

**Product Liability Group**

Garyowen P. Morrisroe, Chair

**Partners**

Allison M. Alcasabas, London

Thomas E. Bezanson

Thomas E. Butler

Joseph G. Falcone

Jay Henneberry, Los Angeles

Dean L. Jarmel, London

Jerome C. Katz

Gregory M. Loss

Thomas J. McCormack

Dennis R. Neutze, London

John Nyhan

Thomas E. Riley

Bruce G. Sheffler

Donald I. Strauber

David L. Wallace

Phoebe A. Wilkinson

Mary T. Yelenick

**Counsel**

Peter K. Eck

Danielle P. Langhoff

Anna McConnell, London

Lawrence E. Savell

Susan St. Denis, Los Angeles

Gretchen N. Werwaiss

**Associates**

Nicholas S. Booke

Lisa Caccavo

Robert E. Conrad

Christian A. Fletcher

Benjamin Gris

Laura M. Jastrem

Jean S. Kim

Michael R. Kelly

Matthew I. Kleigman

Joaquina M. Lazaro

Amy McCarthy, London

Nicole C. Maddox

Maria E. Martinez, London

Alexandra K. Nellos

Philip A. Pfeffer

Gina M. Reif

Benjamin C. Rubinstein

Stacey F. Winograd

For more information about our practice, contact Garyowen P. Morrisroe at +1 (212) 408-5100 (gmmorrisroe@chadbourne.com), Allison M. Alcasabas in London at +44 (0)20 7337-8000 (aalcasabas@chadbourne.com), or visit us at [www.chadbourne.com](http://www.chadbourne.com)

# *In re* Products Liability

NEWSWIRE

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## Inaugural Edition

The attorneys in New York, Los Angeles, and London constituting the Products Liability practice group at Chadbourne & Parke LLP are pleased to publish this inaugural issue of *In re Products Liability* — a periodic review and analysis of noteworthy trends and developments in (and more generally arising out of) the making and litigating of products liability law in the U.S. and in other countries.

Our products liability practice began more than half a century ago, when The American Tobacco Company gave Chadbourne &

Parke LLP the brief to lead its defense in tobacco litigation nationally. From this beginning, our practice has grown in scale and diversity to include the representation of tobacco, pharmaceutical, distilled spirits and other consumer product makers. Over the years, our experience and engagements have put us at the cutting edge of trial work, appeals, and counseling in a wide range of complex tort litigation in both civil and common law jurisdictions.

Since 1902 — to the time now of global business, Chadbourne & Parke LLP has been providing sophisticated legal counsel on matters of high value, and consequent risk, in the diversified fields of the law. We hope you benefit from this review and analysis, and welcome your comments ☉

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## JURISDICTION

# CAFA's Removal Provisions Spawn Splits of Authority

In its effort to expand diversity jurisdiction in federal courts for class action lawsuits, Congress, as part of the Class Action Fairness Act ("CAFA"), enacted 28 U.S.C. § 1453(b), which provides that a class action "may be removed by any defendant without the consent of all defendants." Since CAFA applies only to civil actions commenced on or after its February 18, 2005 effective date, certain plaintiffs have sought to escape CAFA-based removal by dismissing from putative class actions those defendants against whom, by virtue of state law or pleading amendments, the action was only commenced on or after CAFA's effective date. Judicial treatment of this procedural maneuver has been mixed.

In *Dinkel v. General Motors Corp.*, 2005 WL 3006728 (D. Me., November 9, 2005), for example, plaintiff Dinkel brought a putative class action in Kansas state court alleging that certain automobile manufacturers and distributors had conspired to restrict the importation of vehicles from Canada. Pursuant to Kansas law, Dinkel formally commenced the action against all but three of the defendants by serving them with process before CAFA's effective date. Asserting that the lawsuit was not "commenced" against them until after CAFA took effect, the three defendants who were not served until after CAFA's effective date (the "removal defendants") removed the entire lawsuit to the United States District Court for the District of Kansas. The case was subsequently transferred to the District of Maine as part of an MDL proceeding.

To defeat removal, the plaintiff voluntarily dismissed the removal defendants and sought remand to Kansas state court asserting a lack of federal subject matter jurisdiction. Looking to state law to determine when the suit was "commenced," and noting that CAFA applies to class actions commenced on or after February 18, 2005, the district court denied the bid for remand, finding that the Kansas lawsuit was not "commenced" against the removal defendants until after the effective date of CAFA. *Id.* at \*2. Drawing from another recent opinion, the *Dinkel* court stated that "a plaintiff's 'decision to add . . . a defendant presents precisely the situation in which it can and should be said that a new action has 'commenced' for purposes of removal pursuant to CAFA.'" *Id.* at \*2 (quoting *Adams v. Fed. Materials Co. Inc.*, 2005

WL 1862378 at \*4 (W.D. Ky., July 28, 2005)). The court reasoned that to allow plaintiff to "unring the bell" by dismissing the removal defendants "would be contrary to everything Congress thought it was accomplishing in enacting CAFA," *id.* at \*4, since "[t]he plain language of CAFA makes clear that any single defendant can remove without the consent of other defendants and that it is the entire lawsuit that is removed not merely the claims against that defendant." *Id.* at \*3-\*4 (citing 28 U.S.C. § 1453(b)).

Though CAFA unquestionably reversed the long-standing rule that all defendants must consent to removal, other federal district courts faced with essentially the same issue confronted by the *Dinkel* court have reached different conclusions. For example, in *Brown v. Kerkhoff*, 2005 WL 2671529 (S.D. Iowa, October 19, 2005), decided shortly before *Dinkel*, plaintiff commenced a putative class action in Iowa state court alleging fraudulent misrepresentation claims (among others) against several defendants. Though plaintiffs commenced this action prior to the effective date of CAFA, they subsequently amended their complaint days after CAFA's effective date to add several new defendants. After these newly-added defendants removed the case to federal court, plaintiffs voluntarily dismissed them and sought remand.

In remanding the action for lack of subject matter jurisdiction, *id.* at \*12-13, the *Brown* court stated that "if a new party 'should be added as a defendant, it could enjoy a right to remove under [CAFA], for suit *against it* would have been commenced after February 18, 2005.' Thus, . . . if additional defendants were joined after CAFA, *those* defendants could remove." *Id.* at \*13 (emphasis in original) (quoting *Knudsen v. Liberty Mut. Ins. Co.*, 411 F.3d 805, 808 (7th Cir. 2005)). The court rejected the defendants' argument that plaintiff was engaging in questionable tactics to avoid the changes to remand practice that Congress enacted through CAFA: "If CAFA is not and never has been applicable to Defendants, they cannot say Plaintiffs 'manipulated the process' by dismissing the Removal Defendants because Defendants cannot be harmed by the subsequent unavailability of a right (*e.g.*, removal) they never possessed." *Id.* at \*13.

The *Dinkel* court summarily rejected the *Brown* court's analysis as "incorrectly focus[ed] on the defendants rather than upon the court's subject matter jurisdiction over the entire class action." *Dinkel*, 2005 WL 3006728 at \*4, n.6. It remains to be seen whether future courts confronting removal issues under CAFA will continue to disagree about the impact of the revised removal practice instituted by that law. ☉

## Seventh Circuit Says Novel Claim Tacked to Existing Case Commences New Litigation for Removal Purposes Under CAFA

The Class Action Fairness Act (“CAFA”) was enacted in response to a growing belief that class action lawsuits had largely become vehicles for attorney abuse and unfair forum shopping. Importantly, CAFA increased the opportunities for defendants to remove class actions “commenced” in state court after February 18, 2005, the Act’s effective date. Not surprisingly, in cases filed before CAFA’s effective date, efforts by plaintiffs after February 2005 to modify their claims for relief have led defendants to seek removal, generating litigation over the contours and character of claim amendments that can be said to constitute the commencement of a new action for CAFA removal purposes. A recent decision by the Seventh Circuit sheds some light on the subject. See *Knudsen v. Liberty Mutual Insurance Co.*, 435 F.3d 755, 758 (7th Cir. 2006), reversing, 405 F.Supp.2d 915 (N.D. Ill. 2005).

In March 2000, Dr. Kirsten Knudsen on behalf of herself and others (“plaintiffs”) filed a class action lawsuit in Illinois state court against one defendant — Liberty Mutual Insurance Company (“Liberty”) — alleging that Liberty improperly used medical cost and utilization databases to reduce payments on claims under its insurance policies. After CAFA’s enactment, plaintiffs sought to amend the proposed class definition to include a reference to Liberty’s subsidiary, Liberty Mutual Fire Insurance Company (“Liberty Fire”), which actually issued the policies being litigated. Taking the view that the proposed amendment “effectively began a new suit,” Liberty invoked CAFA to remove the case to federal court. *Knudsen*, 435 F.3d at 755-756. The district court granted plaintiffs’ motion for remand and the Seventh Circuit affirmed, finding that “Liberty Mutual remained the only defendant [in the case] and the state judge had not acted on the plaintiffs’ proposal by adding either new claims or new parties.” *Id.* at 756. While affirming the remand order, however, the Seventh Circuit “left open the possibility that a new claim for relief . . . could well commence a new piece of litigation for federal purposes.” *Knudsen*, 405 F.

Supp.2d at 918-919 (internal citations omitted). Then things got interesting.

In September 2005, following remand, the state court certified the class to include all insureds of Liberty and “its affiliates and subsidiaries . . . whose claims were paid for less than the medical charge, based upon the application of a medical cost and utilization database.” *Knudsen*, 435 F.3d at 756-757. Shortly before then, the state court entered a default judgment on the merits in favor of the plaintiffs (as a discovery sanction), finding that “Liberty Mutual is liable because it did not do enough in discovery to alert plaintiffs’ counsel to the need to substitute Liberty Fire as a defendant.” *Id.* at 756. The state court made this determination despite the fact that Liberty Fire’s name was on the policies at issue in the litigation — in fact, the only name. *Id.* Liberty immediately removed the case again, arguing “that the state court certification of Plaintiffs’ amended class definition from all insureds of Liberty Mutual Insurance Company to all insureds of Liberty, its affiliates and subsidiaries, commenced a new action” for removal purposes. *Knudsen*, 405 F. Supp.2d at 919. Plaintiff again moved for remand and the district court again granted that motion, finding that “new legal theories, in particular adding vicarious liability theories of liability, do not create new claims” for purposes of removal under CAFA. *Id.* at 920. Once again, Liberty appealed, this time successfully.

In a decision by Circuit Judge Easterbrook, the Seventh Circuit reversed, focusing its analysis on the consequences of plaintiffs’ exploitation of the state court default judgment to fundamentally alter the character of the relief sought.

“[T]he Complaint did not allege that Liberty Mutual and Liberty Fire are so lax about corporate formalities that their separate existence may be disregarded under veil piercing principles . . . or that Liberty Fire deceived its insureds into thinking that the policies were backed by a firm with deeper pockets \* \* \*

\* After our first decision plaintiffs sought more relief — *much* more relief. They asked the state court to hold Liberty Mutual responsible for *all* policies issued by *any* subsidiary or affiliate, about 35 firms in all. Plaintiffs asked, moreover, that all claims for payment by all insureds on all of these policies everywhere in the nation be covered by / continued page 4

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the default, so that Liberty Mutual would be compelled to pay without proof that an affiliate had failed to honor any policy.” *Knudsen*, 435 F.3d at 756 (internal citations omitted; emphasis in original).

In short, the Seventh Circuit determined that plaintiffs’ amended class definition “initiate[d] new claims” that did not relate back to the original cause of action because the original complaint did not contain a claim of vicarious liability against Liberty for its affiliates’ actions under an alter ego theory, and therefore did not “furnish[] the defendant with notice of the events that underlie the new contention.” *Id.* at 757 (citing Illinois cases). Indeed, the initial complaint “did not mention any insurer other than Liberty Mutual itself.” *Id.* Moreover, there was record evidence that Liberty did not reduce or adjust all demands for payment under all of its affiliates’ policies, thereby lending further support to the view that plaintiffs had commenced new claims for relief. Explaining that “contentions first raised in the second half of 2005 cannot demonstrate that Liberty Mutual was on notice of the claim for relief before February 18, 2005,” the Circuit Court concluded that “a novel claim tacked on to an existing case commences new litigation for purposes of the Class Action Fairness Act.” *Id.* at 758.

Vacating the decision below, the court instructed the district court to revoke its remand and decide the case “on the merits.” *Id.* Noting that “[t]he conduct of plaintiffs and the state judge in this litigation illustrates why Congress enacted the Class Action Fairness Act,” Judge Easterbrook concluded:

“The Class Action Fairness Act provides for federal resolution of the plaintiff’s claims, so the district court need not (and should not) give any weight to the state judge’s order for default and the scope of the class certification. These and all other questions are open to independent resolution in the federal forum.” *Knudsen*, 435 F.3d at 758. ☉

## “Detailed and Specific” FTC Regulations Support Federal Officer Statute Removal

Arguing that it was acting under the “direct control” of the Federal Trade Commission in using brand descriptors such as “lights” and “lowered tar” in the marketing of its cigarettes (the very conduct being challenged by plaintiffs as unlawful), late last year a tobacco company removed a deceptive trade practices class action to federal court under 28 U.S.C. § 1441 — the so-called federal officer removal statute. See *Watson v. Philip Morris*, 420 F.3d 852 (8th Cir. 2005), *reh’g denied*, (Nov. 15, 2005).<sup>\*</sup> It was the first time a tobacco defendant succeeded with this argument. See *Viridin v. Altria Group, Inc.*, 304 F.Supp.2d 832 (N.D. W.Va. 2004); *Paldrmic v. Altria Corp. Services, Inc.*, 327 F.Supp.2d 959 (E.D. Wis. 2004); *Tremblay v. Philip Morris*, 231 F.Supp.2d 411 (D.N.H. 2002). And just a few months later, Philip Morris used *Watson* to achieve another federal officer removal victory in *Kelly v. Martin & Bayley*, 2006 WL 44183 at \*4 (S.D. Ill., Jan. 9, 2006), *interlocutory appeal filed* (7th Cir. Feb. 4, 2005).

Other product liability defendants have not been as successful in this approach. For example, a federal judge in Indiana recently declined to extend the *Watson* holding in a case involving claimed defects in pacemakers subject to Food and Drug Administration regulations. See *Parks v. Guidant Corp.*, 402 F.Supp.2d 964 (N.D. Ind. 2005). Rejecting application of the federal officer removal provision, the district court in *Parks* remanded on the basis that “while the FDA’s regulation of Class III medical devices may be rigorous, defendants have not pointed to anything in the regulations to establish that Defendants have acted under the direction of the FDA in the design, manufacture, or sale of the device at issue.” *Id.* at 968. Distinguishing *Watson*, the court stated that the “tobacco companies have a better case for officer removal” because the FTC’s regulation of cigarettes is “extraordinary and unprecedented,” whereas “the FDA’s regulation of medical devices does not cut to the heart of plaintiffs’ claims to the same degree that the FTC’s regulation of low tar cigarettes did in *Watson*.”

<sup>\*</sup> Plaintiffs have until April 17, 2006 to file a petition for writ of certiorari with the United States Supreme Court.

*Id.* at 969-970. A closer look at *Watson* highlights the obstacles federally-regulated manufacturers face in seeking removal under 28 U.S.C. § 1441.

First, the federal officer statute permits removal by the “United States or any agency thereof or any officer (*or any person acting under that officer*) of the United States or of any agency thereof, sued in an official or individual capacity for any act under color of such office or on account of any right, title or authority claimed under any action of Congress.” *Id.*, § 1442(a)(1) (emphasis added). Although this statute “was not meant to be given a ‘narrow’ or ‘limited’ interpretation,” courts construing it have held that “[m]ere participation in a regulated industry is insufficient to support removal unless the challenged conduct is ‘closely linked to detailed and specific regulations.’” *Watson*, 420 F.3d at 857. To successfully invoke federal officer removal, a defendant must: (1) have acted under the direction of a federal officer; (2) show a nexus or “causal connection” between the alleged conduct and the official authority; (3) have a colorable federal defense; and (4) be a “person” within the meaning of the statute. *Id.* at 855 (collecting cases).

Holding that “[w]hether a defendant is ‘acting under’ the direction of a federal officer depends on the detail and specificity of the federal direction of the defendant’s activities and whether the government exercises control over the defendant,” the *Watson* court proceeded to analyze the extent of the FTC’s direction of Philip Morris’ marketing of its “lights” and “low tar” cigarettes in the light of precedent involving more typical applications of the federal officer removal provision, specifically government contract cases. *Id.* at 856-857 (discussing *Winters v. Diamond Shamrock Chem. Co.*, 149 F.3d 387 (5th Cir. 1998) and *Fung v. Abex Corp.*, 816 F.Supp. 569 (N.D. Cal. 1992)). In doing so, the court found significant parallels between the “comprehensive, detailed regulation” and “ongoing monitoring” at issue in *Winters* (the manufacture of Agent Orange) and *Fung* (asbestos exposure in submarine construction) and the control and direction exercised by the FTC over the testing and marketing of tobacco products as “lights” or “low tar”. *Watson*, 420 F.3d at 857-858. More particularly, it held that besides “specifying a testing method” for determining the tar and nicotine level of cigarettes, the FTC subsequently “modified the testing method” with a great deal of specificity, and that it basically “controls the delivery of tar and nicotine information to consumers.” *Id.* at 858.

The court next turned its attention to the question of whether the FTC could be said to have compelled compliance with its cigarette labeling and marketing directions, notwith-

standing that the tobacco industry as a whole had agreed to test and disclose the tar and nicotine ratings of their cigarettes pursuant to FTC standards as part of a voluntary agreement, instead of in response to formal rulemaking. Noting that (i) the industry only proposed a voluntary agreement after the FTC had issued a notice of proposed rulemaking, (ii) that the FTC made a “policy” decision that “a voluntary agreement was preferable to the formalities of rulemaking,” and (iii) that “after the companies entered the agreement, the FTC has enforced compliance,” the court found that “the FTC has compelled the tobacco industry to advertise the tar and nicotine ratings as determined by the [FTC’s] Cambridge Filter Method.” *Id.* at 858-859. Finding the FTC’s level of involvement in the tobacco industry to be “unprecedented” and “unusual,” the Eighth Circuit determined that Philip Morris was acting under comprehensive and detailed control of the FTC, and therefore, under the direction of a federal officer. *Id.* at 860-861.

As for the “causal connection” prong of the federal officer removal test — the relationship between the challenged conduct and federal officer control or direction — the *Watson* court easily distinguished the earlier cases denying tobacco companies federal officer removal on the basis that the plaintiffs in those cases had attacked the design and manufacture of defendants’ cigarettes, which the FTC does not direct or control. *Watson*, 420 F.3d at 861. Holding that plaintiffs in *Watson* were “challeng[ing] more than just the cigarette design,” namely Philip Morris’ advertising of “lights” or “low tar” cigarettes, the court concluded: “[Plaintiffs] *Watson* and *Lawson* claim it is deceptive for Philip Morris to use a low tar descriptor in conjunction with its cigarettes’ FTC rating. The very combination *Watson* and *Lawson* challenge as deceptive is the same combination the FTC requires to not be deceptive. Whether Philip Morris’s labeling of cigarettes as ‘lights’ is deceptive directly implicates the enforcement and wisdom of the FTC’s tobacco policies.” *Id.* at 862. As such, their claims were “sufficiently related” to FTC regulations to “establish a causal connection.” *Id.* Closing out its inquiry under the federal removal statute’s four-part test, the court found that Philip Morris’ preemption defense constituted a “colorable” federal defense and that it was a “person” within the meaning of the statute. *Id.* at 863-864.

Despite the “broad scope of federal officer removal,” and the Supreme Court’s acknowledgement that its “policy should not be frustrated by a narrow, grudging interpretation of § 1441(a)(1),” *id.* at 856, it is not an easy argument to make or win. As the concurrence notes: “[O]ur decision today should not be construed as an invitation to every partici- / *continued page 6*

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pant in a heavily regulated industry to claim that it . . . acts at the direction of a federal officer merely because it tests or markets its products in accord with federal regulation. [I]n most instances, a contract, principal-agent relationship, or near-employee relationship with the government will be necessary to show the degree of direction by a federal officer necessary to invoke removal under 28 U.S.C. § 1441(a)(1).” *Id.* at 863. ©

## CIVIL PROCEDURE

# Plaintiffs Told To “Beef Up” Their Claims Against Fast Food

In the latest development in plaintiffs’ efforts to get a fast food-related products liability suit off the ground in New York, a federal judge in the Southern District of New York — navigating the tensions between FRCP Rules 8(a) and 12(e) — has ordered the plaintiffs to provide a more definite statement of the deceptive business practice allegations they have made against a fast-food maker in connection with its advertising and promotion practices. The decision is Judge Sweet’s third in a series of published opinions in the case — the earlier two decisions both dismissing the complaint against McDonald’s for failure to state a claim. Plaintiffs appealed Judge Sweet’s second dismissal, which was with prejudice, as to the claims brought under § 349 of New York’s Consumer Protection Act. The Second Circuit reversed and remanded, finding that plaintiffs’ claims “more than meet[] the requirements of Rule 8(a).” *Pelman v. McDonald’s Corp.*, 396 F.3d 508, 512 (2d Cir. 2005).

On remand, in *Pelman v. McDonald’s Corp.*, 396 F. Supp. 2d 439 (S.D.N.Y. 2005), Judge Sweet granted in part defendant McDonald’s Corporation’s motion pursuant to Rule 12(e) of the Federal Rules of Civil Procedure, finding that although the complaint sufficiently stated “a cognizable legal theory,” plaintiffs’ allegations were still sufficiently “vague and conclusory” that they “cannot reasonably be responded to by a defendant.” *Id.* at 444-45.

The complaint made three primary allegations of deceptive business practices by McDonald’s in violation of the New York

Consumer Protection Act (General Business Law § 349). First, plaintiffs alleged that McDonald’s created the false impression, through advertising, that its food products were nutritionally beneficial. Second, McDonald’s allegedly failed to disclose that its use of certain additives in its food, and the manner in which its food was processed, rendered some of its food products substantially less healthy than represented. Third, plaintiffs alleged that McDonald’s deceptively represented that it would provide nutritional information to its New York customers. Heeding the Second Circuit’s observation that “the cure” for vague and conclusory allegations “is a motion for a more definite statement under Rule 12(e),” on remand McDonald’s filed a motion for a more definite statement directed at these claims. *Pelman* 396 F.3d at 512 n.5.

Addressing the tension created by allegations that “constitute a cognizable legal theory,” but which are nevertheless too vague and conclusory to support “good faith” admissions or denials, the court ordered the plaintiffs to identify each advertisement or statement about which they complained, holding that “[w]ithout information as to which of McDonald’s representations comprised the nutritional schemes alleged to have injured the plaintiffs,” McDonald’s could neither admit nor deny the allegations in good faith. *Pelman*, 396 F. Supp. 2d at 444-45. Under similar reasoning, the court held that the plaintiffs’ bare allegation that McDonald’s employed objectively deceptive advertisements was vague and conclusory for purposes of Rule 12(e) because a “defendant cannot be expected to respond to the plaintiffs’ allegations” without “a brief explanation of why the advertisements are materially deceptive to an objective consumer.” *Id.* at 445.

The court reached the opposite conclusion regarding two further arguments urged by McDonald’s — namely, that Rule 12(e) required the complaint to confirm that each individual plaintiff saw or heard each advertisement and to provide a description of how each advertisement injured the plaintiffs. In this context, the court held that it was unnecessary for the plaintiffs to confirm their exposure to each allegedly deceptive advertisement in order for McDonald’s to answer in good faith. However, the court did order the plaintiffs to provide “a brief explanation of how [they] were aware of the [allegedly deceptive] nutritional schemes,” on the grounds that only injuries that are “by reason of” a defendant’s conduct are actionable under the statute. *Id.* at 446. Similarly, the court held that although the complaint need not provide a description of how each advertisement allegedly injured the plaintiffs, it still must “outline” the injuries supposedly suffered by each plaintiff “by

reason of” the alleged deceptive scheme. *Id.*

In its decision, the court recognized that a Rule 12(e) motion for a more definite statement “should not be used to superimpose the heightened pleading requirements of Rule 9(b) on a cause of action, like the one involved here, which is subject only to the notice-pleading requirements of Rule 8(a).” *Id.* at 444. Rather, it held that “only where the absence of information that would be required under Rule 9(b) renders the complaint unintelligible is it appropriate to require plaintiff to provide it.” *Id.* at 445. ☉

## DISCOVERY

# Prior Drafts of Party Affidavit Enjoy Privilege and Work-Product Protection

Plaintiffs in high-stakes litigation have for some time now been aggressively using the discovery process to batter at privilege and work-product protections. Rebuffing just such an argument, Chief Judge David Alan Ezra of the District Court of Nevada recently held that prior drafts of a fact witness affidavit were protected against disclosure.

The case, *Ideal Electric v. Flowserve Corp.*, 230 F.R.D. 603 (D. Nev. 2005), involved a multi-party litigation in which cross-claimant Lake Mead Constructors (“LMC”), in opposing a summary judgment motion by Flowserve, filed an affidavit by one of its employees. Claiming that the affiant had recanted portions of his affidavit in deposition, Flowserve sought to compel production of all prior drafts of the employee’s affidavit, including those containing the written comments and suggested changes of LMC’s outside counsel, over the objection that they were protected against disclosure by the attorney-client privilege and the work-product doctrine.

Finding that the comments of counsel contained in the prior drafts constituted privileged attorney-client communications reflecting legal advice about the best way in which to present the facts, the Court rejected Flowserve’s attempt to pierce the attorney-client privilege on the basis that the draft affidavits related to facts that LMC intended to disclose to the court. In

reaching this conclusion, Judge Ezra reasoned: “[a]ccepting Flowserve’s argument would frustrate the purpose of the privilege, by stifling the attorney’s ability to advise the client.” *Id.* at 608.

At the same time, Flowserve’s bid to get behind the work-product protection — on the theory that since the inherent purpose of an affidavit is to provide evidence from a witness, earlier drafts of a filed affidavit cannot be work product — likewise failed. Drawing an analogy to draft interrogatory responses, the Court held that counsel’s comments on the earlier drafts of the employee’s affidavit qualified as opinion work product, further explaining that “[d]rafts often contain attorney’s and client’s mental impressions, strategies, and either solicit or provide legal advice.” *Id.* at 609.

Finally, the Court rejected Flowserve’s assertion that LMC had waived any privilege or protection against disclosure by filing the final version of the affidavit in support of summary judgment since, in doing so, it had not disclosed (inadvertently or otherwise) the contents of any prior drafts. ☉

## PHARMACEUTICALS

# Makers of Certain Drugs, Biologics and Devices Receive Inoculation Against Civil Liability For Public Health Threats

On December 30, 2005, President Bush signed legislation securing broad immunity from civil liability for manufacturers and distributors of drugs targeted for use in combating epidemics and bioterrorism under certain circumstances.

The Public Readiness and Emergency Preparedness Act of 2005 (“PREP”), 42 U.S.C.A. § 247d-6d, *et seq.*, was part of an emergency supplemental defense appropriations bill. It vests the Secretary of Health and Human Services with broad discretionary power (a) to declare the existence of public health emergencies or threats and, in response, (b) to recommend the manufacture, development, distribution or use of “covered countermeasures” (such as drugs, biolog- / *continued page 8*

## Pharmaceuticals

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ics, and medical devices) to combat health threats of a pandemic, epidemic or biosecurity nature. PREP creates a broad framework for a comprehensive approach to public health threats by municipalities, government agencies and the private sector.

Specifically, PREP immunizes the manufacturers of covered countermeasures (which may include vaccines, among other drugs and devices) from traditional product liability lawsuits. While the immunity's precise scope and duration will ultimately turn on the terms of the Secretary's emergency declarations of current or future public health threats, it does not extend to "willful misconduct" by a manufacturer or other "covered person." 42 U.S.C.A. § 247d-6d(d)(1). "Willful misconduct" is defined as an act or omission taken "intentionally to achieve a wrongful purpose," "knowingly without legal or factual justification," or "in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit." 42 U.S.C.A. § 247d-6d(c).

As part of this exception, PREP creates a new federal cause of action (sounding in tort) for "willful misconduct," requiring all such suits to be heard exclusively in the United States District Court for the District of Columbia before a three judge panel. 42 U.S.C.A. § 247d-6d(e). The Act also modifies the Federal Rules of Civil Procedure for these suits by automatically staying all discovery until a motion to dismiss has been fully litigated — through appeal, if necessary. 42 U.S.C.A. § 247d-6d(e)(6). Beyond this, the Act gives the court discretion to limit discovery to "matters directly related to material issues contested in such action" and to compel discovery responses "only if the court finds that the requesting party needs the information sought to prove or defend as to a material issue contested in such action and that the likely benefits of a response ... equal or exceed the burden or cost for the responding party of providing such a response." *Id.*

The PREP measure was prompted by increasing public awareness of the dangers of avian flu, the country's apparent lack of preparedness to deal with an influenza epidemic, and also to address the steady economic decline in domestic vaccine makers, who have been saddled with increasing liability costs. The legislation is expected to boost private and public efforts in preparing the country for potential threats through naturally-occurring emergencies, like influenza, avian flu, SARS, or even AIDS, as well as from potential man-made threats, like

anthrax and other biological agents. Critics of the Act, however, argue that the authority given to the Secretary to declare "countermeasures" and public health threats is overbroad, and point to the Act's failure to limit its applicability to *new* countermeasures as a potential safe harbor for pharmaceutical companies.

The use and significance of PREP will be revealed in the coming months, as the Secretary is required to begin promulgating corresponding rules and regulations by June 28, 2006. ☉

## Pennsylvania Appeals Court Rejects Application of Heeding Presumption in Failure to Warn Case

In *Lineberger v. Wyeth f/k/a American Home Products Corp., et al.*, 2005 WL 3547682 (Pa. Super., Dec. 21, 2005), the Pennsylvania Superior Court recently rejected a plaintiff's effort to supplant the learned intermediary doctrine in a pharmaceutical failure to warn case with a heeding presumption.

Alleging that her heart disease was caused by her use of the diet drug fen-phen manufactured by Wyeth, plaintiff was appealing an adverse summary judgment ruling in the trial court. At the close of discovery, Wyeth moved for summary judgment, arguing that plaintiff could not establish that her injuries were proximately caused by Wyeth's alleged failure to warn based on her treating physician's testimony that a different warning would not have caused him to prescribe different medications to Lineberger. Invoking the heeding presumption in an effort to extend a pharmaceutical company's duty to warn to the patient, plaintiff claimed that if Wyeth had issued an adequate warning, her treating physician, Dr. Lafferty, would have warned her of the risk of heart disease, and she would have heeded the warning and refused to take fen-phen.

Rejecting plaintiff's argument, the trial court explained that for a plaintiff to establish proximate causation in a pharmaceutical case, "the prescribing doctor must testify that had he received a different warning, he would have altered his prescribing habits." *Id.* at \*2. Based on the deposition testimony of plaintiff's treating physician — to the effect that he would have prescribed the drugs at issue to Lineberger even if defen-

dant had issued a specific warning about the risk of valvular heart disease — and adhering to the well-settled learned intermediary doctrine, the trial court held that Lineberger could not establish the element of proximate cause as a matter of law and dismissed the case.

In affirming, the appellate panel reviewed the foundational underpinning of the learned intermediary doctrine in Pennsylvania as well as case precedent limiting application of the heeding presumption solely to strict liability claims, involving products like asbestos. Concluding that the trial court had committed no error in rejecting application of the heeding presumption to grant summary judgment for lack of proximate cause, the appellate panel held:

“[Lineberger] certifies she would not have taken the drugs if she had known about the risk of valvular heart disease. On these grounds, [she] concludes her case should have gone to the jury. We cannot agree. \*\*\* [Lineberger] presented no evidence that a different warning would have changed Dr. Lafferty’s decision to prescribe fentanyl for [her] . . . Based on this testimony, a reasonable jury would have to agree that even if a different warning had been issued, Dr. Lafferty would still have prescribed the drug for [her].” *Id.* at \*4. ☉

## FIREARMS

# Judge Helps New York City Reload and Aim Its Gun Suit Around Liability Shield

On December 2, 2005, a federal judge in the Eastern District of New York reloaded plaintiff New York City’s gun suit against firearm makers through his interpretation of the Protection of Lawful Commerce in Arms Act (“PLCAA” or “Act”). *See City of New York v. Beretta U.S.A. Corp. et al.*, 401 F.Supp.2d 244 (E.D.N.Y. 2005). Signed into law in October 2005, the PLCAA gives firearm makers a limited form of immunity from liability for harm caused solely by third-party criminal or unlawful misuse of firearm or ammunition products, where the product otherwise

functioned as designed and intended. PLCAA, 15 U.S.C.A. §7901, *et. seq.* (This shield, however, does not extend to garden-variety products liability actions for injury or death based on the design or manufacture of the product. *Id.* at §7903(5)(A)(iv-v).)

Proceeding on a theory of criminal nuisance (in the second degree), the City of New York had filed a lawsuit against Beretta U.S.A. Corp., Smith & Wesson Corp., Colt’s Manufacturing Co., Inc., and Glock Inc. on June 20, 2000, alleging that these firearm manufacturers create a surplus of guns in states with lax gun laws by intentionally oversupplying distributors, thereby establishing an environment conducive to the smuggling of guns into areas with more restrictive laws (like New York City), where they are eventually used criminally or otherwise unlawfully. Shortly after the PLCAA went into effect, defendants moved for dismissal of the case as a “qualified civil action” within the meaning of the PLCAA.

Plaintiff opposed, claiming exemption from the PLCAA’s liability shield under the Act’s exception for “knowing” violations of state or federal statutes “applicable to the sale or marketing of the product” at issue, so long as the “violation was a proximate cause of the harm for which relief is sought.” *Id.* at 258-259. Tacking to cover, defendants argued that since New York’s criminal nuisance statute was not *specifically* “applicable” to the sale and marketing of firearm products, plaintiff could not bring itself within the terms of the immunity exception. Defendants further argued that the PLCAA’s exception was limited to situations involving violations of state and federal record-keeping laws, and to the knowing aiding of buyers prohibited from possessing firearms — neither of which was implicated here.

Siding with plaintiff in his interpretation of the PLCAA’s exception, Judge Weinstein held that Congress did not except “actions in which a manufacturer or seller knowingly violated a state or federal statute ‘directly’ or ‘specifically’ regulating the sale or marketing of firearms, [instead] Congress excepted all actions ‘in which a manufacturer or seller . . . knowingly violated a State or Federal statute *applicable* to the sale or marketing of [firearms].” *Id.* at 264 (emphasis added). From this foundation, Judge Weinstein brushed past the fact that New York’s nuisance statute had never been applied to the manufacture or marketing of firearms, noting that New York’s common law of public nuisance (upon which the statute was founded) was broad enough to apply to such activity. More specifically, he reasoned: “In accordance with the standard meaning of ‘applicable,’ New York courts have repeatedly held that the common law doctrine of public / *continued page 10*

## Firearms

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nuisance is ‘applicable to’ the sale or marketing of legal but potentially harmful products,” and therefore applies to firearms. *Id.* at 263.

With the case scheduled for trial on November 28, 2005, the court initially stayed its decision to allow defendants to pursue an appeal to the Second Circuit. Thereafter, defendants filed a notice of appeal on December 13, 2005, with plaintiff filing a cross notice on December 20, 2005. In an interesting turn of events, however, Judge Weinstein lifted the stay on February 8, 2006, at the same time ordering plaintiff to make an evidentiary showing of how it intended to prove its allegations at trial in light of recent legislation prohibiting the use of a federal firearms database — that is, the Firearms Trace System (“FTS”) — as evidence in civil litigation. The FTS database is central to plaintiff’s ability to prove its case, as it would enable plaintiff to identify the licensed seller of weapons used in crimes. Although signed into law on November 22, 2005, neither the parties nor the court were aware of the provision banning the use of this evidence in civil litigation when the court issued its decision on December 2. On March 8, 2006, Judge Weinstein issued an order taking the position that since the law prohibiting use of the federal firearms database was not part of the briefing in connection with his December 2 decision, the question of its applicability is still before him, notwithstanding defendants’ interlocutory appeal. ☉

## TOBACCO

# Illinois Supreme Court Erases \$10.1 Billion Plaintiffs’ Judgment In “Lights” Tobacco Class Action

Tort litigation against manufacturers of consumer products marketed as “light” or “low” in one ingredient or another continues to increase. This theory of liability has its origins in tobacco litigation, where it continues to run its course.

In a highly-publicized decision issued in December 2005, the Supreme Court of Illinois reversed a \$10.1 billion judgment

awarded to a class of plaintiffs allegedly defrauded by Philip Morris USA’s marketing of Marlboro Lights and Cambridge Lights cigarettes. *See Price v. Philip Morris, Inc.*, No. 96326, 2005 WL 3434368 (Ill., Dec. 15, 2005).<sup>\*</sup> Plaintiffs brought suit under the Illinois Consumer Fraud and Deceptive Business Practices Act (“Consumer Fraud Act”) and the Uniform Deceptive Trade Practices Act (“Deceptive Trade Practices Act”). *Id.* at \*1. The crux of the complaint was that Philip Morris’ “representation that Cambridge and Marlboro Lights cigarettes are lower in tar and nicotine than regular cigarettes is deceptive and misleading . . . [because] consumers receive higher levels of tar and nicotine than the testing apparatus registers . . .” *Id.* at \*15.

In the bench trial, Philip Morris took essentially two bites at the apple. *First*, it argued that plaintiffs’ consumer fraud claims were expressly preempted by the Federal Cigarette Labeling and Advertising Act (“FCLAA”), 15 U.S.C. § 1331 *et seq.*, and that the imposition of state tort liability would therefore conflict with the FTC’s regulatory oversight of cigarette advertising. *Second*, Philip Morris argued that its marketing and advertising of “light” or “low tar” cigarettes was exempt from liability under Section 10b(1) of the Consumer Fraud Act, which by its express terms does not extend to “[a]ctions or transactions specifically authorized by laws administered by any regulatory body or officer acting under statutory authority of this State or the United States.” *Id.* at \*28 (*quoting* 815 ILCS 505/10b(1)) (emphasis added). Pointing to a similar provision in Section 4(1) of the Deceptive Trade Practices Act, exempting from its reach “conduct in compliance with the orders or rules of or a statute administered by a Federal, state or local government,” *id.* (*quoting* 815 ILCS 510/4), Philip Morris argued that this claim failed, too, as a matter of law.

Rejecting Philip Morris’ preemption argument, the trial court found that plaintiffs’ “claims in this case do not conflict with the FCLAA or with any regulations or policies of the Federal Trade Commission.” *Price v. Philip Morris Inc.*, No. 00-L-112, 2003 WL 22597608 at \*21 (Ill. Cir. Ct. March 21, 2003). Turning to Philip Morris’ statutory exemption arguments, the trial court strictly construed the Illinois Consumer Fraud Act’s requirement of specific authorization in light of the evidence to conclude that Philip Morris’ “use of the descriptors ‘Lights’ and ‘Lowered Tar and Nicotine’ has never been specifically authorized by law. Philip Morris voluntarily chose to use these

<sup>\*</sup> Plaintiffs’ petition for rehearing (filed on January 5, 2006) is currently pending before the Illinois Supreme Court.

terms on its packages of Marlboro Lights and Cambridge Lights. No regulatory body has ever required (or even specifically approved) the use of these terms by Philip Morris.” *Id.* at \*22 (emphasis added).

Hearing the case on direct appeal, the Illinois Supreme Court took up the meaning of “specifically authorized” and reversed the trial court’s judgment, holding that Philip Morris’ marketing conduct — even if deemed deceptive by the trier of fact — was nonetheless exempted from Illinois’ consumer fraud statute because its use of “light” and “low tar” brand descriptors was indeed “specifically authorized” by the FTC. *See Price*, No. 96326, 2005 WL 3434368 at \*45. On this basis, the court also dismissed plaintiffs’ deceptive trade practice claims, taking the view that Philip Morris’ conduct was necessarily “in compliance with” FTC orders. *Id.* at \*49. (The court did not reach Philip Morris’ federal preemption arguments. *Id.*)

What makes this result so interesting is that the FTC has never promulgated any formal rulemaking “specifically authorizing” the use of “light” or “low tar” descriptors by tobacco manufacturers. Philip Morris instead built its defense around the terms of two consent orders issued by the FTC in connection with adjudicative proceedings that had been brought against the American Tobacco Company (in 1995) and American Brands (in 1971) involving the use of “light” and “low tar” descriptors — arguing that these consent orders qualified as “specific authorization” within the meaning of the Illinois statute. Accepting this position, the *Price* court held that “neither the language of section 10b(1) nor the public policy of the State of Illinois, as expressed by the legislature, requires that a regulatory agency engage in formal rulemaking before it can specifically authorize conduct by the entities over which it has regulatory authority.” *Id.* at \*34. More particularly, the Illinois Supreme Court found that (a) in 1971, the FTC had specifically authorized American Brands’ use of “the terms ‘low,’ ‘lower,’ ‘reduced,’ or ‘like qualifying terms’ in its advertising and packaging to describe the level of tar and nicotine in its cigarettes, so long as it also provided the actual measurements of the level in milligrams,” *Price*, No. 96326, 2005 WL 3434368 at \*38 (emphasis added) (quoting *American Brands*, 79 F.T.C. 255 (1971)), and that (b) in 1995, it had permitted American Tobacco to present “the tar and/or nicotine ratings of any of [American Tobacco’s] brands of cigarettes and the tar and/or nicotine ratings of any other brand (with or without an express or implied representation that [American Tobacco’s] brand is ‘low,’ ‘lower,’ or ‘lowest’ in tar and/or nicotine),” *id.* (quoting *American Tobacco*, 119 F.T.C. 3 (1995)).

Having concluded that the concept of “specific authorization” did not require formal administrative rulemaking, and that the FTC had previously granted such authorization to at least one other tobacco company, the court next concluded that the two American Tobacco-related consent decrees constituted specific authorization for *all* U.S. cigarette manufacturers to use “light” or other like descriptors. *See Price*, No. 96326, 2005 WL 3434368 at \*45. The court found support for this position in several sources. For instance, the FTC’s own “observation that adjudication could be used to announce ‘a substantive principle or standard of conduct having general application’” suggested to the court “that a consent order may serve as authorization for nonparties to the order to follow its directives.” *Id.* at \*40 (citation omitted). The court also grounded its conclusion in the trial testimony of Dr. John Peterman, “a former FTC bureau director, who stated that the FTC uses consent orders to provide guidance to the entire cigarette industry.” *Id.* at \*41. Finally, the court cited the 1987 congressional testimony of former FTC chairman Daniel Oliver, who testified that it is “entirely reasonable to suppose that one action against [one] cigarette company would have an effect on all of them, and that you would not have to make a rule.” *Id.* at \*44 (citation omitted).

Though the *Price* decision ultimately turned on Illinois statutory law, its precedential value is not necessarily as limited as it may seem. Many other states have consumer protection statutes that similarly exempt certain federally-regulated conduct from state tort liability. *See, e.g.*, General Business Law § 349(d) (New York); M.G.L.A. 93(a) § 3 (Mass.); F.S.A. § 501.212 (Florida); Mich. Comp. Laws § 445.904(1)(a) (Michigan); La. R.S. § 51:1406(4) (Louisiana). Indeed, *Price* is but the latest in a string of tobacco cases finding “light” advertising to be exempted from liability under state consumer protection statutes. *See Flanagan v. Altria Group, Inc.*, No. 05-71697, 2005 WL 2769010 (E.D. Mich., Oct. 25, 2005); *Sullivan v. Philip Morris USA Inc.*, No. 03-796, 2005 WL 2123702 (W.D. La., Aug. 31, 2005); *cf. Watson v. Philip Morris Companies, Inc.*, 420 F.3d 852 (8th Cir. 2005) (removal of “light” fraud action to federal court under federal officer statute upheld). ☉

## PUNITIVE DAMAGES

# California Court of Appeal Clarifies Analysis of “Reprehensibility Guidepost” On Remand from California Supreme Court

A California appellate court, upon remand from the California Supreme Court, has held that a defendant’s entire course of conduct — not just its conduct that allegedly harmed the particular plaintiff — was relevant in determining the reprehensibility of that conduct for punitive damages purposes, although that entire course of conduct could still not justify a punitive award that was disproportionate to the harm suffered by the particular plaintiff. See *Johnson v. Ford Motor Company*, 2005 WL 3508327 (Cal. Ct. App. 5 Dist., Dec. 23, 2005)

In its initial review of a jury verdict rendered against Ford Motor Company, California’s Fifth District Court of Appeal determined that a jury’s \$10 million punitive award against Ford was unconstitutionally excessive in light of the \$17,811.60 in compensatory damages imposed for violations of California’s “lemon law.” According to the court, the trial evidence had revealed that the repair history of the used car that the local Ford dealer provided the plaintiffs, who ultimately purchased the vehicle, omitted repeated and “seemingly unrepairable” problems with that vehicle’s transmission. *Id.* at \*1. The Court of Appeal recognized that Ford’s “entire customer response program was structured precisely to short-circuit lemon law claims whenever defendant plausibly could, by restrictively interpreting state lemon laws and ignoring non-presumptive lemons.” *Id.* at \*2 (citations and quotations omitted). However, in conducting its *de novo* review of the punitive award, the Court of Appeal determined that the maximum punitive award consistent with due process was three times the compensatory award, or \$53,435. *Id.* at \*1.

Though agreeing that the jury’s assessment of punitive damages was constitutionally excessive, the California Supreme Court remanded the matter to the Court of Appeal “for a new determination of the maximum constitutional award,” finding

that the Court of Appeal “may have given insufficient, if any, weight to the scale and profitability of Ford’s fraudulent conduct.” *Johnson v. Ford Motor Co.*, 113 P.3d 82, 97 (2005).

On remand, the Court of Appeal clarified that its earlier opinion “sought to reconcile *State Farm’s* insistence that a punitive damages award bear a reasonable relationship to the harm to individual plaintiffs and what we perceived to have been a broader focus of California punitive damages law that permitted the award to reflect (more or less directly) the harm to all persons affected by the defendant’s course of conduct.” *Johnson*, 2005 WL 3508327 at \*4. It concluded that California’s interest in punishing and deterring misconduct could “be vindicated through the punitive damages imposed for the harm to the individual plaintiffs, not through an award based upon similar harm to other residents of California as well . . . .” *Id.*

The Court of Appeal emphasized, however, that “evidence of an entire course of conduct was relevant and admissible on the issue of the *State Farm/BMW* reprehensibility guidepost because ‘a state is permitted to punish recidivist conduct more severely than an individual instance of malfeasance.’” *Id.* at \*5 (quotation omitted). In other words, while evidence of Ford’s “entire course of conduct” directed at all Californians was relevant for purposes of assessing how allegedly reprehensible Ford’s conduct toward the Johnsons had been, its conduct vis-à-vis all Californians did not justify a punitive damages award that was grossly disproportionate to the actual or potential harm done to the Johnsons themselves. *Id.* at \*5. Since, in the Court of Appeal’s view, Ford’s general policies demonstrated that Ford’s conduct in relation to these plaintiffs was “reprehensible,” it found that a punitive award of \$175,000 (just under 10 times the compensatory award) sufficiently balanced due process concerns regarding excessive punitive damages while still vindicating California’s interest in punishing unlawful conduct and deterring its repetition. *Id.* at \*8. Thus, while the U.S. Supreme Court in *State Farm Mutual Automobile Insurance Company v. Campbell*, 538 U.S. 408, 422-23 (2003) expressly held that “[d]ue process does not permit courts, in the calculation of punitive damages, to adjudicate the merits of other parties’ hypothetical claims against a defendant under the guise of the reprehensibility analysis,” courts in California and elsewhere seem to be doing just that. See, e.g., *Williams v. Philip Morris, Inc.*, 2006 WL 242456, at \*12 (Or. Feb. 2, 2006) (holding that jury could “consider evidence of similar harm to other Oregonians caused (or threatened) by the same conduct” directed at plaintiff under the “reprehensibility” guidepost). ©

## *State Farm v. Campbell* Does Not Preclude Bifurcated Trial Plan For Consolidated Personal Injury Action Involving Approximately 1,000 Claimants

In response to a certified question requested by counsel for approximately 1,000 cigarette smokers asserting consolidated personal injury claims against cigarette manufacturers, the West Virginia Supreme Court has determined that the due process constraints imposed by *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003), do not preclude a bifurcated trial plan in which general defense liability issues, as well as plaintiffs' entitlement to punitive damages and a punitive damages multiplier, would be determined in an initial phase (in the absence of any evidence relating to individual plaintiffs), with trials of individual plaintiffs' related claims and related issues to follow in a second trial phase. See *In re Tobacco Litig.*, 2005 WL 3272823 (W. Va., Dec. 2, 2005).

The West Virginia Supreme Court's ruling is the most recent development in this so-called "mass tort" litigation, which began in 1999 when all pending tobacco litigation in West Virginia's state courts was consolidated and transferred to a single trial court under the state judiciary's mass tort docket. *Id.* at \*1. In January 2000, that trial court approved a trial plan calling for the consolidation of all pending personal injury tobacco cases into a single consolidated and bifurcated trial. The bifurcated plan did not permit evidence relating to any plaintiffs in the initial phase (or even discovery of those plaintiffs), while simultaneously allowing the jury to determine both entitlement to punitive damages as well as a punitive damages multiplier before any finding of injury, causation or compensatory damages.

Defendants (including the major cigarette manufacturers) sought revision of this plan after the issuance of *State Farm*, arguing among other things that due process does not permit

punitive damages to be imposed absent evidence that the injury alleged was related to or arose from the conduct upon which punitive damages were awarded. The trial court subsequently vacated the bifurcated plan, finding that under *State Farm* "the conduct of a party against whom punitive damages are sought must have a direct nexus to a specific person who claims to have been damaged by the conduct," and that the plan could not satisfy *State Farm's* requirement for "a subjective analysis of the defendant's conduct vis-à-vis a specific plaintiff . . ." *Id.* at \*1.

In answering the plaintiffs' certified question, the West Virginia Supreme Court found that nothing in *State Farm* "per se preclude[ed] the [trial] court's original trial plan" in which "certain elements of liability and [a] punitive damages multiplier are determined in the first phase and compensatory damages and punitive damages, based on the punitive damages multiplier, are determined for each individual plaintiff in the second phase." *Id.* at \*3-\*5. The Court acknowledged that under *State Farm* "a defendant's dissimilar acts, independent from the acts upon which liability was premised, may not serve as the basis for punitive damages." *Id.* at \*4. However, it held that the bifurcated plan would not violate defendants' due process rights as long as the trial court made sure that plaintiffs' evidence during the first phase is "relevant, reasonably related to the acts upon which liability is premised, and supports their claim for punitive damages." *Id.* at \*4.

The West Virginia Supreme Court, however, was careful to restrict its holding to the certified question it answered. It specifically did not address "whether there may be other legal reasons to question the [trial] court's bifurcated trial plan," and could not address "in the abstract the specific evidence that may be presented on the issue of reprehensibility." *Id.* at \*3. In a concurring opinion, Justice Benjamin emphasized that in the absence of a fully developed record, the Court could not make any determination as to whether plaintiffs' evidence regarding purported reprehensible conduct would be applicable to all plaintiffs, or whether there is in fact nothing common about the punitive damages claims of the nearly 1,000 plaintiffs at issue. *Id.* at \*13. (Benjamin, J., concurring). Without such factual determinations, the Court "is in no position . . . to say ultimately whether *State Farm's* restricted view on evidence of reprehensibility, and the constitutional considerations which underlie such a view, would sanction a punitive damages multiplier . . ." *Id.* at \*13. (Benjamin, J., concurring). Indeed, the majority stated that it made "no / continued page 14

## Punitive Damages

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judgment on whether the trial court's original plan is the best method for trying the instant tobacco litigation" and noted that it "decline[d] to tell the [trial] court how to proceed." *Id.* at \*5. The matter has been remanded to the trial court, where the trial plan is expected to be addressed in early April. ☉

### EVIDENCE

## Federal Judge Relaxes *Daubert* Burden, Holding That "Scientific Validity" of Evidence Should be Determined by Legal Burden of Proof on Underlying Claims, Not by Usual Practice in Relevant Scientific Discipline

Courts exercising their *Daubert* gate-keeping role continue to generate curious results. A fairly recent example arises from an MDL proceeding in the Southern District of New York involving dietary supplements containing ephedra, where the court allowed its threshold consideration of evidentiary "scientific validity" under *Daubert* to be informed, in large measure, by the burden of proof ultimately applicable to the underlying substantive claims in the action — that is, a preponderance of the evidence. *In re Ephedra Products Liability Litigation*, 393 F. Supp. 2d 181 (S.D.N.Y. 2005).

At issue was the question whether the plaintiffs' experts on general causation should be precluded, under Fed. R. Evid. Rule 702 and *Daubert*, from testifying at trial that ephedra is capable of causing certain injuries, such as strokes and heart-attacks, given the lack of any epidemiological study

showing a statistically-significant increased risk of injury associated with ephedra use. While the court's rejection of the asserted need for epidemiological evidence to prove medical causation was itself neither controversial nor curious, *id.* at 186-187, the reasoning it followed in upholding the admissibility of plaintiffs' causation evidence — namely focusing the analysis on the difference between the scientific concept of epidemiological "statistical significance" and "preponderance of the evidence" as a legal standard — nevertheless seems suspect.\*

The starting point for the court's analysis was its conclusion, following evidentiary hearings, "that general causation [for ephedra use] has not been established by scientific standards of proof," meaning "epidemiological studies establishing an increased risk from ephedra of sufficient statistical significance to meet scientific standards of causality." *Id.* Taking up next the generally inconclusive nature of plaintiffs' causation evidence — grounded as it was on principles of differential diagnosis and inferences drawn from published case studies, adverse event reports and animal studies — Judge Rakoff focused his analysis on the "reliability" of the scientific principles and methods employed by plaintiffs' experts in formulating their opinions, which in the end he decided was the product of sufficient "intellectual rigor" and good scientific practices to allow its use at trial. In doing so, however, he remarkably dismissed — as "certain dictum" — the Supreme Court's mandate in *Daubert* that for threshold admissibility purposes "evidentiary reliability will be based upon scientific validity," adopting in its place the legal standard of a "preponderance of the evidence." *In re Ephedra Products Liability Litigation*, 393 F. Supp. 2d at 193 (emphasis in original). More particularly, the court reasoned:

"*Daubert* was designed to exclude 'junk science'. It was never intended to keep from the jury the kind of evidence scientists regularly

\* Another curious aspect of the *In re Ephedra* court's reasoning was its reliance on the fact that the FDA had banned the use of ephedra despite "the absence of definitive scientific studies establishing causation." 393 F. Supp. 2d 189. This seems to be in stark contrast with several federal appellate court decisions that have found a significant difference between the lower level of scientific certainty required for a federal agency to make decisions directed at preserving the public health, and the more stringent standard required to establish liability in a court of law. See *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1248-1250 (11th Cir. 2005); *Hollander v. Shandoz Pharm. Corp.*, 289 F.3d 1193, 1215 (10th Cir. 2002); *Allen v. Penn. Eng'g Corp.*, 102 F.3d 194, 198 (5th Cir. 1996); *Wright v. Williamette Ind., Inc.*, 91 F.3d 1105, 1107 (8th Cir. 1996).

rely on in forming opinions of causality simply because such evidence is not definitive. The legal standard, after all, is preponderance of the evidence, *i.e.*, more-probable-than-not, and that applies to causality as to any other element of a tort cause of action. Rule 702, a rule of threshold admissibility, should not be transformed into a rule for imposing a more exacting standard of causality than more-probable-than-not simply because scientific issues are involved.” *Id.* at 190.

Notwithstanding the teaching of *Daubert* that “scientific validity” is to be determined by the standards as set by the relevant scientific community — not legal standards of proof, *Daubert v. Merrell Dow Pharmaceuticals, Inc.* 509 U.S. 579, 595 (1993) (discussing requirements of Fed. R. Evid. 703), Judge Rakoff worried that holding plaintiffs to such a standard would improperly “increas[e] the burden of proof imposed by substantive law.” *In re Ephedra Products Liability Litigation*, 393 F.Supp.2d at 193. Refusing to take this course, and in the process arguably misapprehending and misapplying other elements of the *Daubert* test (*e.g.*, the need to account for error rates by the expert, not by the jury), the court observed:

“Scientific convention defines statistical significance as ‘P .05,’ *i.e.*, no more than one chance in twenty of a [sic] finding a false association due to sampling error. Plaintiffs, however, need only prove that causation is more-probable-than-not. Although this legal standard may lead to what some scientists might consider an unacceptably high error rate in jury verdicts, the law has tolerated the jury error rate for centuries because it has not yet found a better way of adjudicating disputes. This Court will be guided by *Daubert*’s ‘general observations’ about scientific knowledge in its determination to keep junk science out of the courtroom. *At the same time, it will not treat Daubert’s dictum about scientific validity as authority for increasing the burden of proof imposed by substantive law.*” *Id.* at 193 (emphasis added).

Here, too, the *Ephedra* decision seems to run headlong into binding precedent to the contrary. First, in *Daubert* the

Supreme Court gave no reason to conclude that the ultimate burden of proof in a case should guide or have any bearing whatsoever on matters of threshold admissibility. In fact, it refers to the burden of proof as coming into play, if at all, only *after* the threshold finding of admissibility has been made — not as part of that inquiry. *Daubert*, 509 U.S. at 596. What’s more, in *Wills v. Amerada Hess Corp.*, 379 F.3d 32 (2d Cir. 2004), the Second Circuit expressly rejected the argument that the standards for determining evidentiary admissibility vary according to a party’s burden of proof, holding that *Daubert*’s admissibility standards were not relaxed simply because the plaintiff’s “burden of proof on the issue of causation is relaxed under the Jones Act.” *Id.* at 47. To the contrary, the court held that “*Daubert*’s standards for determining the admissibility of expert testimony apply regardless of whether the plaintiff’s burden to prove causation is reduced.” *Id.* ☉

## WE THE PEOPLE

# “Cheeseburger Bills” Introduced in Mississippi and Oklahoma

In January, the Mississippi and Oklahoma state legislatures each introduced their own versions of what are commonly referred to as “cheeseburger bills.” The Mississippi and Oklahoma bills are nearly identical and seek to prevent “frivolous lawsuits” against food manufacturers and sellers. *See* S.B.1323, 2006 Leg., 2nd Sess. (Okla. 2006); H.B. 764 Leg., Regular Sess. (Miss. 2006).

The “Common Sense Consumption Act” of Oklahoma exempts food manufacturers and sellers from civil liability for any claim arising from “weight gain, obesity, a health condition associated with weight gain or obesity, or other generally known condition allegedly caused by or allegedly likely to result from long-term consumption of food.” *See* S.B.1323, 2006 Leg., 2nd Sess. (Okla. 2006). The Mississippi Bill exempts food distributors, manufacturers and restaurants from liability for “personal injury or death arising out of weight gain, obesity, or a health condition associated with weight gain or obesity.” H.B. 764 Leg., Regular Sess. (Miss. 2006). Both bills provide exceptions for claims arising from / *continued page 16*

## We The People

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a “knowing and willful” violation of federal or state law applicable to the manufacturing, advertising and labeling of food products. In addition, both include a provision requiring a stay of discovery pending a motion to dismiss. In Mississippi, the defendant is required to tender all potentially relevant docu-

ments to the court, pending disposition of its motion to dismiss, while in Oklahoma a defendant is merely required to safeguard all potentially relevant documents while the motion is pending.

Over twelve other states, including Arizona, Colorado, Florida, Illinois and Michigan have enacted similar legislation. ☉

Contributors to this edition of *In re Product Liability* are: David L. Wallace, Joseph G. Falcone, Philip A. Pfeffer, Robert E. Conrad, Benjamin Rubinstein, Lisa Caccavo, Michael R. Kelly and Gina M. Reif.

## Etcetera

### Publications

- ☉ Allison M. Alcasabas and Philip A. Pfeffer, “Litigation’s Changing Face” *Scrip Magazine*, April 2006 (forthcoming)
- ☉ Thomas E. Riley and Robert E. Conrad, “Fitting U.S. Law to Extraterritorial Activities,” *New York Law Journal*, February 21, 2006
- ☉ Allison M. Alcasabas and Philip A. Pfeffer, “Pharmaceutical Firms to Face New Threats in US,” *Insurance Day*, January 20, 2006
- ☉ Mary T. Yelenick and Gretchen N. Werwaiss, Chadbourne & Parke LLP Client Alert, “New FDA Rule on Prescription Drug Package Inserts,” January 2006
- ☉ Mary T. Yelenick and Christian A. Fletcher, “Unjust Enrichment: An Alternative Theory in Product Liability Actions,” *International Law Office*, December 22, 2005

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### Speaking Engagements

- ☉ On April 21, 2006, Gregory M. Loss will participate in a panel discussion of the “Challenges of a World-Wide Pharmaceutical Law-Suit” at the Pharmaceutical Regulation and Product Liability Conference in London sponsored by the British Institute of International and Comparative Law.
- ☉ On April 25-26, 2006, Mary T. Yelenick and Phoebe A. Wilkinson will deliver a presentation entitled “Aggregate Litigation: Plaintiffs’ Tactics and Strategies to Defeat Them” at the Drug and Medical Device Litigation Conference in New York sponsored by Marcus Evans Ltd.

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### Chadbourne & Parke LLP

**New York**  
30 Rockefeller Plaza  
New York, NY 10112  
+1 (212) 408-5100

**Washington**  
1200 New Hampshire Ave., NW  
Washington, DC 20036  
+1 (202) 974-5600

**Houston**  
1100 Louisiana, Suite 3500  
Houston, TX 77002  
+1 (713) 571-5900

**Los Angeles**  
350 South Grand Ave., Suite 3300  
Los Angeles, CA 90071  
+1 (213) 892-1000

**Beijing**  
Beijing Representative Office  
Room 902, Tower A, Beijing Fortune Centre  
7 Dongsanhuan Zhonglu, Chaoyang District  
Beijing 100020, China  
+86 (10) 6530-8846

**Almaty**  
90 Shevchenko Street, 3rd Floor  
Almaty 050022, Kazakhstan  
+7 (3272) 585-088

**Moscow**  
Riverside Towers  
52/5 Kosmodamianskaya Nab.  
Moscow 115054 Russian Federation  
+7 (495) 974-2424  
Direct line from outside C.I.S.:  
(212) 408-1190

**St. Petersburg**  
Italianskaya Str., office 56/57  
St. Petersburg 191186 Russian Federation  
+7 (812) 326-9300

**Kyiv**  
11 Mykhailivska Street, 4th Floor  
Kyiv 01001, Ukraine  
+380 (44) 230-2534

**Warsaw**  
Chadbourne & Parke  
Radzikowski, Szubielska and Partners LLP  
ul. Emilii Plater 53  
00-113 Warsaw, Poland  
+48 (22) 520-5000

**London**  
Chadbourne & Parke  
a multinational partnership  
Regis House  
45 King William Street  
London EC4R 9AN, UK  
+44 (0)20 7337-8000

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