

Inre Products Liability

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NANO LAW

Debating Nanotechnology Risk and Reward

Introduction

With nanotechnology-rooted innovation forecasted to account for upwards of \$1.5 trillion in global commerce by 2015, the stakes are high. The low-hanging fruit of nanotechnology is being harvested now, with upwards of 600 nano-labeled products on the market internationally. But the bigger investment and return on nanotechnology is poised to unfold over the next 5 to 15 years and beyond — in the form of personalized medicine (targeted drug delivery, with fewer side effects); improved, cleaner means of energy production, storage and distribution; faster (more powerful, miniaturized) computers and personal communication devices; and major advances in infrastructure improvement, in the form of lighter, stronger cement and steel. Examples of its promise abound.

In late January, the Congressional Nanotechnology Caucus convened a briefing, called “Nanotechnology and Innovation, Commercialization and Prize Competitions,” which squarely framed current debate over the emergent promise of nanotechnology in a panel discussion. On one side — entrepreneurially minded, high-tech enthusiasts, representing scientific and commercial interests; on the other — a cautious band of public interest groups and think-tanks poking sticks into the spokes of innovation, emphasizing the risk side of the cost-benefit equation.

The Two Faces of Nanotechnology: Risk and Reward

A summary and analysis of the issues raised by the Congressional Nanotechnology Caucus’ briefing follow. In many ways, they are familiar. / continued page 2

THE AGENDA

- 1 NANO LAW
 - High Stakes of Nanotechnology Innovation
- 4 PREEMPTION
 - FDA Clarifies Trigger for CBE Supplements
- 6 PUNITIVE DAMAGES
 - Diverging Decisions Post-Williams
 - Ohio’s Constitutional Cap on Damages
- 9 CLASS ACTIONS
 - Consumer Fraud Certification Denied
- 12 CONSUMER FRAUD
 - Taking the “What if?” Out Of Consumer Fraud
- 15 ASBESTOS
 - “Tort Math” Subtracts Claims in U.K.
- 17 MULTIDISTRICT LITIGATION
 - Round-up: Hormone Replacement, Welding, and Patch Litigation
- 20 ET CETERA

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NANO LAW

continued from page 1

iar ones — echoed in earlier public debates over the risks and rewards of innovation and the commercialization of emerging technologies generally.

In transiting the Atlantic by airplane in 1925, Lindberg claimed a privately endowed prize of \$25,000, the offering of which generated (or leveraged) some \$400,000 worth of pioneering aviation research and development work — the current equivalent of some \$4.5 million dollars — by the French and American teams that competed for the prize. It also gave birth to commercial aviation. Similar scientific, technological and engineering prize challenges have been financed over the years by private and other investors, more recently leading to innovation like “SpaceShipOne” — the world’s first privately funded manned space flight, an achievement spurred by the \$10 million Ansari X-Prize. Ten months after claiming this prize, Scaled Composites leveraged its research and technology investment (and resulting visibility) into a partnership with Sir Richard Branson to form a new aerospace production company to build a fleet of commercial sub-orbital spaceships and launch systems.

Investment of this sort cuts at the edge of high-tech research and technology, sowing the seeds for innovation — basically, out-of-the-box thinking. This was the substance of remarks Mr. William Pomerantz, the Director for Space Operations at the X-Prize Foundation. Through the innovation-oriented scientific challenges it mounts, this foundation is, in effect, laying the foundation for all manner of future progress. His point? Nanotechnology should be part of that equation.

Mr. Edward Cupoli, an economist, told the story of his employer: the nation’s first (and leading) college of nanotechnology in upstate New York — the University at Albany, part of the public university system known as SUNY. Functioning on a business innovation model, as opposed to the traditional academic research model, the University at Albany has attracted over \$4 billion in private sector R&D nanotechnology investment under the umbrella of its operations since its creation in 2004. He described it as a virtual “nano-mall,” offering high-tech “critical mass” to the private sector — in the form of state-

of-the-art research infrastructure, equipment and related expertise — for the incubation, development and commercialization of nanotechnology-based products on a public-private partnership basis.

Reflecting the interdisciplinary nature of nanotechnology, Mr. Cupoli explained that Albany’s college of nanotechnology integrates chemistry and physics under the curriculum head of “nanoscience” and (through the “nanoeconomics” part of its academic program) trains future scientists to “see through” the development and deployment of nanoscience principles, products and process from economic and business perspectives.

Mr. David Rejeski, the Director of the Project on Emerging Nanotechnologies at the Woodrow Wilson Center, raised a different perspective on nanotechnology, opining that nanotechnology represented not a promised “green” revolution, but instead a “brown” one — characterizing nanotechnology as “chemical synthesis on steroids.” In nanotechnology, particularly its convergence with biotechnology, he sees great risks, which must be “engineered out of” nanotechnology products and production.

Calling for the nanotechnology “stick” to be pulled back a bit, Mr. Rejeski then outlined the following roadmap for nanotechnology stewardship. *First*, given the trans-disciplinary nature of nanotechnology, it is critical that researchers get into its “white spaces” — the interstitial gaps separating the various scientific disciplines behind the field — to ensure the full spectrum of environmental, health and safety risks are run to ground before greater commercialization. To do this, he proposed adopting the DARPA model (for the Defense Advanced Research Projects Agency). *Second*, create a centralized venture capital fund to attract and leverage private-sector investment in order to cover the void between university laboratories as well as small start-ups — where much nanotechnology is originating — and the market. He specifically advocates feeding this funding through the Department of Energy, on the model of the Manhattan Project. *Last*, he proposed offering “a Green Nano” X-Prize-type competition to jump-start the renewable energy and environmental promise of nanotechnology. At the same time, Mr. Rejeski expressed skepticism about the likely adoption of his recommendations given

what he described as America's less than enthusiastic approach to risk management issues historically.

Mr. Scott Livingston, of Axiom Capital Management, an investment banker who has focused almost exclusively on nanotechnology since 2002, closed the session by highlighting the promise of nanotechnology investment from a variety of commercial perspectives. In doing so, he particularly emphasized the healthcare, energy, environmental, infrastructure and security sectors. Stressing the longer view, he dismissed concern over the recent "troughing" of nanotechnology investment, pointing out that in roughly 15 years Apple went from "dog" to "top-dog," investment-wise, on the back of emerging technology.

He said that while there is considerable interest in nanotechnology research and technology as a means of addressing global challenges, the investment and political "connections" necessary to make it happen are not yet sufficiently systematized.

Where Do We Go From Here? Novel Innovation Paradigms and the New York Model

To be sure, the debate over nanotechnology's risk and reward calculus is one that must be had as a matter of public policy and, to the extent necessary, regulation — although not necessarily along the lines and nature of traditional risk-management models and operating principles in respect of innovation.

The state-of-the-art, high-tech platform from which nanotechnology commerce is launched and traded may well require altogether new public policy and business paradigms, which — for example — might bring the various stakeholders in nano-based product and technology lifecycles to the table for constructive dialogue and debate. This dialogue should include those with a perspective on the potential public risks. Indeed, rather than mechanically repeat the example of past experience with other emerging technologies, some nanotechnology stakeholders have already opted instead for another way: funding, organizing and empowering research-driven universities to operate on a business innovation model, in dynamic partnership with private industry, to support critical nanotechnology research and development work, along with the creation of

related high-wage, high-tech manufacturing jobs that typically must be close to R&D facilities.

This is the New York model, pioneered by the Honorable George E. Pataki (now counsel at Chadbourne & Parke LLP), whose public policy initiatives in support of nanotechnology as Governor of New York have revitalized parts of the upstate economy, chiefly in and around the Albany area, centered at the college of nanoscale science and engineering at SUNY-Albany that he was so instrumental in creating. Through nanotechnology, this model is powering the development of an internationally significant regional market for high-tech, nanotechnology-specific research and development support — on the basis of novel public-private partnerships and business models.

New York's initial capital investment in this nanotechnology project, which began earlier this decade at a cost of roughly half a billion dollars (just recently increased \$300 million dollars by the current governor), has since leveraged and lured approximately \$5 billion in private sector investment to public benefit in the operations of a sleek, sprawling, high-tech complex known as Albany NanoTech.

The New York model reflects the spirit of the X-Prize Foundation's periodic scientific or engineering prize-money challenges discussed by Mr. Pomerantz; it embodies Mr. Cupoli's "nano-mall"; it reaches the "white spaces" referenced by Mr. Rejeski; and it naturally facilitates the necessary investment and political "connections" stressed by Mr. Livingston — helping to bridge the great divide between innovation (the spark of an idea) and its commercialization: the marketplace.

Conclusion: Getting Nanotechnology Right

This marketplace, like time and tide, waits for no one, notwithstanding the shadow of risk and uncertainty. In the event, the chances of striking the right balance between the promotion and regulation of nanotechnology along the way would seem to be greatest, intuitively, as a product of public-private partnerships and ventures along the lines of something like the New York model. Collaboration of this sort would seem more likely to better inform, mature and synthesize related nanotechnology public policy, regulation and liability considerations.

/ continued page 4

NANO LAW

continued from page 3

In sum, the issue of nanotechnology is too important — strategically, commercially and socially — for the historical cycle of an initial laissez faire approach and then mortal risk by litigation or regulation. Perhaps, as Mr. Rejeski suggested, it calls for something akin to another Manhattan Project for the study, identification, characterization and management of its potential health and safety risks. If nothing else, nanotechnology — which is not going to go away — calls for the creation and deployment of new policy and business paradigms every bit as innovative as nanotechnology itself. ☺

PREEMPTION

FDA Stakes Position in Face of Looming Preemption Battle in *Wyeth v. Levine*

See Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics and Medical Devices, 73 Fed. Reg. 2848 et seq. (Jan. 16, 2008)

Background

The plot has thickened in the long-simmering preemption debate surrounding the labeling of FDA-approved drugs, biologics and medical devices.¹ In January, amidst closely watched U.S. Supreme Court scrutiny of FDA-related preemption issues in a trio of cases — *Riegel* (an 8-1 victory for device manufacturers), *Warner-Lambert* (a 4-4 draw leaving undisturbed a Second Circuit decision finding no preemption of a “fraud on the FDA” claim) and *Levine* (a drug labeling case to be argued next term) — the FDA has announced its own view on the subject.

It did so by notice of proposed rulemaking intended “to make explicit the agency’s longstanding view of when a change to the labeling of an approved drug, biologic, or medical device may be made in advance of the agency’s

[formal] review of the change.” 73 Fed. Reg. 2852. More specifically, FDA’s proposed rulemaking relates to the proper use of so-called CBE supplements (shorthand for “changes being effected supplements”), which FDA explains were originally “intended to apply only if the sponsor became aware of newly discovered safety information that was appropriate for inclusion in the labeling for the product.” *Id.* at 2849.²

The Battle Lines

Conflicting interpretation of these regulations is at the very heart of the implied conflict preemption debate around which the battle lines have been drawn in *Wyeth v. Levine* (Docket No. 06-1249). In this case, the Vermont Supreme Court affirmed a jury verdict against the maker of Phenergan for nearly \$7 million — following the trial court’s rejection of Wyeth’s preemption defense — holding that FDA regulations regarding CBE supplements “allow unilateral changes to drug labels whenever the manufacturer believes it will make the product safer.” *See Levine v. Wyeth*, No. 2004-384, 2006 WL 3041078, at ¶ 32; *id.* at ¶ 6 (“federal labeling requirements create a floor, not a ceiling, for state regulation”). *See also* “Preemptive Effect Owed FDA Pharmaceutical Labeling Rule Generates Debate,” *In re Products Liability* 8 (Nov. 2006).

Staking out its position as the “expert public health agency” vested by Congress with “ultimate authority over drug, biologic, and medical device labeling,” the proposed rulemaking notice reiterates that “FDA[] review and prior approval of both the product and its proposed labeling is a necessary condition of lawful distribution of the product in interstate commerce” and a clear statutory requirement. 73 Fed. Reg. at 2849 (emphasis added). This is true notwithstanding the CBE supplement procedures, which the FDA

¹ See generally “*The Federalist Papers*: Medical Equipment Makers Take Dispositive Preemption Question to U.S. Supreme Court,” *In re Products Liability* at 1 (July 2007); “Senator Leahy Pushes Back Against Bush Administration’s Preemption Policies in Judiciary Committee Hearings,” *In re Products Liability* at 6 (Nov. 2007) (discussing Senate Judiciary Committee hearings on current FDA preemption debate).

² “These supplements would describe changes placed into effect to correct concerns about newly discovered risks from the use of the drug.” *Id.* (quoting 47 FR 46622, 46623, Oct. 19, 1982) (emphasis in original).

several times repeats “are narrow exceptions to this general rule.” *Id.*

FDA Tightens Focus on CBE Supplement Disclosure Triggers

Referring (obviously among other things) to changes made to the Food, Drug and Cosmetics Act by last year’s Food and Drug Administration Amendments Acts (see Public Law 110-85, Sept. 27, 2007), which were designed to enhance the FDA’s ability to respond to “new or emerging information about an approved drug or biologic,” the FDA expressed a need to amend its regulations to make its “understanding” of the purpose and operation of CBE supplements — specifically, that they are intended to capture and report only “newly acquired” or “novel [safety] information” — “explicit.” *Id.* at 2850. To this end, it explained:

The objective of the proposed rule is to make explicit the agency’s longstanding view of when a change to the labeling of an approved drug, biologic, or medical device may be made in advance of the agency’s review of the change. More specifically, the purpose of the proposed rule is to codify the agency’s understanding that a CBE supplement is appropriate to amend the labeling for an approved product only to reflect *newly acquired information*, and to clarify that a CBE supplement may be used to add or strengthen a contraindication, warning, precaution, or adverse reaction *only if there is sufficient evidence of a causal association with the approved product*.

Id. at 2852 (emphasis added).

Sharpening the point, the FDA instructed that “newly acquired” or “novel” safety information refers to “a risk that is different in type or severity than previously known risks about the product.” *Id.* at 2850. As such, “a postmarket study” providing “cumulative” data about a product, or reports of “adverse events” that are “consistent in type, severity, and frequency with information previously provided to FDA, would not typically constitute “newly acquired information appropriate for CBE supplement.” *Id.* In short, the FDA takes the position that “[a]llowing a sponsor, without prior FDA approval, to add information to the

labeling for a product based solely on data previously submitted to the FDA” — as decisions like *Levine v. Wyeth* require — would “undermine FDA’s approval process and could result in unnecessary or confusing information being placed in the labeling for a drug, biologic, or medical device.” *Id.* at 2851.

Leaving no doubt as to its position, the FDA also expressly addressed the issue of implied conflict preemption, stating that:

To the extent that state law would require a sponsor to add information to the labeling for an approved drug or biologic without advance FDA approval based on information or data as to risks that are similar in type or severity to those previously submitted to the FDA, or based on information or data that does not provide sufficient evidence of a causal association with the product, such a state requirement would conflict with federal law. In such a situation, it would be impossible to market a product in compliance with both federal and state law, and the state law would “stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress” . . .

Id. at 2853 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)). Finally, the agency declared that “federal law governs not only what information must appear in labeling, but also what information may not appear.” *Id.* at 2850 n. 3 (citing 71 Fed. Reg. 3922, 3935, Jan. 24, 2006, for the proposition that the FDCA “establish[es] both a ‘floor’ and a ‘ceiling’”).

In making these statements, the FDA specifically expressed concern that state product liability laws and judgments are leading to an “[e]xaggeration of risk” and the “inclusion of speculative or hypothetical risks, which can “discourage appropriate use of a beneficial drug, biologic, or medical device or decrease the usefulness and accessibility of important information by diluting or obscuring it” — causing “meaningful risk information to lose its significance. *Id.* at 2851.

Opposition Politics

The FDA’s proposed rulemaking quickly drew pointed crit-

/ continued page 6

PREEMPTION

continued from page 5

icism from Congress and various interest groups. Accusing the FDA (and Bush administration) of a power grab, the American Association for Justice charged that the measure “would allow drug companies to claim immunity for failing to warn patients of potential drug hazards,” *BNA Product Safety & Liability Reporter* at 67 (Jan. 21, 2008). Within a week of the rulemaking’s issuance, Senator Kennedy and Congressman Waxman and other congressional democrats had begun a letter-writing campaign expressing “profound regret” about the FDA’s alleged abdication of its “mission” and responsibility to consumers in favor of protecting “companies in the pharmaceutical and device industry from being held liable for marketing products they know are unsafe.” See Letter from H. Waxman *et al.* to FDA Commissioner A. von Eschenbach, M.D. at 1 (Jan. 23, 2008).

Ignoring the fact that the FDA (like other federal agencies) does not fund itself, these lawmakers began their letter by heaping scorn upon the agency as “all but starved of resources,” and as such “unable to protect the American public from even the most basic threats” to food, drug and medical device safety. *Id.* at 2. Not once acknowledging the FDA’s statement of concern — as an “expert public health agency” — about the serious risk to public health created by the pressure for a proliferation of exaggerated, speculative and cumulative warnings in regard to drugs, biologics and medical devices, 73 Fed. Reg. at 2851, they deny any “purpose” or justification for the proposed rulemaking “other than to shore up the industry’s legal arguments for avoiding liability. See Waxman Letter at 2 (“[T]he proposed rule fails to identify a single problem associated with these regulations that would warrant a modification, much less a public health threat of such magnitude as to put issuing the proposal at the top of the FDA’s priority list.”).

Conclusion: What Says the Supreme Court?

The picket lines having been firmly established on drug labeling preemption between the Executive and Legislative branches of the U.S. government, the way forward awaits guidance by the U.S. Supreme Court next Term through *Wyeth v. Levine*. ©

PUNITIVE DAMAGES

The Devil’s In the Details: Courts Diverge on Punitive Damages Post-Williams

See *Williams v. Philip Morris Inc.*, 344 Or. 45 (Or. Jan. 31, 2008); *Bullock v. Philip Morris USA, Inc.*, 159 Cal. App.4th 655 (Cal. App. 2 Dist., Jan. 30, 2008)

Overview

Two recent decisions by appellate courts in California and Oregon shed some early light on how state courts across the country are likely to interpret the U.S. Supreme Court’s constitutional mandate in *Philip Morris USA v. Williams*, 127 S. Ct. 1057, 1064-65 (Feb. 2007), which obligates state courts to employ “procedural safeguards” to prevent “an unreasonable and unnecessary risk” that juries will “punish a defendant [with punitive damages] on account of harms it is alleged to have visited on nonparties.” *Id.* In one instance, the Oregon Supreme Court — on remand in *Williams* from the nation’s high court — basically ignored the mandate; in the other, the California Court of Appeals remanded for a new trial on punitive damages.

Oregon Supreme Court Rebuffs U.S. Supreme Court to Affirm Punitive Damages Award On Procedural Grounds

On remand in *Williams*, the Oregon Supreme Court never addressed whether the trial court’s jury instructions failed to safeguard Philip Morris’s due process rights. Ignoring this constitutional question on which remand was predicated, the Oregon Supreme Court came up with an “independent and adequate state ground” for affirming the jury’s punitive damages verdict. *Williams*, 344 Or. at 55.¹ Specifically, Oregon’s high court held that because Philip Morris’s proposed jury instruction on punitive damages was not free of error, it was barred by state law from challenging the trial court’s failure to accept it.

Significantly, the “erroneous” part of Philip Morris’s pro-

posed charge had nothing to do with the portion that cautioned the jury to refrain from “punish[ing] the defendant for the impact of its alleged misconduct on other persons . . .” *Id.* at 49 (quoting proposed charge). The Court instead found error in two unrelated aspects of the charge — one that proposed instructing the jury that the statutory factors bearing on the propriety of a punitive damage were discretionary, rather than mandatory; and another that would have urged the jury to consider Philip Morris’s profit-making *motives and intent* as opposed to simply its *profits*. *Id.* at 59-61.

Elevating procedure over substance, the Oregon Supreme Court then criticized Philip Morris for putting all its “eggs in one instructional basket” by incorporating its punitive damages instructions under the heading of a single proposed instruction. *Id.* at 56.

Concluding its maneuvering around the clear mandate of the U.S. Supreme Court, Oregon’s high court ended by faulting Philip Morris for failing to add an objection to the punitive damage instructions actually given by the trial court to the objection, even though Philip Morris had lodged an objection to that court’s failure to give Philip Morris’s proposed instruction. In doing so, the Oregon Supreme Court reasoned that new trials for instructional error were proper only when a proposed instruction can be said to be “clear and correct *in all respects*, both in form and in substance, and . . . *altogether free from error*.” *Id.* at 56. (quotation and citation omitted) (emphasis added). It “is not enough,” it said, “to offer a proposed instruction that is

correct in part and erroneous in part, leaving the trial court to solve the problem for itself.” *Id.*

In doing so, the Oregon Supreme Court ignored the fact that Philip Morris’s proposed jury instruction on punitive damages was entirely consistent with the type of procedural safeguards the U.S. Supreme Court in *Williams* deemed necessary to avoid what it considered the “unreasonable and unnecessary risk” of juries asking themselves “the wrong question.” Avoiding this critical issue altogether, the Oregon court detoured instead from substantive ground in favor of a discourse on procedural requirements.

Heeding *Williams*, California Appeals Court Orders New Trial on Punitive Damages

In another tobacco case decided just a day earlier, a California appellate court reached a different conclusion from their brethren up the coast, finding Philip Morris entitled to a new trial on punitive damages based on the trial court’s refusal to instruct the jury — at Philip Morris’s request — “not to impose punishment for harms suffered by persons other than the plaintiff before you.” *Bullock*, 159 Cal. App. 4th at 693 (quoting proposed charge).

According to the *Bullock* court, this instruction “expressed the rule of law later confirmed in *Williams*, that the jury could not award punitive damages for the purpose of punishing Philip Morris for harming nonparties to the litigation.” *Id.* In regard to defendant’s failure to include the *Williams* reprehensibility “qualification” in its instruction — “that evidence of harm caused to others could be considered to determine the *reprehensibility* of the conduct that [had] harmed” plaintiff, but not for punishing defendant (emphasis added and original emphasis omitted) — the court concluded that this technical shortcoming did not “render the instruction incomplete or misleading,” since a litigant has no “duty to . . . qualify its proposed instruction in order to encompass a rule of law favorable to” one’s adversary.” *Id.* at 693-94. Thus, because Philip Morris’s proposed instruction accurately stated the law as subsequently clarified by *Williams*, the *Bullock* trial court’s refusal to give it warranted a new trial on punitive damages.

/ continued page 8

¹ This was not the first time in this case that Oregon’s Supreme Court avoided a U.S. Supreme Court mandate. In 2003, the U.S. Supreme Court remanded *Williams* in light of a then-recently decided U.S. Supreme Court opinion — *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003). *Id.* at *3 (citing *Philip Morris USA Inc. v. Williams*, 540 U.S. 801 (2003)). In *State Farm*, the U.S. Supreme Court determined that “few awards exceeding a single-digit ratio between punitive and compensatory damages, to a significant degree, will satisfy due process.” 538 U.S. at 425. On remand, both the Oregon Court of Appeals and the Oregon Supreme Court “concluded that the \$79.5 million punitive damages award [in *Williams*] comported with due process,” even though the compensatory damages award against Philip Morris was only \$821,000 (thereby creating a 97 to 1 ratio between the two awards).

PUNITIVE DAMAGES

continued from page 7

Conclusion

For cases already on appeal, the record is what it is. For defendants gearing up for trials involving punitive damages claims, however, these two recent opinions sound a cautionary note. Both illustrate the importance of drafting proposed punitive damages charges with extreme care. Unfortunately, as we noted in these pages last year, exactly “[h]ow 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.”² ☉

Ohio Supreme Court Upholds Punitive Damages Cap on Constitutional Challenge

See *Arbino v. Johnson & Johnson*, 116 Ohio St. 3d 468 (Ohio Dec. 27, 2007)

Background

Plaintiff brought a product liability lawsuit against Johnson & Johnson (and others) in federal court in the Southern District of Ohio, claiming “she suffered blood clots and other serious medical side effects from using . . . a hormonal birth-control medication.” *Id.* at 468-69. Thereafter, she filed a summary judgment motion challenging the constitutionality of several recent tort-reform statutes enacted by the Ohio legislature, one of which — Ohio Revised Code § 2315.21 (the “Code”) — capped “punitive damages in tort actions to a maximum of two times the total amount of compensatory damages awarded to a plaintiff per defendant.” *Id.* at 486. While this motion was pending, the federal judicial panel on multidistrict litiga-

tion consolidated the case with other similar cases, following which the federal judge overseeing these cases certified several questions to the Ohio Supreme Court for review, including the constitutionality of Ohio’s statutory cap on punitive damages.

Ohio Supreme Court Upholds Cap’s Constitutionality

Plaintiff unsuccessfully advanced several constitutional challenges, arguing that the cap violated (1) her right to a jury trial, (2) her right to open court remedy, (3) her due process rights, (4) her equal protection rights, and (5) the separation of powers doctrine (because “the statute unconstitutionally seizes the judicial power to determine damages”). *Id.* at 486-90.

No Trespass on Jury’s Province

First, the Court said “the fact that a statute limits potential damages as a matter of law does not mean that it violates the right to a jury trial.” *Id.* at 487. Distinguishing a case cited by plaintiff in which the Court struck a statute as unconstitutional for “wholly remove[ing] the jury from the [punitive damages] fact-finding process,” *id.* (referring to *Zoppo v. Homestead Ins. Co.*, 71 Ohio St. 3d 552 (Ohio 1994)), the Court held that the Code permitted juries to fashion their own punitive damages awards, subject only to any degree of remittitur necessary to ensure that such awards do not exceed the statutory cap. In distinguishing another case forming the basis of plaintiff’s constitutional attack on the statute, the Court dismissed as *dicta* its prior judgment “that a similar limit on punitive damages [imposed by an earlier statute] would unconstitutionally infringe on the jury’s fact-finding function” — since the statute at issue in that case was struck *in toto*. *Id.* (referring to *Ohio Academy of Trial Lawyers v. Sheward*, 86 Ohio St. 3d 451 (Ohio 1999)). Past this point, the Court held that it was still necessary to “revisit” the issue in light of more recent U.S. Supreme Court punitive damages jurisprudence recognizing that state legislative bodies have “broad discretion in authorizing and limiting permissible punitive damages awards.” *Id.* (quoting *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424, 433 (2001)).

² See “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,” *In re Products Liability* at 1 (April 2007).

Right to Open Court Remedy Not Compromised

Second, the Court found that the statute worked no denial or abridgment of plaintiff's right to remedy in open court because plaintiff maintained "the ability to seek a 'meaningful' remedy for [her] injuries," notwithstanding the statutory cap on punitive damages. More to the point, the Court reasoned that since punitive damages "are not compensation for injury," but rather "private fines levied by civil juries to punish reprehensible conduct and to deter its future occurrence," *id.* at 488 (citations and quotations omitted), they are "separate and apart" from any private remedies available to plaintiff. As such, the Code did not bar her "from bringing a successful cause of action for [her] injuries." *Id.*

Rational Basis for Due Process/Equal Protection Infringements

On plaintiff's *third* and *fourth* points — due process and equal protection claims — the Court employed a "rational basis" standard of review in finding that plaintiff's due process and equal protection rights were not compromised by the Code. It did so on the view that the "general goal of making the civil justice system more predictable" was "logically served by placing limits that ensure punitive damages generally cannot exceed certain dollar figures." *Id.* at 489. In support, the Court noted that part of the legislature's stated reason for enacting the statutory cap was the "absence of a statutory ceiling upon recoverable punitive or exemplary damages in tort actions," which was spawning awards bearing "no rational connection to the wrongful actions or omissions of the tortfeasor." *Id.*

Finally, the Court rejected plaintiff's separation-of-powers argument for reasons similar to its denial of plaintiff's right-to-trial-by-jury argument — namely that "statutory damages limits do not intrude on the judicial power to determine damages." *Id.* at 490.

Dissent Focuses on Perceived Constitutional Flaws

A lone dissent distilled several constitutional flaws from its review of the Code, beginning with a finding that the Code violated plaintiff's right to trial by jury because it "impairs the traditional function of the jury in determining

the appropriate amount of punitive damages." *Id.* at 517 (quoting *Zoppo*, 71 Ohio St. 3d at 557).

On plaintiff's due process and equal protection arguments, the dissent rejected the majority's application of the rational-basis test, holding instead that the Code "should be subjected to strict scrutiny because it involves or infringes upon a fundamental right." *Id.* Applying this test, the dissent eviscerated the legislature's factual findings in support of the punitive damages cap law, choosing to characterize these findings as "vaporous," "not relat[ing] specifically to Ohio," "not objective or verifiable," and consequently insufficient to justify any impingement of fundamental constitutional rights. *Id.*

In sum and substance, according to the dissent, the Code directly undermined the state's interest in punishing and deterring wrongdoing via punitive damages since "caps" on punitive damages "enable wrongdoers to assess the cost of their malfeasance up front without regard to the individualized damage they cause." *Id.* at 518. ©

CLASS ACTIONS**Class Certification Denied in Consumer Fraud "Lights" Case on Absence of "Predominance" and "Superiority"**

See *Stern v. Philip Morris*, No. MID-L-2584-03 (Sup. Ct. N.J. Nov. 16, 2007)

Introduction

As part of an emerging trend in products liability litigation, the plaintiff's bar has focused on state-law consumer fraud statutes to support claims for the recovery of economic damages (typically through class actions). One of the primary targets of this developing area of the law has been tobacco manufacturers, on claims that they deceptively and misleadingly market "light" and "low tar" cigarettes, and pharmaceutical companies accused of using fraud and deceit to justify premium pricing. Using consumer-fraud

/ continued page 10

CLASS ACTIONS

continued from page 9

laws, plaintiffs typically seek to recover damages in the form of the difference in monetary value between the product (or benefit) for which they supposedly bargained and what they instead received.

To date, New Jersey courts — at the vanguard of this skirmishing — have not been too receptive to this effort, as the *Stern* case illustrates. See generally “N.J. Supreme Court Uponds Nationwide Vioxx Cost-Reoupment Class Action of Failure of ‘Predominance’ and ‘Superiority,’” *In re Products Liability 12* (Nov. 2007).

Background

In *Stern*, plaintiffs brought a putative class action seeking economic damages under New Jersey’s consumer fraud statute (CFA) on the theory that Philip Morris “designed, promoted and marketed their ‘Marlboro Lights’ cigarettes in a way that deceptively conveyed” the impression “that they delivered lowered tar and nicotine.” *Id.* at 4.¹ While holding that plaintiffs had satisfied the general requirements for class certification — *i.e.*, numerosity, commonality, typicality and adequacy of representation — the trial court denied class certification on finding a predominance of individual issues.

The Predominance Analysis

On “rigorous analysis” of the “predominance” question, the court concluded that while defendant’s alleged “unlawful conduct” was a common question, the other two essential elements of a *prima facie* CFA cause of action — “ascertainable loss” connected by a “causal relationship” to defendant’s “unlawful conduct” — implicated predominantly individual issues. *Id.* at 10-12. In reaching this conclusion, the court stressed the inherently individualistic nature of the reasons behind each smoker’s purchasing decision, combined with each class member’s smoking history, and the ineluctable salience of these issues to the question of causation.

Reason For Purchasing Decision — Individual Issue

Plaintiffs’ up-front concession of myriad possible indi-

vidual reasons for the use of “light” cigarettes hardly helped advancement of their common-question position. On this point, the court held:

There exists many reasons why a class member may have chosen to smoke Marlboro Lights. That reason is not necessarily related to any representation made by defendants as to their ability to deliver lower amounts of tar and nicotine. . . . Plaintiffs must prove a causal nexus between defendant’s alleged misrepresentation and any ascertainable loss. Since there are many non-health related reasons why people purchased light cigarettes, defendant shall be permitted to individually inquire why that class member chose Marlboro Lights *i.e.*, was the reason motivated by taste, habit, personal preference, peer influence or health related reasons?

Id. at 14. Plaintiffs’ request for a rebuttable presumption of causal nexus failed for the same reason, making “individual inquiry” unavoidable. *Id.* at 14-15 (“The record before this Court reveals that consumers have reasons other than alleged deception or misrepresentation to choose Marlboro Lights.”).

Smoking History and Behavior— Individual Issue

Unable to controvert the fact that “individual smoking habits raise individual issues,” plaintiffs argued instead that individual smoking behavior was “not relevant” to the certification question, on the basis that the nub of their claim was that the “light” cigarettes at issue were not “consistently or verifiably” what they were “represented to be.” *Id.* at 15-16. Defendants countered that the only way to prove that each class member failed to receive what “Marlboro Lights” were said to offer — that is, “less tar and nicotine . . . than a full flavor Marlboro” — was through individual cross-examination of smoking behavior and smoking history. *Id.* at 16.

Siding with defendants, the court characterized the

¹ The class was defined to include individuals who had purchased “Marlboro Light” brand cigarettes in New Jersey over a three-decade period — from 1971 to 2003.

issue as one wholly “dependent upon a number of issues unique to each individual class member.” *Id.* In reaching this conclusion, the court analyzed a case cited by both parties — *Gordon v. Boden*, 586 N.E. 2d 461 (Ill. App. Ct. 1991) — in which class certification was granted on claims that defendant had misrepresented its product as being “100 percent orange juice” when that was not so. *Id.* at 17. The court noted that the fraudulent nature of defendant’s representations in *Gordon* could be determined “by a single scientific test” uniformly applicable to all class members, whereas the question of “whether each smoker received less tar and nicotine can only be determined by examining how each particular class member smoked, and how and to what extent that smoker may have compensated when smoking Marlboro Lights.” *Id.* at 17. As such, “[t]his is an individual issue not amenable to class-wide proof.” *Id.*

No Ascertainable Loss — Individual Issue

In an effort to establish that class members suffered a quantifiable “ascertainable loss” as required by the CFA, plaintiffs proposed using as the measure of damages “the difference in value between the Marlboro Lights that plaintiffs bargained for (*i.e.*, a safer cigarette that delivered the ‘lowered tar and nicotine’ as represented) and the product as delivered.” *Id.* at 19. In turning plaintiffs’ damage model aside, the court cited the recent New Jersey Supreme Court decision in *Int’l Union Loc. 68 Welf. Fund v. Merck & Co., Inc.*, 929 A.2d 1076 (2007), which rejected a similar “price effect” approach (in the context of a Vioxx cost recoupment action) as “the equivalent of a fraud on the market” theory not recognized by New Jersey law. *Id.* at 20.²

The court would have none of plaintiffs’ attempted end-run of the “ascertainable loss” element of their consumer fraud claim. Elaborating, it said that “[t]he theory on which plaintiffs seek to rely” — basically aggregating class-wide damages based on nothing more than the mere fact of purchase — “would eliminate the requirement that there be a

connection between the deception/misrepresentation complained of and the loss suffered.” *Id.* at 21. The fact resolution of this issue required individual proof made class certification inappropriate.

Conclusion: Failure of “Predominance” and “Superiority”

Ultimately, the court found individual issues predominant because “the core of the litigation is the proposed *class members’ reaction* to the alleged misrepresentations and the individualized decisions they made concerning defendant’s product,” which “outweighed any common questions concerning *defendant’s conduct*.” *Id.* at 23 (citing *Int’l Union*, 929 A.2d at 1087) (emphasis added).

While analysis of the remaining class certification elements was not necessary to deny certification, the court did so in the “interest of completeness.” *Id.* at 23. To this end, it held that the proposed class action was not a “superior” means of adjudication given:

- (a) “the size of plaintiff’s individual damages is hardly nominal” (giving individual class members “substantial stake and motivation” to litigate their claimed injury),
- (b) the greater practicality of “adjudicat[ing] by way of a ‘test case’ involving one or more plaintiffs,”
- and (c) the fact that “individual questions related to causation, loss and affirmative defenses would severely complicate resolution of this action,” necessitating protracted individual “mini-trials.”

Id. at 24-26. ©

² We previously reported on this case in these pages. See “N.J. Supreme Court Upends Nationwide Vioxx Cost-Recoupment Class Action on Failure of ‘Predominance’ and ‘Superiority,’ *In re Products Liability* at 12 (Nov. 2007), see also “New Jersey Court Affirms Nationwide Class in Vioxx Recoupment Litigation,” *In re Products Liability* at 7 (July 2006).

CONSUMER FRAUD

Hypothetical (“What If?”) and Remote Damages Cannot Sustain Consumer Fraud Claims

See *DaimlerChrysler Corp. v. Inman*, No. 03-1189, 2008 WL 274903 (Tex. Feb. 1, 2008); *Independence County v. Pfizer, Inc.*, No. 1:07cv00033-WRW, 2008 WL 398980 (E.D. Ark. Feb. 11, 2008)

Background

Unlike traditional products liability claims, plaintiffs pursuing causes of action under state consumer fraud and deceptive trade practices theories generally do not allege personal injury. In creatively articulating the alleged economic injury, however, plaintiffs often fail to establish a legally cognizable injury for standing purposes — pushing their claims afoul of subject-matter jurisdiction requirements.¹

Two recent cases illustrate the point. In one, the Supreme Court of Texas dismissed a lawsuit in which a putative class of DaimlerChrysler car owners alleged a design defect in seatbelt buckles, finding that plaintiffs did not suffer the kind of “concrete,” “actual or imminent” injury needed for standing purposes. In the other, a federal district court in Arkansas dismissed a lawsuit brought by several Arkansas counties — alleging that defendant drug companies were liable for failing to prevent people from using cold remedies to make methamphetamine — because plaintiffs could not demonstrate the requisite causal link between defendants’ conduct and the injuries alleged.

Inman: Lack of Injury Dooms Standing Requirement

In *Inman*, three plaintiffs sued for themselves and a multistate class of ten million owners and lessees of cars manufactured by DaimlerChrysler equipped with Gen-3 seatbelt buckles. 2008 WL 274903, at *1. Their theory of liability —

sounding in traditional tort law, coupled with claims under the Texas Deceptive Trade Practices-Consumer Protection Act — was that it was possible to engage the seatbelt’s release button without actually intending to do so. *Id.* at *1. Two of the three named plaintiffs never experienced anything like what they claimed might happen, and the other was unsure whether it had ever happened to him, but conceded that he had never suffered injury as a result. *Id.*

Plaintiffs “[did] not seek damages for personal injury, property damage or death.” *Id.* at *2. Citing “fear of possible injury,” they sought damages solely for the cost of replacing the buckles, which was approximately \$75 per buckle, and any lost use while repairs were made (approximately \$500 per vehicle) — that is, economic damages. *Id.* Multiplied by some 10 million potential class members, plaintiffs basically sought upwards of \$8 billion in damages for the class.² *Id.*

Contending that plaintiffs had failed to state a viable cause of action, defendant moved for summary judgment. *Id.* In opposition, plaintiffs argued that the Gen-3 buckle design violated a Federal Motor Vehicle Safety Standard requiring that a “[b]uckle release mechanism shall be designed to minimize the possibility of accidental release.” *Id.* (citation omitted). Plaintiffs additionally offered evidence that the buckles had failed “ball tests” used by the automobile industry to gauge the degree of force required to engage the release button, but no proof that federal regulators required such testing. *Id.* Plaintiffs also showed that defendant had received 50 consumer complaints concerning the spontaneous unlatching of Gen-3 buckles; and, further, that the buckles unlatched in two National Highway Traffic Safety Administration crash tests as well as crash tests conducted by the Canadian government and DaimlerChrysler itself. *Id.* Plaintiffs failed to prove, however,

¹ As a federal district court in Massachusetts observed just a few years ago in remanding such an action to state court, which subsequently refused class certification, these lawsuits appear “to be as manufactured as defendant’s cars.” See *Inman*, 2008 WL 274903, at *1 n.1 (citing *Hiller v. DaimlerChrysler Corp.*, No. Civ. A. 02-10533-RWZ, 2004 U.S. Dist. LEXIS 4578, at *3, 2004 WL 574331 (D. Mass. Mar. 23, 2004)).

² Notably, plaintiffs did “not contend that the Gen-3 buckles made their vehicles worth less than they paid for them.” *Id.* at *2.

that the buckles unlatched more easily than contemplated by defendant's design tolerances and standards. *Id.*

The trial court denied defendant's motion and certified two multistate classes of automobile owners — one for "new" and the other for "used" vehicles equipped with Gen-3 seatbelts. *Id.* at *2-3. On interlocutory appeal, the court of appeals rejected defendant's argument that plaintiffs' fear of possible injury from an accidental release of a seatbelt was too remote to confer standing. *Id.* at *3. Still, it reversed and remanded for further proceedings given the trial court's failure to conduct the necessary choice-of-law analysis. *Id.* Defendant then petitioned the Supreme Court of Texas for review, where it prevailed 5-4.

Standing Requires Actual — Not Hypothetical — Injury

Reasoning that the possibility of a "concrete" injury to the named plaintiffs was extremely remote, a majority of the Supreme Court of Texas dismissed the case for lack of subject-matter jurisdiction, against a vigorous dissent. *Id.* at *5. In reaching this result, the court offered bench and bar an extended primer on standing — largely in response to a vituperative protest by the dissent that the majority had "stretched the doctrine" of standing to disguise a "visceral distaste for class actions" and thereby essentially decided the case on the merits at the certification stage. *Id.* at *7 & 14. Summarizing, the majority said:

A court has no jurisdiction over a claim made by a plaintiff without standing to assert it. For standing, a plaintiff must be personally aggrieved; his alleged injury must be concrete and particularized, actual or imminent, not hypothetical. *A plaintiff does not lack standing simply because he cannot prevail on the merits of his claim; he lacks standing because his claim of injury is too slight for a court to afford redress.*

Id. at *4 (citations omitted) (emphasis added).

Answering plaintiffs' contention that the "ball tests" demonstrated how easily the buckle-release button could be engaged, and that crash tests showed that the buckle could somehow become unlatched — supposedly demonstrating injury — the court said: "there is nothing to indicate that the design of the buckle failed to minimize the

risk of accidental release versus the risk of non-use so as to pose any concrete threat of injury to the plaintiffs." *Id.* at *5 (citing *Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315 (5th Cir. 2002), where plaintiff — despite never suffering any physical or emotional harm from her use of the drug Duract — sued the manufacturer for a refund of the purchase price on behalf of all other similarly situated Duract users on a claim that the product was defective, and had her case dismissed for lack of standing).

"Mere Possibility" of Injury and Consumer Complaints Do Not Confer Standing

The Texas Supreme Court reasoned that any possibility of injury to the *Inman* plaintiffs was "even more remote than it was in *Rivera*." *Id.* DaimlerChrysler "received only fifty complaints from ten million vehicle owners and lessees" over a ten-year period — roughly "one for every 200,000 owners and lessees." *Id.* More fatal to plaintiffs' contentions than the relative strength of numbers, however, was the fact that "complaints cannot prove defect," much less injury. *Id.*

Addressing the dissent's criticism that the majority had erroneously jumped the procedural rails to address the suit's merits on certification, the majority carefully explained the distinction between standing and the merits, observing that "when a claim of injury is extremely remote, the jurisdictional inquiry cannot be laid aside in an expectation that the claimant will lose on the merits." *Id.* at *6. More practically and pragmatically, it reasoned that "timing is important, because a disagreement over \$2,400 is one thing and a disagreement over \$8 billion is quite another." *Id.* at *3 (referring to plaintiffs' *ad damnum*).

The named plaintiffs being without standing to assert their own individual claims, the majority dismissed the entire action for want of subject-matter jurisdiction with these words:

We simply think that the rights of ten million vehicle owners and lessees across the United States should not be adjudicated in an action brought by three plaintiffs who cannot show more than the merest possibility of injury to themselves. To hold that [the named plaintiffs] have standing would drain virtually

/ continued page 14

CONSUMER FRAUD

continued from page 13

all meaning from the requirements that a plaintiff must be “personally aggrieved” and that his injury must be “concrete” and “actual or imminent”.

Id. at *6.

Like Two Ships Passing in the Night: The Dissent

In a dissent (drawing three votes), the Texas Supreme Court’s chief justice took the majority to task for “improperly equat[ing] standing with the merits of plaintiffs’ claim” and, in doing so, allegedly contravening “fundamental tenets of the standing doctrine, our rules of procedure, and the statute governing interlocutory appeals.” *Id.* at *7. Ironically, given this particularly barbed charge, the dissent’s analytical platform — that plaintiffs’ economic injury (equal to the cost of replacing the defective buckles) was complete, and not speculative, “because the economic value of the product they purchased is not as warranted” — required the minority to rewrite plaintiffs’ complaint in order to read into it a contract-based “benefit of the bargain” claim never alleged by plaintiffs.³ *Id.* at *9-11.

Independence County: Court Rejects Causal Chain that Would Make Mrs. Palsgraf Blush

Introduction

Defendants in *Independence County*, including Pfizer, Warner Lambert Company, LLC, Johnson & Johnson and Perrigo Company, manufacture and market FDA-approved cold remedies containing ephedrine and pseudoephedrine, both of which are capable of being used to produce methamphetamine — an illicit substance. 2008 WL 398980, at *1.

Plaintiffs — county governments — brought action against defendants in Arkansas federal district court seeking to recover the “significant amounts of money” they spend annually combating illicit trade in and use of methamphetamines in Arkansas. *Id.*

Human Nature, the Failure of Social Policy and the Hunt for “Deep Pockets”

Claiming that defendants had known since at least 1986

that their products could be used to make methamphetamine, plaintiffs argued that defendants “could have taken steps on their own to impede or eliminate the use of their products in the manufacture of methamphetamine” that occurs in “homes, tents, barns, or hotel rooms” across Arkansas. *Id.* Plaintiffs sought to hold defendants liable under the Arkansas Deceptive Trade Practices Act along with public nuisance and unjust enrichment theories of liability. In support, plaintiffs asserted that defendants opposed proposed restrictions on the sale of their products; knew how to make a cold remedy “without ephedrine or pseudoephedrine,” and that “but-for Defendants’ products, the methamphetamine problem would not be of the scale that it is today.” *Id.*

Defendants moved for judgment on the pleadings, arguing lack of standing, remoteness and lack of proximate cause. *Id.*

No Standing Because Alleged Injuries Not Result of Any Statutory Violation

Granting defendants’ motion and dismissing the suit with prejudice, the court ruled that to sustain a private cause of action for damages under Arkansas’ deceptive trade practices statute, the plaintiffs must suffer actual damage or injury “as a result of” a violation of that law, which plaintiffs could not show. *Id.* at *2 (citation omitted). This was because the harm plaintiffs sought to remedy flowed not from violations of Arkansas trade practice laws, but instead directly from “the criminal acts of third persons” for which defendants had no obligation to answer. *Id.* Unable to prove that they “suffer[ed] actual damage or injury as a result of an offense or violation” of the Act, plaintiffs were without standing to proceed under it. *Id.* (citation omitted) (emphasis added).

Causal Chain Unduly Elongated — Too Many “Intervening Acts” Implicated

Apart from standing, plaintiffs’ claims failed for remoteness — lack of proximate cause. *Id.* In this regard, the Court held:

³ See n.2, *supra*, at 12.

It is undisputed that Plaintiffs expend tremendous resources in combating methamphetamine, but it is the methamphetamine cooks, distributors, and users who proximately cause Plaintiffs' damage, not Defendants.

Id. at *3. Put differently, without any “direct link” between the alleged misconduct and the damage alleged, plaintiffs' injury was simply too “remote” for liability to attach. *Id.*, citing *Arkansas Carpenters' Health & Welfare Fund v. Philip Morris Inc.*, 75 F. Supp. 2d 936 (E.D. Ark. 1999) (involving lawsuit by employee welfare benefit plan against tobacco manufacturers to recover expenses incurred in paying for its beneficiaries' tobacco-related illnesses).

The court then summarily disposed of plaintiffs' public nuisance and unjust enrichment claims, the former because Arkansas nuisance law applies only to landowners, and the latter because a party “free from fault cannot have been unjustly enriched only because he chose to exercise a legal right.” *Id.* at *4-5. ©

ASBESTOS

Tort Math: Symptom-Less Pleural Plaques Plus Fear of Future Injury Not Actionable Injury in U.K.

See Johnston et al. v. NEI International Combustion Ltd. et al., [2007] UKHL 39 (Oct. 17, 2007)

Overview

In the United Kingdom it has been accepted by lawyers and insurers alike for roughly 20 years that claimants with pleural plaques are entitled to damages at law. *Id.* at ¶ 43. But no more.¹

Recently, U.K. insurers successfully defended a number of claims in a bid to challenge the long-accepted principle that a diagnosis of pleural plaques is actionable for claimants exposed to asbestos in the course of their

employment — notwithstanding that these plaques “cause no symptoms” and do not cause “other asbestos-related diseases.” *Id.* at ¶ 1.

With the House of Lords firmly shutting the courthouse door to claims of this sort, Lord Hoffman explained:

[T]he development of pleural plaques, whether or not associated with the risk of future disease and anxiety about the future, is not actionable injury. The same is true even if the anxiety causes a recognized psychiatric illness such as clinical depression. . . . The risk of a future disease is not actionable and neither is a psychiatric illness caused by contemplation of that risk.

Id. at ¶ 2.

The Ancien Régime and the Aggregation Theory

Prior to this decision, at least three UK courts of first instance had set the standard in favor of plaintiffs — finding that pleural plaques did indeed constitute compensable damages, albeit for inconsistent reasons. One court did so on the basis that damage from plaques was not “so minor that the law should disregard it;”² another found that a “definite change in the structure of the pleura” was enough all by itself to constitute actionable damage.³ A third court, fashioning a “theory of aggregation,” held that a physiological change (not compensable damage in its own right) can be aggregated with the risk of future disease and anxiety and add up to a cause of action.⁴

Dusting off black-letter principles of tort law to restate and more clearly settle “pleural plaque” law, the House of Lords rejected the reasoning behind all three of the lower court rulings that had been used for years to run this sort of litigation. Beginning with the elemental need for actual injury — proof of damage — it held that damage, albeit an abstract concept, means being “worse off” (physically or

¹ Pleural plaques “are areas of fibrous thickening of the pleural membrane which surrounds the lungs.” *Id.* at ¶ 1.

² *Church v Ministry of Defence*, (1984) 134 NLJ 623.

³ *Sykes v Ministry of Defence*, THE TIMES (Mar. 23, 1984).

⁴ *Patterson v Ministry of Defence* [1987] CLY 1194.

/ continued page

ASBESTOS

continued from page 15

economically) and does not mean “simply a physical change . . . having no perceptible effect upon one’s health or capability.” *Johnson, supra*, at ¶ 7. It identified the critical question as being, how much “worse off” must a claimant be to give rise to compensable damages? *Id.* at ¶ 8.

Answering that question in regard to pleural plaques, the House of Lords said that while the claimants had changed physically (in the form of pleural thickening), they could not overcome the *de minimis* threshold for compensable damages — intended to exclude “trivial injury” from legal action — because, in the words of Lord Scott, “[n]one of the appellants has yet contracted any asbestos related disease.”⁵

As Policy Matter, “Harmless” Injuries Do Not Attract Damages

In dismissing the theory of aggregation, which had been the most robust basis of lower court rulings, Lord Hope was tempted to invoke “the simplest of formulae: two or even three zeroes, when added together, equal no more than zero”; “it is not possible, by adding two or more components, none of which in itself is actionable, to arrive at something which is actionable.” *Id.* at ¶ 42.

Recognizing, however, that this would not “do justice to . . . a genuine problem of legal analysis,” *id.*, he ultimately grounded his ruling on a firmer, more fundamental point of legal policy, holding:

It is well settled in cases where a wrongful act has caused personal injury there is no cause of action if the damage suffered was negligible. In strict legal theory a wrong has been done whenever a breach of the duty of care results in a demonstrable physical injury, however slight. But the policy of the law is not to entertain a claim for damages where the physical effects of the injury are no more than negligible. . . . The policy does not provide clear guidance as to where the line is to be drawn between effects which are and are not negligible. *But it can at least be said that an injury which is without any symptoms at all*

because it cannot be seen or felt and which will not lead to some other event that is harmful has no consequences that will attract an award of damages. Damages are for injuries that cause harm, not for injuries that are harmless.

Id. at ¶ 47 (emphasis added).

“Foreseeability” and Unrealized Risks

All of the claims save one were rejected on the basis that the harm alleged was inconsequential for purposes of legal remedy. However, one plaintiff did suffer from clinical depression — not just anxiety about increased risks of negative long-term health. Here the court questioned whether defendants owed a duty of care in respect of a psychiatric illness caused by the claimant’s apprehension of an increased risk of future illness. To answer this question, the court addressed itself to the issue of foreseeability, finding it absent. Closing the analytical circle, Lord Hoffman reasoned:

[T]he foreseeable event was that the claimant would contract an asbestos-related disease. . . . But the event has not occurred. The psychiatric illness has been caused by the apprehension that the event might occur. The creation of such a risk is, as I have said, not in itself actionable.

Id. at ¶ 33.

Legislative Fall-Out

Whether this ruling will have any effect on asbestos litigation elsewhere in the world remains to be seen. In Scotland, which falls under the House of Lords’ jurisdiction, it appears that the government hopes to blunt its impact altogether. Since *Johnson* was handed down, the Scottish Parliament has laid plans to introduce a bill to ensure that “people negligently exposed to asbestos who are diagnosed with pleural plaques will continue to be able to raise an action for damages.”⁶

In the English Parliament, meanwhile, at least one MP is

⁵ *Id.* at ¶62.

signaling that the government will opt for a less hasty approach. For now, it intends to “consider the ruling of the court and . . . see what happens as the issue is debated in the Scottish Parliament.”⁷ ©

MDL

Multidistrict Litigation Roundup

HRT Litigation

See *Rush v. Wyeth*, No. 07-1822, 2008 U.S. App. LEXIS 2055 (8th Cir. Jan. 31, 2008); *Scroggin v. Wyeth*, No. 04-1169 (E.D. Ark. March 6, 2008)

Introduction

The Prempro multidistrict litigation continues, with two recent results indicating that courts and juries continue to grapple with these cases. In *Rush v. Wyeth*, the Eighth Circuit recently upheld a jury verdict for pharmaceutical-maker Wyeth. Denying plaintiff’s claims that the trial judge committed evidentiary and instructional error, the Eighth Circuit issued its opinion shortly before another Prempro MDL trial began — which ultimately resulted in a plaintiff’s verdict in *Scroggin v. Wyeth*. Both cases were tried in the Eastern District of Arkansas.

Defense Verdict in Rush

In *Rush*, plaintiff was prescribed Premarin and Prempro beginning in 1989 and took the drugs for nearly ten years before she was diagnosed with breast cancer in 1999. *Rush*, 2008 U.S. App. LEXIS 2055, at *1. Six years later, in March 2005, plaintiff filed her lawsuit, which became part of the hormone replacement therapy MDL. *Id.* This litigation has generally involved claims relating to an increased risk of breast cancer, and other diseases, in users of HRT drugs.

At trial, the jury found that plaintiff did not prove (1) any failure to warn about the drugs’ risks; (2) any negligence or

defective design on Wyeth’s part; or that (3) any of these claims proximately caused injury. *Id.* at *1-2.

Chief among plaintiff’s appellate points was her challenge to the failure to warn instruction, which directed the jury to find for Wyeth if it determined that plaintiff was aware of the drugs’ risks before her breast cancer diagnosis — through either her physician or by independent knowledge. *Id.* at *6-8. Because the lack of a warning cannot be the proximate cause of an injury where the product user is already aware of the dangers, the Eighth Circuit found that the instruction was supported by the factual record based on trial evidence showing that Rush’s doctors warned her of the association between HRT treatment and breast cancer as early as 1992, when a breast abnormality was detected. *Id.* at *3. Additionally, plaintiff received (but denied reading) patient information sheets explicitly warning that breast cancer was a possible risk of the medications if taken for a prolonged time period. *Id.* at *4.

The Eighth Circuit rejected plaintiff’s other claimed instructional error, and found no abuse of discretion in either the admission of certain defense expert testimony (*id.* at *10-14), or the exclusion of testimony by plaintiff’s experts regarding data from NCI’s SEER (Surveillance Epidemiology and End Results) database to prove causation, since plaintiff’s expert previously testified that such a study could not establish causation. *Id.* at *15-17. Because the Eighth Circuit affirmed the jury verdict on other grounds, it did not address Wyeth’s appellate contentions that Rush’s claims were time barred and that her labeling claim was preempted. *Id.* at *17.

Plaintiff’s Verdict in Scroggin

A far different result ensued in *Scroggin*, where plaintiff alleged that her use of Premarin and Prempro resulted in a breast cancer diagnosis, claiming that defendants failed to warn her about the risks of breast cancer. At trial, defendants countered that plaintiff had pre-existing risk factors, including a family history of breast cancer, and that both plaintiff and her physicians were properly warned about the drugs’ risks. On February 25, 2008, a Little Rock federal court jury awarded \$2.75 million in compensatory damages against Wyeth and co-defendant Upjohn, and thereafter, on March 6, awarded roughly \$19 million in punitive damages

/ continued page 18

⁶ “Asbestos Claims Bill Planned,” Government of Scotland (Jan. 29, 2007) (<http://www.scotland.gov.uk/news/releases/2007/11/29102156>).

⁷ See “Scotland Plans Pleural Plaque Reversal” (Dec. 18, 2007) (<http://healthandsafetyprofessional.co.uk>).

MDL

continued from page 17

against Wyeth and \$7.7 million against Upjohn. An appeal is anticipated.

Recent SEC filings indicate that Wyeth is defending approximately 5,400 personal injury actions brought on behalf of approximately 7,900 women in various federal and state courts around the country, involving claims for breast cancer, stroke, ovarian cancer and heart disease stemming from use of Prempro or Premarin.

Of the seven cases tried against Wyeth to date, four resulted in defense judgments, two resulted in plaintiffs' judgments (now under appeal), while another was remanded for a new trial. Four other cases set for trial were dismissed by courts on summary judgment and a dozen other trial-ready cases were voluntarily dismissed by the plaintiffs before trial.

Welding Fume Litigation

See In re Welding Fume Products Liability Litigation, No. 1:03-cv-17000 (N.D. Ohio Feb. 6, 2008); *Tamraz v. BOC Group Inc., et al.*, No. 04-18948 (N.D. Ohio Dec. 6, 2007).

Over four years ago, the Judicial Panel on Multidistrict Litigation conferred MDL status on welding fume lawsuits because they allegedly shared common questions concerning, among other things, whether exposure to welding fumes caused plaintiffs' claimed injuries and whether defendants knew or should have known of any health risks associated with exposure to welding fumes. *See In re Welding Fume Products Liability Litigation*, No. 1:03-17000, 2007 WL 2701925, *1 (N.D. Ohio Sep. 14, 2007).

Since then, three bellwether cases have been tried. The first two ended in defense verdicts. Before the close of last year, however, an Ohio federal court jury awarded \$20 million in compensatory damages to a welder who alleged injuries from exposure to manganese in welding fumes. The jury found for plaintiffs on their strict liability, negligence and loss of consortium claims, but rejected claims asserting fraudulent concealment, and did not award punitive damages. *See Tamraz v. BOC Group Inc., et al.*, No. 04-18948 (N.D. Ohio Dec. 6, 2007). Post-trial motions are currently pending.

Notwithstanding this plaintiff's verdict, would-be welding class representatives asserting medical-monitoring claims have fared far differently. As previously reported in these pages, Judge Kathleen O'Malley, who oversees the welding fume MDL in the Northern District of Ohio, denied certification of a proposed medical-monitoring class action on September 14, 2007. *See In re Products Liability* at 14 (Nov. 2007).

In response, 16 welders who had been seeking a medical monitoring program for an alleged increased risk of brain damage moved on February 6, 2008 to dismiss their claims voluntarily, while reserving the right to file separate injury claims or to toll their claims under general tolling agreement in the welding fume litigation. *See "Plaintiffs' Motion for Voluntary Dismissal Without Prejudice and Notice of Election for Some Plaintiffs to Participate in Tolling Agreement," In re Welding Fume Products Liability Litigation*, No. 1:03-cv-17000 (N.D. Ohio Feb. 6, 2008).

Several months ago, we posited that "[w]ith back-to-back defense trial verdicts, [in] an MDL that has seen the number of claims systematically winnowed from over 10,000 to less than 2,000 claims today . . . defendants would seem to have the advantage." *In re Products Liability* at 16 (Nov. 2007).

With retreat being beaten by certain medical-monitoring plaintiffs, the recent \$20 million jury award in *Tamraz* suggests the fight in welding-fume litigation will shift to the pursuit of more traditional individual claims.

Ortho Evra Litigation

See In re Ortho Evra Products Liability Litigation, No. 06-cv-40000 (N.D. Ohio Jan. 30, 2008).

In a move with potential to alter the course of the Ortho Evra MDL, defendants Johnson & Johnson, Johnson & Johnson Pharmaceutical Research & Development, L.L.C., and Ortho-McNeil Pharmaceutical, Inc. have sought to block plaintiffs' effort to consolidate seven bellwether cases into two groups for trial this Summer. *See "Defendants' Brief Opposing Motion of Bellwether Plaintiffs for Consolidation of Trials," In re Ortho Evra Products Liability Litigation*, No. 1:06-cv-40000 (N.D. Ohio Jan. 30, 2008).

Ortho Evra is a prescription birth control patch that

releases ethinyl estradiol (an estrogen hormone) and norelgestromin (a progestin hormone) through the skin into the blood stream. Per recent Johnson & Johnson SEC filings, approximately 4,000 claimants have filed lawsuits or asserted claims regarding injuries allegedly due to Ortho Evra. On March 1, 2006, the Judicial Panel on Multidistrict Litigation centralized various actions (and potential tag-along actions) alleging that the patch was defectively designed and that its users received inadequate warnings as to its side effects and safety for pre-trial proceedings. See *In re Ortho Evra Products Liability Litigation*, 422 F.Supp. 2d 1379 (J.P.M.L. 2006).¹

In opposing plaintiffs' motion for trial consolidation (with four "Group 1" cases proposed for a June 2008 trial to be followed by a July 2008 trial for the remaining three "Group 2" cases), defendants argued that the Ortho Evra litigation is an "immature" mass tort, meaning that individual cases are not ripe for trial consolidation — especially since there have been *no* trials to date. See Defendants' Opposition Brief, *supra*, at 1-4.

Defendants also opposed consolidation given the predominance of individual fact issues that will make determination of liability, causation and damages different for each individual plaintiff. *Id.* at 4. For example, the four Group 1 plaintiffs used the patch for different periods of time (2 to 20 months), for different reasons (ranging from adolescent menses to contraception), had different risk factors for their alleged injuries, were different ages (from 14 to 41), and had four different prescribing physicians, each of whom is a learned intermediary with different information forming the basis of their prescribing decisions. *Id.* Similarly, the three Group 2 plaintiffs used the patch during different years, at different ages, for different lengths of time, had different prescribing and treating doctors, had different risk factors, and different injuries, including one

post-partum cardiomyopathy resulting in death. *Id.* at 6.

Ultimately, defendants asserted that consolidation of Groups 1 and 2 will cause juror confusion and unfair prejudice to them, given the highly individualized facts in each plaintiff's case, and the potential "evidence spillover" between the consolidated cases that may require defendants "to defend against the 'fictional composite' of a perfect plaintiff." *Id.* at 11. The district court's resolution of the consolidation issue is likely to have far-reaching consequences for the ultimate resolution of the Ortho Evra MDL overall. ©

¹ Recently, the FDA approved additional changes to the Ortho Evra label to include the results of a new epidemiology study finding that found that users of the birth control patch were at higher risk of developing serious blood clots than women using birth control pills. See FDA Approves Update to Label on Birth Control Patch (Jan. 18, 2008); (available at <http://www.fda.gov/bbs/topics/NEWS/2008/NEW01781.html>).

Et cetera

Publications

- Thomas E. Riley and Ellen A. Black published “Case Law Highlights Puffery as a Defense to Consumer Fraud Class Actions,” on *law.com* (Feb. 21, 2008).
- Joseph G. Falcone and Lawrence E. Savell published “Preserving Reasonableness in Electronic Discovery,” in *Bloomberg’s Law Reports* (Feb. 11, 2008).
- David L. Wallace published “Nanotechnology and the Power of Innovation,” in *Technology Law360* (Jan. 25, 2008).
- David L. Wallace and Nicholas Booke published “Industrial Revolution Redux — Nanotechnology: Law and Business at One-Billionth of a Meter,” in *Product Liability Law & Strategy* (Jan. 2008).
- David L. Wallace and Nicholas Booke published “Nanotechnology: Small Is the New Big,” in *IPFrontline Magazine of Intellectual Property and Technology* (Nov. 27, 2007).
- David L. Wallace and Nicholas Booke published “Nanotechnology and Product Safety,” in *Product Liability Law360* (Nov. 26, 2007).

Speaking Engagements

- On February 7, 2008, David L. Wallace addressed the topic of “Managing Production in Foreign Countries and Related Global Litigation,” at DRI’s 2008 Annual Product Liability Conference — *Product Liability in the Global Economy* — in Phoenix, Arizona.
- On January 31, 2008, David L. Wallace chaired a Chadbourne & Parke conference on “Nanotechnology Law & Commerce: Business at One-Billionth of a Meter,” in New York, New York.

Press Coverage

- David L. Wallace discussed nanotechnology with the editor of *Metropolitan Corporate Counsel* in an interview published in that newspaper in December 2007, under the title “Nanotechnology: The Future is Now.”

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