiff’s entitlement to medical monitoring:

the significance and extent of plaintiffs’ exposure to the toxins, their toxicity, the seriousness of the diseases for which the exposed plaintiffs were at risk, the level of increased risk presented, and the value of early diagnosis.

Id. at *9.

All in all, the *Sinclair* approach stands in stark contest to the *Paz* approach and ironically could further clog already burdened dockets and lead to “delay and decrease in remedy for those with manifested illnesses.” *Paz, supra*, at *5. ☹

PREEMPTION

“Sorry, Charlie!” — Informal and Light FDA Regulatory Touch Preempts Methylmercury Litigation in New Jersey

See Fellner v. Tri-Union Seafoods, L.L.C., 2007 WL 87633 (D.N.J. Jan. 9, 2007)

This case demonstrates the increasing judicial trend to dismiss products liability actions on preemption grounds in deference to the jurisdiction of federal agencies. This trend encourages defense creativity to craft preemption arguments even when the relevant statutory or regulatory scheme contains no express preemption provision or when there has not been aggressive regulation in the area. Significantly, this trend is seen in pharmaceutical litigation, based on a “Preamble” inserted into FDA rulemaking regarding certain medical device and pharmaceutical labeling — notwithstanding “the presumption in the law against preemption.” *Id.* at *4; *see, e.g., In re Products Liability*, at 8 (Nov. 2006).

Background

In *Fellner*, a New Jersey federal district court ruled that a putative class action alleging failure to warn of the risk of mercury poisoning from tuna consumption was preempted based on FDA “advisories” and “informal” statements of preemptive intent and understanding. Plaintiff claimed that defendant seafood company violated the New Jersey Products Liability Act, the New Jersey Consumer Fraud Act, and committed common law fraud by failing to warn the public that consumption of canned tuna fish can cause mercury poisoning. *Id.* at *1. Plaintiff consumed canned tuna “almost exclusively” from 1999 to 2004, and was eventually diagnosed with mercury poisoning, for which she sought to make defendant responsible. *Id.* Defendant sought dismissal, arguing that FDA’s establishment and regulation of tolerances for the mercury content of fish, together with FDA’s rejection of package warnings from a cost-benefit standpoint, preempted plaintiff’s claims.

Informal FDA Action — Through “Advisories” — Can Have Preemptive Effect

To rebut the presumption against preemption, defendant introduced an FDA “advisory” and “backgrounder,” along with a 2005 letter written by the FDA Commissioner to California’s attorney general regarding the preemptive effect and intent of FDA action regarding “the potential health hazards of methylmercury in food.” *Id.* at *4. Interestingly (in light of the effect the letter was given by the *Fellner* court), the 2005 FDA Letter was generated in response to litigation commenced in June 2004 in California against the same defendant.¹ In it, the FDA Commissioner said the methylmercury warnings California wanted placed on tuna cans “frustrate[d] the carefully considered federal approach to advising consumers of both the benefits and possible risks of eating fish and shellfish. . . . After many years of analysis on this issue, [the] FDA has chosen to issue an advisory rather than to require a warning on fish and shellfish product labels for several reasons.” *Id.* at *3-4 (emphasis added).

Also, the FDA had previously (in 2004) issued a methylmercury “advisory” and “backgrounder” for pregnant women, nursing mothers and parents of young children on how to minimize mercury exposure. *Id.* at *4. Not only did this advisory regulate the levels of mercury allowed, but also explicitly rejected the requirement of a warning label on cans of tuna. *Id.*

Tellingly, considering the plethora of failure-to-warn litigation nowadays afoot implicating FDA jurisdiction, the FDA contended that a governmental “advisory approach is more effective than a product label statement in relaying *the complex messages about mercury in seafood.*” *Id.* at *6 (emphasis added). Its rationale was:

[f]irst, consumer advisories are communicated to the target audience directly, rather than to all consumers. . . . [Also,] a label statement that reaches the public at large can also have unintended adverse public health consequences. FDA focus group results have suggested that people who are not in the target audience . . . might eat less fish or refrain from eating fish altogether when they receive information about the mercury content of fish”

Id.

Such a “nuanced approach” was needed, the FDA said, “to avoid overexposing consumers to warnings, which could result in them ignoring all such statements and hence creating a far greater public health problem.” *Id.* at *7.

Plaintiff argued that the FDA letter was merely “intended to derail litigation against the seafood industry,” and besides was not persuasive. *Id.* at *4-5. She (who allegedly ate nothing but canned tuna for five years) claimed, too, that the FDA “advisory” and “backgrounder” were not entitled to deference because the FDA had not “officially prohibited mercury warning on cans of tuna.” *Id.*

Deference Owed FDA’s “Balanced Approach” to Mercury Poisoning Risk

Despite the lack of any formal FDA regulation, the court ultimately deferred to the FDA by dismissing the products liability and fraud claims since defendant could not comply with both New Jersey and FDA regulation — saying it would “not turn a blind eye” to evidence, which in the latter case represented a “ten-year deliberately balanced approach to the issue of methylmercury in fish.” *Id.* Plaintiff’s fraud claims were held “clearly subsume[d],” and likewise dismissed as preempted.

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¹ See *State of California v. Tri-Union Seafoods, LLC*, 2006 WL 1544377 (Cal. Super. Ct.).

Preemption

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In closing, the court described its preemption analysis as follows:

To ask this Court to ignore the evidence of the FDA's carefully balance approach in favor of Plaintiff's claim that the FDA's treatment of this issue is a contrived response to potential lawsuits against the seafood industry distorts logic.

Id. ☉

Circuits Split Over Federal Preemption of “Fraud-on-the-FDA” Claims Under Exception to Michigan Products Liability Statute

See Desiano v. Warner-Lambert & Co., 467 F.3d 85 (2nd Cir. 2006); *Garcia v. Wyeth-Ayerst Lab.*, 385 F.3d 961 (6th Cir. 2004)

In the ever-evolving arena of federal preemption, the Second Circuit recently determined that federal law does not preempt state law fraud claims under an exception to a Michigan statute that otherwise immunizes FDA-approved pharmaceuticals from products liability claims. This ruling is contrary to an earlier Sixth Circuit decision finding the same provision of the Michigan statute preempted because it is tied to proof of a fraud on the FDA. These rulings appear to create a circuit split with respect to the preemptive effect of this Michigan law, raising ambiguity about the viability of plaintiffs' claims against pharmaceutical companies under Michigan law.

Background

The provision confronted by both *Garcia* and *Desiano* was the 1995 amendment to Michigan's products liability statute

immunizing the makers of pharmaceutical products with FDA approval from products liability claims. *See* Mich. Comp. Laws § 600.2946(5) (2000). This provision contains an exception for drug manufacturers who intentionally withhold or misrepresent information they are required to submit to the FDA, under the Food Drug and Cosmetic Act (“FDCA”), absent which the drug would not have received FDA approval. *Id.*; *see also Desiano*, 467 F.3d at 87-88.¹

Sixth Circuit Finds Preemption

In *Garcia*, the Sixth Circuit found that the fraud exception to Michigan's general statutory immunity for pharmaceutical manufacturers was preempted by federal law, but still upheld the statutory immunity — and the grant of summary judgment for defendant — in light of a severability provision under Michigan law, reasoning that the Michigan legislature clearly evinced a preference for statutory immunity for drug makers rather than no immunity at all. 385 F.3d at 965-67.

The Sixth Circuit predicated its holding on *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347 (2001), in which the U.S. Supreme Court held that federal law impliedly preempted state law fraud-on-the-FDA claims, since “[p]olicing fraud against federal agencies is hardly ‘a field which the States have traditionally occupied.’” While acknowledging that the Michigan statute presented a “somewhat different legal regime” from the one invalidated in *Buckman*, the Sixth Circuit found the differences “immaterial,” since *Buckman* required preemption of all state tort claims requiring proof of fraud-on-the-FDA. *Id.* at 965-66.

¹ In relevant part, this statute provides: “In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller. . . . This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following: (a) Intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act . . . and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.”

Second Circuit Reaches Opposite Conclusion

In construing the same Michigan statute, but reaching the opposite result, in *Desiano* the Second Circuit declared that it was not required to defer to the Sixth Circuit's conclusions in *Garcia* as to preemption of the Michigan statute because *Garcia* depended upon the Sixth Circuit's analysis of federal law (i.e., the Sixth Circuit's reading of *Buckman*), and not state law. 467 F.3d at 92. The Second Circuit thereafter concluded that the *Desiano* plaintiffs were not, like the *Buckman* plaintiffs, asserting fraud-on-the-FDA claims; rather, their claims were all based on traditional state tort law duties between a manufacturer and a Michigan consumer. *Id.* at 94-95.

In finding no preemption, the Second Circuit disagreed with *Garcia* that the differences between the claims presented in *Buckman* and those presented by the Michigan plaintiffs were "immaterial." For the Second Circuit, the crucial differences between these cases were that, contrary to *Buckman*, the Michigan statute does not attempt to police fraud against the FDA. Rather, Michigan merely sought "to regulate and restrict when victims could continue to recover under preexisting state products liability law." *Id.* at 94. In addition, *Desiano* involved traditional tort claims, not the "fraud-on-the-FDA claims" seen in *Buckman*. The Second Circuit concluded that "*Buckman* cannot be read as precluding such preexisting common law liability based on other wrongs, even when such liability survives only because there was also evidence of fraud against the FDA." *Id.* at 95.

For the Second Circuit, "[u]ntil and unless Congress states explicitly that it intends invalidation of state common law claims merely because issues of fraud may arise in the trial of such claims, we decline to read general statutes like the FDCA . . . as having that effect." *Id.* at 96. ☺

RISK-UTILITY TEST

The Slow Extinction of the "Open and Obvious" Danger Rule: No "Simple Product" Exception to the Risk-Utility Test Under Illinois Law

See Calles v. Scripto-Tokai Corp., 2007 WL 495315 (Ill. Feb. 16, 2007)

Continuing a familiar trend, the Illinois Supreme Court recently declined to adopt an exception to the risk-utility test in design-defect cases for "simple" products with "open and obvious" dangers.

Background

In March 1998, Calles left her home one evening with one child to rent a movie at the local video store, leaving behind three-year-old twins in the care of their eleven-year-old sibling. *Id.* at *1. In their mother's absence, one of the twins started a fire with an "Aim N Flame" utility lighter, which "was ignited by pulling a trigger after the 'ON/OFF' switch was slid to the 'on' position." *Id.* The other twin suffered smoke inhalation and died several weeks later. *Id.* Plaintiff sued the lighter's manufacturer claiming that the lighter was "defectively designed and unreasonably dangerous because it did not contain a child-resistant safety device." *Id.*

Defendant moved for summary judgment, arguing that the lighter was not defective "because it worked as expected" and that it "had no duty to make an adult product child-resistant" or to "warn because the dangers of the [lighter] were open and obvious." *Id.* Of relevance here, defendant argued that plaintiff's defect claims should be decided under the consumer expectations test (and not the risk-utility factors) — because the lighter was a "simple product" with "open and obvious" dangers, making the risk-utility test inapplicable. *Id.* at *5-6. In doing so, defendant cited a 1991 decision by an intermediate

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Risk Utility Test

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Illinois appeals court — *Scoby*.¹ The trial court agreed and granted summary judgment for defendant.

Plaintiff appealed, asserting that the trial court's adoption of a *per se* "simple product" exception to the risk-utility test was error. The Illinois Supreme Court agreed.

"Open and Obvious" Danger Part of Risk-Utility Test, Not Per Se Exception

Noting that it had "never [before] had occasion to squarely address the simple-product exception" adopted by *Scoby*, the Illinois Supreme Court declared that the so-called "simple product" exception "is nothing more than the adoption of a general rule that a manufacturer will not be liable for open and obvious dangers." *Id.* at *7. Stressing that "the open and obvious nature of the risk" is but one factor "in the range of considerations required by the risk-utility test," and taking comfort in the judicial trend against recognition of "open and obvious" dangers as an absolute defense to design-defect claims, the court explained that:

the obviousness of a risk inherent in a product, *simple or nonsimple*, does not by itself obviate a manufacturer's liability.

Id. (emphasis in original).

With the issue finally squarely before it, the Illinois Supreme Court expressly rejected "a *per se* rule excepting simple products with open and obvious dangers from analysis under the risk-utility test." *Id.* at *8. It anchored its holding on public policy considerations intended to "prevent[] future harm[,] which is at the heart of strict liability law." *Id.* More to the point, it said:

Policy reasons . . . support rejection of a *per se* rule excepting simple products with open and obvious dangers from analysis under the risk-utility test. *Adoption of such a rule would essentially absolve manufacturers from liability in certain situations even though there may be a reasonable and feasible alternative design available that would make a product safer, but which the manufacturer declines to incorporate because*

¹ See *Scoby v. Vulcan-Hart Corp.*, 211 Ill. App.3d 106 (1991).

it knows it will not be held liable. This would discourage product improvements that could easily and cost-effectively alleviate the dangers of a product.

Id. (emphasis added). It then held the open and obvious nature of a "simple" product to be "one factor that may be weighed in the risk-utility test." *Id.* ©

E-DISCOVERY

Pair of Missouri Decisions Examine Electronic Discovery Within the "Reasonably Accessible" and "Good Cause" Context

See Ameriwood Industries, Inc. v. Liberman, 2006 WL 3825291 (E.D. Mo. Dec. 27, 2006) (*Ameriwood I*); *Ameriwood Industries, Inc. v. Liberman*, 2007 WL 496716 (E.D. Mo. Feb. 13, 2007) (*Ameriwood II*)

Last December's amendments to the Federal Rules of Civil Procedure sought to strike a practical balance between the guiding principle of liberal discovery in litigation and the realities and burdens of data management in the information age. The burden-shifting provision to FRCP 26(b)(2) — relieving producing parties from disclosing information that is "not reasonably accessible" absent a showing of "good cause" by the requesting party — received recent attention in a pair of decisions from Missouri's federal district court.¹

¹ In pertinent part, Rule 26(b)(2) provides: "On motion to compel discovery..., the party from whom discovery is sought must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the Court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(c)." *Id.* at *2.

Ameriwood I: Discovery Lapse and Computer's Role in Underlying Legal Wrong Constitute "Good Cause"

Background

In *Ameriwood I*, a trade secret misappropriation case, the court granted plaintiff's motion to compel the "mirror imaging" of defendants' hard drives.² Plaintiff alleged that the individual defendants — its former employees — unlawfully forwarded customer information and other confidential information from plaintiff's computers to their personal email accounts, then used this information to sabotage plaintiff's business relationships and generally divert plaintiff's business to defendants' newly formed company. Plaintiff requested discovery of all hard drives used by the individual defendants since May 2005, including computer and portable hard drives in their homes. Defendants objected generally to the breadth and vagueness of the requests, and also argued, first, that the requested information had already been disclosed and, alternatively, that the costs of imaging, recovering and translating the data from the hard drives to a usable format were prohibitive.

Defendants' Prior Failure to Produce Document Justifies "Mirror Imaging" Order

The district court rejected defendants' first argument on two grounds. Citing the advisory committee's notes to revised Rule 26(f), the court ruled that examination of the hard drives themselves might unearth additional information (often referred to as "metadata" and "embedded data") not discernable by typical searches of electronic information, which "may provide answers to plaintiff's other pertinent inquiries." *Id.* at *3. In reaching this conclusion, the court was influenced by the revelation that one defendant had failed to produce an email he had sent from his personal account to an employee at Samsung — one of plaintiff's clients — while he was still

employed by plaintiff. (Samsung later brought the document to plaintiff's attention.) Based on this inconsistency, the court found that defendants' hard drives might contain other deleted or active versions of emails, and that mirror imaging the data might yield other pertinent information showing what defendants did — or attempted to do — with the allegedly stolen files. *Id.*

Defendants' Cost Objection Trumped by Plaintiff's "Good Cause" Showing and Agreement to Pay Discovery Costs

While the court agreed with defendants that the "significant costs" associated with mirror imaging rendered the requested information "not reasonably accessible" under Federal Rule 26(b)(2), it found that plaintiff had met its "good cause" burden. *Id.* at *3-4.

In conducting the good-cause inquiry, the court cited the seven factors set out in the advisory committee's notes — weighing most heavily "the failure to produce relevant information that seems likely to have existed but is no longer available on more easily accessed sources," given the "discrepancies" and "inconsistencies" evidenced by defendants' failure to produce the Samsung email. *Id.* at *4. It reasoned that because the computer itself was used to commit the wrongs at issue, a "sufficient nexus" existed between the claims and the requested information to permit mirror-imaging discovery. *Id.* In reaching this result, the court was also influenced by plaintiff's willingness to "incur[] the costs for the requested" discovery. *Id.* at *5.

Ameriwood II: Poorly Bounded Electronic Discovery Requests Do Not Support Good Cause

In *Ameriwood II*, the court addressed a discovery challenge based not on the form of the electronically stored information, but instead its quantity. More particularly, in support of an "affirmative defense" attributing plaintiff's lost sales to its own mismanagement, defendants requested production of "all communications and documents" concerning plaintiff's television stand business and its management for a six-month period — amounting to hundreds of thousands of documents, most stored electronically. *Id.* at *2.

For the six individuals named in defendants' request, plaintiff identified over 52,000 potentially responsive emails and

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² "Mirror imaging" basically involves the creation of an exact duplicate of stored information — by copying hard drives, recovering deleted information, and translating the recovered data into searchable and reviewable formats. *Id.* at *3. Because this method of storage — typically voluminous — makes recovery of usable information both time-consuming and expensive, many courts consider the data to be "inaccessible." See, e.g., *Zubulake v. UBS Warburg LLC*, 217 F.R.D. 309, 319 (S.D.N.Y. 2003).

E-Discovery

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more than 4,000 additional computer files. Based on the sheer volume of information reached by defendants' discovery request, the court ruled that the information sought was "not reasonably accessible because the request is unduly burdensome," and turned to defendants for a showing of "good cause" under rule 26(b)(2)'s burden-shifting analysis. *Id.* Finding that defendants' requests were "not narrowly tailored" or restricted to the information "relevant to the affirmative defense," the court held that defendants had failed to show "good cause," and denied their motion to compel. *Id.* ©

CLASS ACTIONS

Pennsylvania Court Denies Class Certification in Paxil Case

See *Blain v. Smithkline Beecham Corp.*, No. 06-1247 (E.D. Pa. Jan. 25, 2007)

A federal judge in Pennsylvania recently refused to certify a national class action against Glaxosmithkline — manufacturer of the antidepressant Paxil — for lack of typicality, predominance and superiority.

Background

The sale of Paxil in the U.S. was first approved in December 1992. *Id.* at 2. The drug, however, has never been approved for use with children. Nonetheless, doctors are permitted to prescribe Paxil for "off-label" uses without FDA approval, and often do so. Slip. op. at 3.¹ Plaintiffs alleged that between 1998 and 2001, Glaxo conducted studies on the use of Paxil in treating pediatric depression revealing a high risk of adolescent suicidality, which Glaxo supposedly concealed to promote Paxil (off-label) as safe and effective in the treatment of pediatric depression. *Id.* at 4.

Plaintiffs moved for class certification of "all persons ... who

committed suicide, attempted to commit suicide, or engaged in other self-injurious behavior while under the influence of the prescription drug Paxil and who were under the age of 18 at the time of the person's suicide." *Id.* at 5. Class representatives were Pamela Blain, mother of an 11-year old Kansas boy who committed suicide after being prescribed Paxil, and Tonya Brooks, an adolescent from Texas who attempted suicide while taking Paxil at age 17. *Id.* at 13-16.

Trevor Blain was prescribed Paxil for "separation anxiety disorder" in October 2000 and immediately began having angry outbursts and sleeping problems. *Id.* at 14. He continued to take Paxil until early November 2000, when he attempted suicide. *Id.* at 13. After the suicide attempt, Trevor remained in a coma until his death on December 7, 2000. *Id.* Plaintiff Tonya Brooks was prescribed Paxil in 2004, after being diagnosed with social anxiety disorder. *Id.* at 15. She first attempted suicide by taking an overdose of Paxil and Ambien, a sleep aid. When that attempt failed, she gouged a hole in her leg two days later with a pair of scissors, and was hospitalized for several days. *Id.* at 15-16. After Tonya ceased taking Paxil, her suicidal and self-mutilation desires subsided. *Id.*

Too Many Plaintiffs, Too Many Differences For "Typicality"

Using the class representatives as examples, the court cited numerous critical and factual differences among the putative class members that defeated typicality. Among other things, it noted that each class member had a unique medical and family history, different physician, took Paxil in varying doses, for varying indications, at different developmental stages, and for different durations. *Id.* at 16-17. In addition, Glaxo demonstrated "individualistic defenses" peculiar each class member. *Id.*

Finding the respective interests so divergent as to render the named plaintiffs completely "inadequate representatives" of the absent class members, the court held that plaintiffs had failed to meet the "typicality" requirement.

¹ Since 1997, drug manufacturers have been permitted to disseminate "off-label" information about products generated from independent sources, such as journal articles and textbooks, so long as there is disclosure of its interest in the drug, together with the fact that the suggested use has not been approved by the FDA. *Id.*

Predominance and Superiority Absent — Fact-Finding Too Individualized

The Court also found failure to establish predominance and superiority, the latter in light of insurmountable choice-of-law issues.

[T]he predominance and superiority requirements of Rule 23(b)(3) are lacking — predominance because the proposed common issues are overwhelmed by the differences among the factual and legal issues affecting individual causation, damages and defenses; and, superiority because the proposed class would be unmanageable in light of the choice-of-law conflicts that are resolved in favor of each individual's home state. In essence, the plaintiffs have failed to define a class capable of ascertaining membership without individualized fact-finding.

Id. at 2.

Summary

Blain underscores a trend common to pharmaceutical and other class action litigation for personal injuries — “predominance poses a problem.” *Id.* at 21. “Individual issues in such cases normally overwhelm common ones.” *Id.* ☉

French Class Action Legislation Stalled

See *Consumer Protection Bill, No. 3430* (2006)

On January 31, 2007, the French Parliament canceled debate on class action reform legislation, effectively suspending any further action until the next parliamentary session in October 2007, following upcoming presidential and parliamentary elections. The future of this legislation remains in question.

History of the Class Action Reform Bill

As briefly stated in the November 2006 issue of *In re*

Products Liability,¹ class action reform in France was promoted by President Jacques Chirac in his annual New Year's address on January 4, 2005, when he proposed:

to give consumers ways to ensure their rights are respected: today, they are defenseless because, considered individually, the extent of the damages that they may have suffered is never enough to justify the expense of a legal action. . . . This is why I am asking the Government to propose a change in the law to allow consumer groups and associations to bring class action lawsuits against wrongful practices encountered in some markets.

Prompted by Prime Minister Dominique de Villepin, a committee began analyzing the subject and preparing a draft bill in April 2005. Unable to agree on a unanimous draft after months of debate, in December 2005 the group proposed several alternative class action systems for review and comment by the Ministries of Justice and Finance. Nearly one year later, Finance Minister Thierry Breton submitted a draft bill to the Council of Ministers in November 2006, entitled “Consumer Protection Bill,” to regulate various consumer law issues — class actions among them.

The bill's class action provision appeared to strike a “middle ground” between the competing alternatives promulgated in December 2005. It clarifies that while aiming to assist consumers, the government has two key countervailing concerns: to protect French companies against the risk of litigation abuses (as seen in some foreign jurisdictions), and to establish a system compatible with French legal principles and judicial organization. As a result, the bill's class action provision would:

- ☉ permit only registered national consumer associations, not individuals, to bring class actions;
- ☉ limit claims to those involving consumer goods linked to a contract, with a value of less than €2,000 per plaintiff;
- ☉ exclude claims for medical malpractice, transportation accidents, and other personal injury or non-commercial disputes; and
- ☉ require individuals to opt-in to the class.

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¹ See “A Look Into The Migratory Tort Phenomenon,” *In re Products Liability*, at 4 (Nov. 2006).

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Unsurprisingly, these terms were criticized by the French press and consumer associations as too restrictive and cautious, especially to the extent products liability claims were excluded. What is more, division emerged in the French Parliament, where the measure drew some 200 proposed amendments.

The Present

Although Parliament's review of the proposed legislation was expected to be completed by February 2007, the bill was removed from the agenda on January 31 because of Parliament's inability to debate and vote on the amendments in the 15 hours allocated to the measure. Mr. Breton promised that the bill would be presented to the newly elected Parliament when it re-convened in October 2007.

Time constraints may not be the only explanation, however. The bill failed to garner support from various business organizations, including the Movement of French Enterprises — a group comprised of large French business interests opposed to the legislation because of its potentially negative economic impact. Jean-François Roubaud, president of the Federation of Small & Medium Enterprises, viewed the postponement as “reasonable” because the class action provision did not afford much in terms of consumer protection, and also could pose dramatic consequences for businesses. In contrast, consumer associations expressed frustration at the decision to cut-off debate, stating that although the current draft was “imperfect,” consumers have been expecting it for two years.²

Future of Reform: A Political Challenge

At the moment, predictions as to whether the current legislation will be re-examined by the new government later this year, or instead retooled, are near impossible to make in light of the uncertainty of election outcomes. Some have speculated that the politicians, especially from the current majority party (“*Union pour un Mouvement Populaire*”), want to keep the hot-button topic of class action reform alive as a campaign issue that simultaneously grabs the attention of consumers and business leaders alike.³

Developments in Other European Countries

In contrast to the circuitous route being followed by French class action reform, the march toward some semblance of a class action regime seems to be proceeding in a straighter line in other parts of Europe. Most do not, however, cover products liability litigation.

In 2005, for instance, the Netherlands enacted the Act on Collective Settlement of Mass Damages, which allows consumer associations representing injured parties to negotiate settlements for all class members. Court approval of the settlement would benefit all class members who do not opt out. In Germany, the Capital Markets Model Case Act provides a way to handle mass proceedings related to securities transactions through the establishment of a model case. Although is not a class action system *per se*, plaintiffs benefit from cost-sharing and prompt decision-making on key issues in the litigation.⁴ Finland's Parliament, too, is analyzing a bill that would allow consumers to participate in joint lawsuits filed by the Consumer Ombudsman — the only one empowered to initiate class actions, with consumers not considered parties to the litigation.⁵

Finally, the European Commission has published a Green Paper suggesting that class actions might be the way forward for smaller antitrust-related claims, stating:

[i]t will be very unlikely for practical reasons, if not impossible, that consumers and purchasers with small claims will bring an action for damages for breach of antitrust law. Consideration should therefore be given to ways in which these interests can be better protected by collective actions. Beyond the specific protection of consumer interests, collective actions can serve to consolidate a large number of smaller claims into one action, thereby saving time and money.⁶ ©

² See Statement from Gaëlle Patetta, Legal Director of UFC-Que choisir, in *Le Monde*, Jan. 30, 2007.

³ *Les Echos*, Jan. 30, 2007.

⁴ The “Act on Model Case Proceedings in Disputes under Capital Markets Law (Capital Markets Model Case Act)” entered into force in Germany on Nov. 1, 2005. The text of the bill can be found on the German Ministry of Justice's website (www.bmj.bund.de/kapmug and www.bmj.de/files/-/1056/EnglishInfoKapMuG.pdf).

⁵ R. Paanila, N. Pitkajarvi, “Finland: Litigation; Class Action,” *I.C.C.L.R.*, 18(3), N21-22 (2007).

⁶ See Commission of the European Communities, Green Paper, “Damages Actions for Breach of the EC Antitrust Rules,” at 8 (Com/2005/0672 Final, Dec. 19, 2005).

EMERGING TRENDS

Nanotechnology: A Regulatory Void

In our last issue, we reviewed developments in the nascent field of nanotechnology.¹ To recapitulate, “nanotechnology” is defined by the federal government’s National Nanotechnology Initiative (“NNI”) as the science of engineering and manipulating matter at the scale of approximately 1 to 100 nanometers, with a nanometer equaling one-billionth of a meter.² (The sheet of paper on which these words are written is roughly 100,000 nanometers thick.) More generally, the term refers to the creation and use of structures, devices and systems with novel properties and functions owing to their small size.

Road to Nanotechnology Regulation Under Construction

Nanotechnology is expected in coming years to transform many industries dramatically, including computers, electronics, medicine and food. One research firm predicts that by 2014, 15% of global economic output will incorporate nanotechnology.³ This technology has grown so rapidly, however, that there are as yet no federal regulatory regimes specifically dedicated to nanotechnology. As a step toward filling this gap, the NNI is charged with setting research agendas on the potential health and safety risks of the technology, and helping federal agencies — such as FDA, EPA and OSHA — understand nanotechnology and develop appropriate regulations. Private industry and non-profit scientific research groups are also involved in these efforts.

There is a school-of-thought, however, that nanotechnology poses novel risks to health that are poorly understood. As noted in recent congressional testimony by Dr. Andrew Maynard, Chief Science Advisor to the Project on Emerging Nanotechnologies at the Woodrow Wilson Center for Scholars:

“Make no mistake, nanotechnology is different and there will be some materials and products developed under this banner that have the potential to cause harm.”⁴

Among the concerns is recognition that familiar substances, known to be non-toxic as currently used, may be transformed into new, potentially dangerous compounds when engineered into discrete nanoparticles. Gold, for example, is biologically inert as used routinely in various medical products implanted in the human body, but dramatically transformed by nano-scale engineering:

“[i]ts color changes to a striking red” and it is “no longer the inert metal used in home and biological appliances. . . . [G]old nanoparticles may be very reactive, may penetrate the blood/brain barrier, or may enter into cells.”⁵

Last September’s congressional hearing on nanotechnology underscored the enormous amount of work to be done to identify and define the risks inherent in nanotechnology and establish a regulatory framework for its use. In the meantime, widespread press coverage of possible health and safety risks is generating public alarm not unlike that associated with genetically modified food products, creating the risk that public opinion and law will lead science — instead of vice-versa.

Duty to Warn Issues

Anecdotal evidence indicates that fear of adverse consumer perceptions and legal actions, such as those directed toward titanium dioxide-based sunscreens, along with uncertain or

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- ¹ See “Uncharted Products Liability Waters: Nanotechnology,” *In re Products Liability*, at 10 (Nov. 2006).
- ² NNI is a federal R&D program established to coordinate the efforts of 22 federal agencies in the area of nano-scale science, engineering and technology issues.
- ³ See <http://www.nanotechwire.com/news.asp?nid=1248>, (accessed on Mar. 8, 2007).
- ⁴ See *Research on Environmental and Safety Impacts of Nanotechnology: What are the Federal Agencies Doing?* Before the House Comm. on Science, 109th Cong., 2nd Sess. (Sept. 21, 2006) (statement of Andrew D. Maynard, Ph.D., slip op. at 1) (emphasis in original) (available at <http://gop.science.house.gov/hearings/full06/Sept%2021/Maynard.pdf>, accessed on Mar. 8, 2007).
- ⁵ *Research on Environmental and Safety Impacts of Nanotechnology: What are the Federal Agencies Doing?* Before the House Comm. on Science, 109th Cong., 2nd Sess. (Sept. 21, 2006) (statement of Dr. Arden Bement, Jr., slip op. at 2) (available at <http://gop.science.house.gov/hearings/full06/Sept%2021/Bement.pdf>, accessed on Mar. 8, 2007).

Emerging Trends

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speculative health concerns, are raising challenging duty-to-warn issues for many U.S. companies whose products contain nanoparticles. At present, there are no labeling requirements in the U.S. requiring such disclosure — at either the wholesale or retail level. In contrast, outside the U.S., particularly in Asia and Europe, manufacturers often tout the nanotechnology aspects of their products as a selling tool.⁶

The Road Ahead: The ISO Model?

It is clear that no comprehensive federal regulation of nanotechnology will be instituted anytime soon. Until then, the clearest (and only) framework seeking to regulate and communicate nanotechnology risk is the current International Standards Organizations (“ISO”) program.⁷

On January 4, 2007, in Virginia, approximately 150 people took part in an NNI Public Meeting on research needs related to the environmental, health, and safety aspects of nanotechnology. One of the speakers, Dr. Vladimir Murashov, of the National Institute for Occupational Safety and Health (and an ISO delegate), detailed an ISO Technical Committee’s ongoing development of comprehensive standards for nanotechnology health risk assessment and product labeling.⁸ According to Dr. Murashov, this project will take another three to eight years to complete. Development of such international standards will likely be a prerequisite for any meaningful regulatory and labeling regimes to be instituted in the U.S. ©

⁶ The Woodrow Wilson International Center’s Nanotech Project maintains a database of products containing labeled nano-scale materials. A recent review indicates that most of these products originate in Asia and Europe. See <http://www.nanotechproject.org/index.php?id=44&id=44&action=view&p=17> (accessed on Mar. 9, 2007).

⁷ ISO — the world’s largest developer of technical standards — is a network comprised of the national standards bodies of 157 countries, all coordinated by a Central Secretariat based in Geneva.

⁸ See *Public Meeting on Research Needs Related to the Environmental and Safety Aspects of Engineered Nano-scale Materials* at 127-148 (Jan. 4, 2007), available at https://nnco.nano.gov/public_ehs/uploads/EHS_public_mtg_transcript_20070104.pdf (accessed on Mar. 9, 2007); see also Accompanying slide presentation of Dr. Murashov, available at https://nnco.nano.gov/public_ehs/uploads/Murashov_TC229_EHS_20070104.pdf (accessed on Mar. 9, 2007).

PROTECTIVE ORDERS

Federal Judge Issues Injunction and Rebuke For Document Leak

See In re Zyprexa Litigation Injunction, No. 07-CV-0504, related to MDL No. 1596 (E.D.N.Y. Feb 13, 2007)

Introduction

Unlike the Australian and U.K. legal systems, where parties receiving discovery in litigation generally undertake to maintain confidentiality of the documents — the so-called “undertaking,” lawyers in the U.S. are routinely sharing the fruits of discovery, typically bundled as “trials-in-a-box.” The problem is particularly acute given the scope of modern-day document discovery in complex litigation, and the insatiable hunger of consumer-oriented websites and related advocacy databases for content.

In the *Zyprexa* litigation in Brooklyn federal court, Judge Weinstein recently had occasion to address a similar problem involving the dissemination of defendant’s documents to a reporter for *The New York Times* in violation of the court’s protective order.

The Context

In August 2004, parties in the *Zyprexa* litigation agreed a protective order permitting them to designate discovery materials as “confidential” that the producing party believed in good faith were protected under the Federal Rules. *Id.* at 17. Once a document was deemed confidential, it could only “be used by the receiving party ... for the prosecution or defense of this Litigation, to the extent reasonably necessary to accomplish the purpose for which disclosure is made.” *Id.*

Plaintiffs’ expert, Dr. David Egilman, duly signed the protective order before receiving any documents for review. *Id.* at 21. As it turned out, Egilman was simultaneously discussing the *Zyprexa* litigation with reporter Alex Berenson at *The New*

York Times. *Id.* Berenson wanted to review the confidential Zyprexa documents, but was aware of the court's protective order. *Id.* Circumventing the order, Berenson suggested Egilman contact James Gottstein, an attorney in Alaska. *Id.* at 22. Egilman then informed Gottstein that he possessed confidential documents and would produce them in response to a subpoena, if certain procedures were followed, including notice to Lilly. *Id.* at 23. On December 11, 2006, Gottstein — without notice to Lilly — served a subpoena requiring Egilman to deliver the confidential documents to him for use in a deposition. *Id.* at 24. The documents were subsequently disseminated to multiple parties, including Congressional staffers and various websites. They also supported articles published in *The New York Times*. *Id.* at 27-30.

Lilly's Attempts to Reclaim Documents

Immediately after discovering the improper dissemination of its confidential documents, Lilly informed the Special Master. *Id.* at 30. After unsuccessfully trying to reach attorney Gottstein on the phone, the Special Master issued an order requiring him to return the confidential documents. *Id.* Gottstein objected to the order, but volunteered that he had ceased disseminating the documents as of December 15, 2006. *Id.* After receiving Gottstein's response, Lilly sought formal intervention by Judge Weinstein. *Id.*

Judge Weinstein's Response

In a 78-page ruling, Judge Weinstein labeled the disseminators' actions "illegal," "stealing," and "brazen flouting" of his protective order. *Id.* at 14, 63, and 75. He then issued an injunction requiring return of the documents and enjoining respondents from any further dissemination. *Id.* at 77-78.

Turning back the disseminators' First Amendment challenge, the court declared the protective order constitutional because "the right to speak and publish does not carry with it the unrestrained right to gather information." *Id.* at 65 (quoting *Zemel v. Rusk*, 381 U.S. 1, 16-17 (1965)). As for the injunction against additional dissemination, Judge Weinstein said it was content neutral, because it did "not depend on the nature of the content of the idea [to be expressed] but only on the materials that would be the medium of expression." *Id.* at 66 (quoting *Lindsey v. Bloomberg*, slip op. at 18-19

(2d Cir. Feb 1, 2007)). He explained the injunction was necessary to "prevent irreparable harm to Lilly," and served important governmental interests — by

allow[ing] the court to protect the privacy and property rights of litigants appearing before it, which is essential to a fair and efficient system of adjudication. By prohibiting dissemination in violation of the court order[,] the court's ability to enforce its own pretrial orders it preserved.

Id. at 66, 68.

Contrary to Lilly's request, the court did not, however, enjoin any of the various websites in possession of the documents from posting, on the ground that prohibiting the websites from posting the documents would not substantially lower any risk of harm to Lilly. According to Judge Weinstein, "limiting the fora" — five of the Internet's millions of websites — "available to would-be disseminators by such an infinitesimal percentage would be a fruitless exercise of the court's equitable power." *Id.* at 70.

"Ends Do Not Justify Means"

While Lilly did not seek an injunction against Berenson, *The New York Times* reporter, the court did not spare him the rod. Judge Weinstein stated that such conduct could not be condoned by courts, even if the actions were done for what was perceived as the greater good.

Even if one believes, as apparently did the conspirators, that their ends justified their means, courts may not ignore such illegal conduct without dangerously attenuating their power to conduct necessary litigation effectively on behalf of all the people.... Such unprincipled revelation of sealed documents seriously compromises the ability of litigants to speak and reveal information candidly to each other; these illegalities impede private and peaceful resolution of disputes.

Id. at 13. ©

Et cetera

Publications

- ⊙ Thomas Riley and Gina Ilardi published “When Is A Tort Complete? Courts Address Whether Plaintiffs Can Assert Claims Without Injury,” on *Law.com* (forthcoming March 2007).
- ⊙ In January 2007, Thomas Riley and Robert Conrad published “Recent Decision Undercuts Device Manufacturer’s Pre-emption Defense,” on *Law.com*.
- ⊙ In January 2007, David Wallace published “Lost in Translation: The Blurring of the Distinction Between Assumption of Risk and Comparative Fault by Tort Plaintiffs For Profit,” in *Strictly Speaking*, a DRI newsletter.
- ⊙ Phoebe Wilkinson published “Foreign Plaintiff’s Attempts to Use U.S. Courts to Litigate Personal Injury Product Liability Claims,” in Volume 18, Issue 2 of *Products Liability* (Winter 2007), a newsletter published by the ABA Section of Litigation, Committee on Products Liability Litigation.

Speaking Engagements

- ⊙ On February 26-27, 2007, Joseph Falcone and Phoebe Wilkinson spoke on the use of state consumer protection statutes in products liability class actions at a seminar entitled “*The Advanced Legal, Regulatory and Commercial Guide to Medical Devices: Best Practices, Key Regulatory Issues and Future Prospects in the Changing Medical Devices Market*,” in Munich, Germany.
- ⊙ 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.

Press Coverage

- ⊙ On February 4, 2007, David Wallace was interviewed by Bloomberg Radio in connection with a segment on *Bloomberg Law* about the preemptive effect of FDA pharmaceutical labeling rules on the Prempro hormone therapy litigation.

To view the full articles please visit Chadbourne’s online publications at <http://www.chadbourne.com/publications/index.html>.

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