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In This Issue:

Silence Is Not Golden for Corporate America: An Evaluation of the High Court's Opinion in *Philip Morris USA v. Williams*

By Carol Jean Gatewood

Splitting the Baby?

One may argue that the Justices of our highest court adopted King Solomon's approach[1] in their most recent decision addressing the morass of issues surrounding punitive damage assessments. The plaintiffs' bar and corporate America have closely watched this case, each of the respective groups hoping for differing outcomes, because this case squarely presented the high court with ample opportunity to unravel the tangled web of procedural and substantive issues surrounding punitive damages.[2] The highly anticipated decision in *Philip Morris USA v. Williams,* 127 S. Ct. 1057 (2007)[3] seemingly "split the baby."

Justice Stephen G. Breyer delivered the Court's 5–4[4] majority opinion. As is evidenced by the dissenting opinions,[5] most notably Justice Ruth Bader Ginsberg's

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Advances in Technology May Spur Class Action Lawsuits Arising From Outbreaks of Foodborne Illnesses

By John M. McIntyre

On Feb. 14, 2007, ConAgra Foods, Inc. issued a voluntary recall of Peter Pan and Great Value peanut butters after the spreads were linked to a salmonella outbreak that has sickened almost 300 people in 39 states. According to the U.S. Centers for Disease Control and Prevention (the "CDC"), product testing confirmed the presence of the outbreak strain of *Salmonella* Tennessee in opened jars of peanut butter that were obtained from consumers who had become ill.[1] By Feb. 23, 2007, plaintiffs had already filed class action lawsuits against ConAgra in Pennsylvania, Florida, and Washington related to the outbreak.

The peanut butter recall follows a number of other high-profile outbreaks of foodborne illnesses involving salmonella and other pathogens such as E. coli and

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Bi-Annual Update Regarding Pharmaceutical Drug and Medical Device Federal Preemption

By Michael K. Brown, Lisa M. Baird, Mildred Segura and Michelle Lyu

This current update addresses the continued impact of the FDA's Final Rule on the labeling of pharmaceutical drugs, and provides a summary of the new state and federal decisions addressing express preemption for medical devices complying with the FDA-approved requirements.

Since our last update in September 2006, the defense of federal preemption continues to remain a strong argument for medical device manufacturers defending against common law state claims. Pharmaceutical manufacturers applying preemption principles in the drug labeling context, however, have received a more mixed reception. This current update addresses the continued impact of the FDA's Final Rule on the labeling of pharmaceutical drugs, and provides a summary of the new state and federal decisions addressing express preemption for medical devices complying with the FDA-approved requirements.

Implied Preemption

Implied conflict preemption principles, in contrast to express preemption, are applied where "state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress' [citations omitted]." *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 873 (2000). In particular, implied preemption usually is invoked in the pharmaceutical context against failure-to-warn claims premised on the argument that the drug label should have contained a warning different from what the FDA approved. Traditionally, this defense enjoyed the most success in cases where the manufacturer can demonstrate that the FDA reviewed and rejected the very label plaintiffs propose in litigation. *See, e.g.*, *Dusek v. Pfizer Inc.*, 2004 WL 2191804 (S.D. Tex. Feb. 20, 2004) (holding that FDA's regulations could not be considered minimum standards of conduct because the FDA explicitly stated the the plaintiff's proposed warning was inappropriate and would constitute misbranding if used). That position also has been bolstered by amicus briefs filed by the FDA in some cases. *See Kallas v. Pfizer, Inc.*, Case No. 04CV0998 (D. Utah 2005); *Motus v. Pfizer, Inc.* Case Nos. 02-55372 and 02-55498 (9th Cir. 2002); *In re Paxil*, Case No. CV-01-07937 (C.D. Cal 2002).

At the beginning of 2006, the FDA affirmed its position on preemption in its Preamble to the Final Rule, "Requirements on the Content and Format of Labeling for Human Prescription Drug and Biological Products," released in January. *See* 71 Fed. Reg. 3922 (2006). The Preamble to this Final Rule stated that under "existing preemption principles, FDA approval of labeling under the act, whether it be in the old or new format, preempts conflicting or contrary State law," and listed six types of claims it considered preempted by its regulation of the drug's labeling. *Id.* at 3934, 3936. While a clear and specific statement of agency intent has never been required to determine whether a conflict exists [*see Geier*, 529 U.S. at 884-84], it was expected that the agency's position would boost the use of preemption against common law claims.

Decisions since Reed Smith's last preemption update, however, show that many courts' analysis on conflict preemption turns upon the level of deference it is willing to extend to the agency. Ultimately, the Final Rule has not yet tilted the balance, and the mixed treatment of implied preemption in drug cases continues.

That the analysis has not tilted more heavily in favor of preemption is well demonstrated by *McNellis v. Pfizer, Inc.*, 2006 WL 2819046 (D.N.J. Sept. 29, 2006). There, before the Final Rule was issued, the district court initially determined that conflict preemption principles did not shield the manufacturer from common law liability, even though the FDA had considered and

rejected the very warnings the plaintiff was seeking. *McNellis v. Pfizer, Inc.*, 2005 WL 3752269 (D.N.J. Dec. 29, 2005). After the Final Rule, the district court reconsidered its ruling, but declined to hold that the Final Rule changed the analysis. *McNellis*, 2006 WL 2819046 at *5. The district court's finding turned on its unwillingness to afford the FDA's views deference, largely because it believed them counter to the Supreme Court's instruction to find preemption only where there "is a clear and manifest purpose of Congress [citations omitted]." *Id.* at *5. Because the Food, Drug, and Cosmetic Act regulating pharmaceutical drugs contained no express preemption clause and the court did not consider the FDA's views on preemption to be consistent over time, the court declined to give the Final Rule the full force of law. *Id.* at *8; *see also Desiano v. Warner Lambert & Co.*, 467 F.3d 85, fn. 9 (2d Cir. 2006) (declining to apply preemption despite Preamble view favoring preemption); *Levine v. Wyeth*, ___A.3d ___, 2006 WL 3041078 (Vt. Oct. 27, 2006) (same).

While the district court in *McNellis* declined to vacate its pre-Final Rule order rejecting preemption, it did certify the issue for interlocutory appeal before the Third Circuit, recognizing that the issue of preemption was a controlling question of law; that "numerous conflicting decisions" on the issue existed; and that resolution of the issue would materially advance the litigation's end. 2006 WL 2819046, at *11–12. This interlocutory appeal has since been accepted by the Third Circuit, which is coordinating its oral argument with that in *Colacicco v. Apotex*, 432 F. Supp. 2d. 514 (E.D. Pa. 2006), a decision upholding preemption against the common law state claims. *See Colacicco v. Apotex Inc.*, No. 06-3107 (3d Cir. filed June 12, 2006). *Colacicco* involved claims that sought to impose liability for the failure to provide particular warnings that the FDA had considered and rejected as being scientifically unsubstantiated. 432 F. Supp. 2d at 527, 529. In determining that the FDA's decision about the particular warning preempted claims to the contrary, the *Colacicco* court deferred to the FDA's views as espoused in the Final Rule, an *amicus* brief that it requested and received from the FDA, and the FDA's *amicus* briefs from *Kallas v. Pfizer, Inc.*, Civ. No. 2:04-cv-0998 (D. Utah Sept. 15, 2005) and *Motus v. Pfizer Inc.*, Civ. No. 02-cv-55372 (9th Cir. Sept. 10, 2002). *Id.* The court further rejected the common argument advanced by manufacturers—that the FDA labeling requirements constitute "a minimum safety standard"—and agreed with the FDA's position that its requirements established both a "floor and a ceiling" that plaintiffs could not circumvent. *Id.* at 529.

At the time of this publication, both parties to the appeal in *Colacicco* have filed their briefs, and the United States filed an *amicus* brief on behalf of the appellee manufacturers. On Dec. 29, 2006, the Third Circuit agreed to stay the *Colacicco* appeal until the briefing in *McNellis* was completed, and ordered the two cases listed before the same merits' panel. *See Colacicco*, No.

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Since the FDA issued the Final Rule, more than 15 pharmaceutical-implied preemption cases were decided, with most addressing the impact of the Final Rule on their analysis:

- *Abramowitz v. Cephalon, Inc.*, 2006 WL 560639 (N.J.Super.L. March 3, 2006)
- *Ackermann v. Wyeth Pharmaceuticals,* 2006 WL 2591078 (E.D. Tex. Sept. 8, 2006)
- *Brockert v. Wyeth Pharma.*, Cause No. 2003-49357 (151st Judicial District Jan. 25, 2007)
- *Buckland v. Threshold Enterprises, Inc.*, Case No. BC344046 (L.A. Sup. Ct. June 19, 2006)
- *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Pa. 2006)
- *Conte v. Wyeth*, Case No. CGC-04-437382 (S.F. Sup. Ct. Sept. 14, 2006)
- *Coutu v. Tracy*, 2006 WL 1314261 (R.I. Super. May 11, 2006)
- *Desiano v. Warner-Lambert*, 467 F.3d 85 (2d Cir. 2006)
- *Jackson v. Pfizer*, 432 F. Supp. 2d 964 (D. Neb. 2006)
- *In re Bextra and Celebrex,* 2006 WL 237474 (N.D. Cal. Aug. 16, 2006)
- *In re Prempro Liab. Litig.*, 05-CV-004970WRW (E.D. Ark. June 15, 2006)
- *Laisure-Radke v. Par Pharmaceutical*, (W.D. Wash. March 29, 2006)
- *Levine v. Wyeth*, ___ A.3d ___, 2006 WL 3041078 (Vt. Oct. 27, 2006)
- *McNellis v. Pfizer Inc.*, 2006 WL 2819046 (D.N.J. Sept. 29, 2006)
- *Perry v. Novartis Pharma.*, 456 F. Supp. 2d 678 (E.D. Pa. 2006)
- *Weiss v. Fujisawa Pharmaceutical*,___ F.Supp.2d ___, 2006 WL 3422688 (E.D. Ky. Nov. 28, 2006)

06-3107 (3d Cir. filed Dec. 29, 2006). The *McNellis* appellant manufacturer filed its opening brief Feb. 6, 2007, and full briefing should be complete in April.

Keeping in mind that preemption rulings often turn on the level of deference accorded the Final Rule, two other courts also have rejected preemption over the past six months, but with varying types of deference and reasoning. In *Perry v. Novartis Pharma. Corp.*, ___ F. Supp. 2d ___, 2006 WL 2979388 (E.D. Pa. Oct. 16, 2006), the court considered the Final Rule to be an "advisory opinion" that was entitled some deference, but the court was only willing to grant such deference where the FDA had specifically considered and rejected a given warning as unsubstantiated. *Id.* at 684. Therefore, the court's level of deference towards the FDA remained the greatest where the FDA sought to address ambiguities in the FDCA or its own regulations, but was entitled to little where the FDA purported to supply congressional intent overcoming the presumption against preemption. *Id.* at *3. That the FDA filed an *amicus* further elaborating FDA's view favoring preemption did not sway the court.

In a slightly different analysis in *Weiss v. Fujisawa Pharmaceuticals, Co.*, ___ F. Supp. 2d ___, 2006 WL 3422688 (E.D. Ky. Nov. 28, 2006), a district court addressing the same product warnings at issue in *Perry* also declined to find preemption. However, in *Weiss*, the court declined to defer to the FDA because of the agency's apparent inconsistency in its view on preemption. *Id.* at p. 7. It characterized the FDA's "long-standing" view on preemption as being first advanced in 2001, and believed this position contrasted with much earlier statements regarding the preemptive scope of the FDA's regulatory scheme and state law. *Id.* at p. 6; *but see Colacicco* 432 F. Supp. 2d at 527 (finding the Preamble consistent with prior FDA opinions on preemption, such as found in the *amicus* briefs filed in *Kallas v. Pfizer.*, Civ. No. 2:04-cv0998 (D. Utah Sept. 15, 2005) and *Motus v. Pfizer, Inc.*, 2002 WL 32303084 (9th Cir. Sept. 10, 2002)); *see also Fellner v. Tri-Union, LLC., d/b/a/ Chicken of the Sea*, 2007 U.S. Dist. LEXIS 1623 (D.N.J. Jan. 8, 2007) (deferring to the FDA's regulatory scheme for controlling levels of methylmercury in tuna because of the agency's "ten-year deliberately balanced approach" to the issue).

Clearly the final word has not yet been written about implied preemption in pharmaceutical cases. Trial courts will continue to rule in the cases before them in which the issue is raised, but the Third Circuit in *McNellis* and *Colacicco* may well be the first post-Final Rule appellate decision issued.

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One final pharmaceutical case warrants brief mention, although it involved the government compliance defense rather than preemption issues. In *O'Neill v. Novartis Consumer Health*, ___ Cal. Rptr. 3d ___, 2007 WL 586606 (Cal. App. Feb. 27, 2007), plaintiffs appealed defense verdicts, arguing that the trial court should have instructed the jury that compliance with FDA standards was irrelevant to the issue of whether phenylpropanolamine (PPA), a pharmaceutical used in over-the-counter products, had a design defect. Instead, likely relying on *Ramirez v. Plough, Inc.*, 6 Cal. 4th 539 (1993), the trial court had instructed that "FDA action or inaction" could be considered on the question of PPA's safety but that it was not dispositive, and the appellate court agreed that instruction was appropriate. Accordingly, even in those cases where the preemption defense is rejected and summary judgment refused, the FDA's regulatory efforts can serve as the basis for the corollary government standards defense.

Latest Medical Device Express Preemption Cases

Several decisions analyzing the express preemption clause of the Medical Device Amendment ("MDA") have been rendered since Reed Smith's last preemption update in early September 2006. One Minnesota District Court declined to hold that state law tort claims were preempted *In re: Medtronic, Inc., Implantable Defibrillators Litigation*, __ F. Supp. 2d ___, 2006 WL 3478987 (D. Minn. Nov. 28, 2006). The district court agreed with the "majority of circuits" holding that the FDA's premarket approval for the Class III medical devices constituted specific federal requirements for the devices' "design, testing, intended use, manufacturing methods, performance standards, and labeling." *Id.* at *6. The district court also followed the Supreme Court's majority holding in *Medtronic v. Lohr*, 518 U.S. 470 (1996), which acknowledged that jury verdicts could constitute a state "requirement" that could conflict with the federal requirements. *Id.* at *7. However, the district court held that plaintiffs' state law causes of action alleging a failure to comply with the FDA regulations were *not* conflicting requirements, but constituted parallel requirements that were not preempted. *Id.* at *8.

By contrast, a district court in Tennessee held that the FDA's PMA-approved specifications preempt state law claims alleging liability for a Class III medical device. In *Hughes v. Cook*, 452 F. Supp. 2d 832 (W.D. Tenn. 2006), the court held that plaintiff's strict product liability, negligence, and breach of implied and express warranty claims were preempted because the device was a PMA-approved device that fully complied with all of its approved design, labeling and manufacturing specifications. *Id.* at 839-42 (following *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000), cert. denied, 534 U.S. 818 (2001)). The court specifically stated that it was of no relevance that the device allegedly failed to function properly, for the PMA Supplement approval constituted approval of the devices' "design, testing, intended use, manufacturing methods, performance standards and labeling'— not the device's *success rate*." *Id.* at 842 (emphasis added) (quoting *Mitchell v. Collagen Corp.*, 126 F.3d 902, 913 (7th Cir. 1997)). Therefore, because successful state law claims premised on the alleged failure of the device despite its approval constituted an additional or different state requirement beyond the approved requirements, those claims were properly preempted. *Id.*

Following the Fifth Circuit, the district court in Louisiana also held that state law claims were preempted under the MDA. *Rousseau v. Depuy Orthopaedics, Inc.*, 2006 WL 3716061 (W.D. La. Dec. 13, 2006). The case involved polymethlmethacrylate bone cement that was initially approved through NDA process, which Congress subsequently declared to be the equivalent of the PMA process; but the FDA later reclassified the bone cement as a Class II device. *Id.* at *2. While the bone cement was reclassified from Class III to Class II, the manufacturing, labeling, and design specifications approved by the FDA remained unchanged. *Id.* Of particular contention was whether the reclassification affected the preemption analysis for the plaintiff's state law claims, for the bone cement was classified as Class II at the time of use. *Id.* The court stated that whether a medical device was subject to a rigorous FDA approval process mattered more than a regulation's designation. *Id.* at *8. Because reclassification of bone cement to a Class II device at the time of its use did not alter existing design, manufacturing or label requirements imposed through the original, rigorous approval process, the court held that the preemption analysis for the device was the same as for other majority-view cases. *Id.*

As a matter of first impression, the Kansas Court of Appeals held that the PMA requirements constitute device-specific federal requirements preempting a plaintiff's state law claims. *Troutman v. Curtis*, 143 P.3d 74, *1 (Kan. 2006). The court in *Troutman* found it particularly helpful that in another context, Kansas' highest court had already held that state law claims can constitute specific state requirements triggering federal preemption. *Id.* at *10. The court further expounded that despite the FDA's approval of the federal requirements, an adverse jury verdict would compel the manufacturer to modify the design to avoid potential adverse jury verdicts in other cases, and therefore amounted to a state requirement. *Id.* at *13.

Finally, as we mentioned in our last preemption update, a petition for certiorari is pending in *Riegel v. Medtronic, Inc.*, 451 F.3d 104 (2d Cir. 2006), a decision in which the Second Circuit join the majority view of medical device preemption and upheld the district court's order granting summary judgment in favor of manufacturer. The Supreme Court has invited the Solicitor General to weigh in on whether review should be granted, but the Solicitor General has not yet advised of its position and has no firm deadline to do so. Once the Solicitor General does take a position, the Supreme Court will again take up plaintiff's petition and determine whether certiorari should be granted.

Like pharmaceutical implied preemption, medical device express preemption is an area of the law that continues to regularly produce new decisions, and it is likely to continue to do so over the next six months. Reed Smith's next preemption update will be published in September, and will review any new decisions released by then. ■

dissent, the practical implications of the majority's holding appears only to *add* to the bewilderment presented to counsel, jurors and trial judges across the nation when presented with the myriad issues surrounding punitive damages. The Supreme Court held that constitutionally acceptable boundaries prohibit a jury from exacting punishment upon a defendant for injuries allegedly caused by the defendant to nonparties. Simultaneously, however, Justice Stephen G. Breyer's majority opinion provides that a jury *may* consider a defendant's acts to nonparties when evaluating the reprehensibility of a defendant's misconduct.[6] The Supreme Court, albeit disappointing, completely side-stepped the issue of whether the lower court's $79.5 million punitive award was beyond the pale of constitutionally permissible damages, and failed to engage in or attempt to set any numerical limits on excessive punitive damages.

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Lower Court Proceedings

At trial, an Oregon jury awarded Mayola Williams, the widow of Jesse Williams, $821,000 in compensatory damages.[7] Jesse Williams died of lung cancer after smoking Marlboro cigarettes for 45 years.[8] Despite the fact that Mayola Williams was the only plaintiff litigating claims against Philip Morris USA, she successfully convinced the jury that Philip Morris' conduct directed at her husband and *at an unspecified number of unidentified potential Oregon plaintiffs* justified a punitive award 97 times the amount of compensatory damages.

The $79.5 million punitive judgment is indicative that the jurors were convinced by plaintiff's argument that Philip Morris should be punished for all smoking-related injuries that it *may have caused* to the unnamed, unidentified, nonparty Oregon plaintiffs. The argument was successful, despite the fact that Williams did not introduce *any* evidence tending to prove that Philip Morris' conduct had caused injury to *any specific person* (other than Jesse Williams).

Philip Morris remained relentless in its efforts to obtain relief from the staggering punitive judgment via multiple requests for judicial intervention. In one instance, the United States Supreme Court provided Philip Morris some relief—but that relief was momentary.[9] The Court vacated the multi-million dollar award and remanded the case for reconsideration in light of the Court's then-recent holding in *State Farm Mut. Automobile Ins. Co. v. Campbell*, 538 U.S. 408 (2003).[10] Upon reconsideration, however, the Oregon Court of Appeals determined that the $79.5 million punitive judgment should be reinstated[11] and the Oregon Supreme Court subsequently affirmed.[12]

The Oregon high court's agreement that the punitive assessment warranted reinstatement was not without the express acknowledgment that it, in fact, had carefully considered the United State Supreme Court's counsel that a single-digit ratio of punitive damages to compensatory damages is an appropriate demarcation of a constitutionally acceptable punitive judgment.[13] Philip Morris appealed, arguing *inter alia*, that the $79.5 million punitive judgment, if upheld, would equate to an arbitrary deprivation of its property, thereby resulting in a violation of its 14th Amendment due process rights.[14] Philip Morris argued that the trial court erred in refusing to instruct the jury that it could not punish Philip Morris for alleged harms that it may have caused to nonparties. Additionally, Philip Morris argued that the stunning multi-million judgment was so extreme that it violated the permissible constitutional boundaries set forth in *State Farm*.

A Swell of Muddy Waters?

On Oct. 31, 2006, Philip Morris' counsel urged the Justices to overturn the $79.5 million judgment for two exclusive reasons:

- It is constitutionally impermissible for a jury in a non-class setting to factor into its calculation of punitive damages harms *that may have been caused* to nonparties by a defendant's alleged misconduct; and
- The Oregon Supreme Court's reinstatement of the $79.5 million award was in direct contravention of the United States Supreme Court's earlier *counsel* [15] that punitive damage awards meeting the single-digit multiplier benchmark are more likely constitutionally permissible.

In delivering the majority's opinion, Justice Breyer appeared to clarify the fairly recent landmark decision in *State Farm*.[16] He unambiguously stated, "We did not previously hold explicitly that a jury may not punish for the harm caused others. But we do so hold now."[17] At first blush, it appears that the defense bar and corporate America now have their much-desired impenetrable piece of arsenal against excessive punitive awards. But do they?

A careful examination of the Court's opinion reveals that the majority did not *eradicate* a jury's consideration of a defendant's alleged misconduct and potential resultant harms to nonparties in the punitive assessment calculation. Even though the majority expressly admonishes a jury's *direct* punishment of a defendant for alleged harms to nonparties,[18] it, in an incongruent manner, affirmatively endorses a jury's *consideration* of alleged harms to nonparties under the guise of the assessment rubric of reprehensibility set forth in *BMW of North America, Inc. v. Gore.*[19] In fact, the Court *sanctioned* the introduction of such evidence, but in one fell swoop imposed limitations upon the *purpose* for which a jury may actually use the evidence. The Court's endorsement of such evidence is really impracticable:

> Evidence of actual harm to nonparties can help to show that the *conduct* that harmed the plaintiff also *posed a substantial risk of harm to the general public*, and so was *particularly reprehensible*…. Yet for the reasons given above, *a jury may not* go further than this and use a punitive damages verdict to *punish a defendant directly* on account of *harms it is alleged* to have visited on *nonparties*.[20]

The Court's forbiddance of *directly* punishing a defendant for harm to nonparties, juxtaposed with its endorsement of evidence demonstrating harm to nonparties, poses an untenable quagmire for trial judges, litigants and jurors. The majority failed to provide any meaningful mechanism to ensure compliance with the unwieldy holding. Seemingly shirking away from the palpable incongruity, the majority simply delegated to the states the job of ensuring compliance to the outwardly inconsistent principles. In so doing, the Court advised:

> …it is constitutionally important for a court to provide assurance that the jury will ask the right question, not the wrong one . . . – it is particularly important that States avoid procedure that unnecessarily deprives juries of proper legal guidance. We therefore conclude that the Due Process Clause *requires States to provide assurance* that juries are not asking the wrong question, *i.e.*, seeking, not simply to determine reprehensibility, but also to punish for harm caused strangers.[21]

Although the defense bar and corporate America may initially view the "head line" decision (*i.e.,* a jury may not punish for harm allegedly caused to nonparties) as a step in the right direction, they should do so with an abundance of caution because the opinion is full of land mines for the unwary defendant. The practical ramification of the Court's opinion is that it just muddies the already troubled waters of punitive damages. On one hand, a jury is instructed to consider the defendant's alleged misconduct and resultant harm to nonparties in determining the reprehensibility of a defendant's conduct, but on the other hand is effectively told, "don't think about the reprehensible nature" of the misconduct in calculating the amount of punitive damages to award. The internally inconsistent holding provides yet another pathway to more appeals.

The Court's Silence Speaks Volumes

To the disappointment of the entire legal community, litigants and lawyers alike, the Court refused to consider the penultimate question of whether the $79.5 million award, with a ratio of 97:1, is constitutionally grossly excessive. The majority rationalized that it did not need to resolve that issue because "the application of this standard [*i.e.*, no direct punishment for alleged harm to nonparties] may lead to the need for a new trial, or a change in the level of the punitive damages…."[22] Thus, the Court again refrained from providing the much-desired guidance squarely addressing the issue of numerical limits on excessive punitive damages.

Since the Court's advisory in *State Farm*,[23] that single-digit punitive-to-compensatory ratios are more likely to be constitutionally acceptable than are larger, more disparate ratios, crafty

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litigators on each side of counsel table have been able to present equally compelling arguments using the imprecise language advancing paradoxical objectives. That is the case because the majority opinion provided "wiggle" room for plaintiffs seeking to affirm punitive awards with ratios exceeding the single-digit benchmark. In delivering *State Farm's* majority opinion, Justice Kennedy expressly acknowledged that there are "no rigid benchmarks that a punitive damages award may not surpass, ratios greater than those we have previously upheld may comport with due process where a particularly egregious act has resulted in only a small amount of economic damages."[24] Further, Justice Anthony Kennedy deemed it necessary to affirmatively recognize that the injuries in *State Farm* were economic in nature, and conceded that in cases in which the injuries are physical, a single-digit benchmark ratio might not "hold up."[25]

Query then, whether the outcome in **Philip Morris** *would have been desirable to defendants and to corporate America had the Justices* **actually agreed** *to evaluate the constitutionality of the 97:1 punitive-to-compensatory ratio.*

In light of this Court's refusal to address numerical limitations when confronted with the sizeable 97:1 punitive-to-compensatory ratio in *Phillip Morris*, coupled with the uncanny alliances by the Justices in the 5–4 decision, the Court's silence on the issue may be very telling for future litigants. The composition of the high court has changed since the majority issued its 6–3 opinion in *State Farm*. Two of the justices, then-Chief Justice Rehnquist and Justice Sandra Day O'Connor, who participated in the majority opinion, are no longer members of the Court; and Justice Stevens, another participant in the majority's opinion in *State Farm*, actually filed his own dissenting opinion in *Philip Morris*. Moreover, Justice Stevens' dissenting opinion concluded with his judgment that the Oregon Supreme Court's decision should have been affirmed.[26] Query then, whether the outcome in *Philip Morris* would have been desirable to defendants and to corporate America had the Justices *actually agreed* to evaluate the constitutionality of the 97:1 punitive-to-compensatory ratio. I submit that it would not. Had the Court opted to scrutinize the constitutionality of the $79.5 million award, all factors point to a plaintiff-friendly outcome. Changes in the Court's composition post-*State Farm*, due consideration to Justice Kennedy's numerable caveats to the *State Farm* single-digit benchmark,[27] and Justice Stevens' unequivocal conclusion that the *Philip Morris* award should be upheld, signal an alignment of a *new* majority—Justices Kennedy, Stevens, Thomas, Ginsburg and Scalia—one that unquestionably will *not* bode well for defendants and for corporate America on the issue of numerical limitations on punitive damages. ■

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1 The biblical King Solomon was known for his wisdom and his writings. Upon being confronted by two women, each claiming to be the mother of an infant, King Solomon proposed that the child should be split in half since he did not know the true identity of the birth mother. The wisdom of his solution was borne out when the birth mother, fearful that her only child would be killed in the process of resolving the dispute, volunteered to let the other woman take the child. Hence, the identity of the birth mother was revealed to Solomon.

2 *See* Carol J. Gatewood, *Philip Morris Case Gives Justices a Chance to Exorcise 'Phantom' Plaintiffs,* (October 31, 2006) *at http://www.law.com.*

3 *Philip Morris USA v. Williams,* 127 S. Ct. 1057 (2007); *see also Williams v. Philip Morris USA Inc.*, 127 P.3d 1165 (Or. 2006), *cert. granted,* 126 S. Ct. 2239 (U.S. May 30, 2006), *judgment remanded by Philip Morris USA v. Williams,* 127 S. Ct. 1057 (2007).

4 Chief Justice John Roberts, Jr., Justice Anthony M. Kennedy, Justice David H. Souter and Justice Samuel Alito, Jr. joined in the opinion.

[5] Justice John Paul Stevens and Justice Clarence Thomas filed dissenting opinions. Justice Ruth Bader Ginsberg filed a dissenting opinion in which both Justices Antonin Scalia and Clarence Thomas joined.

[6] *Philip Morris USA,* 127 S. Ct. at 1059-60.

[7] *Williams v. Philip Morris USA Inc.*, 48 P.3d 824 (Or. App. June 5, 2002) (appeal from Circuit Court, Multnomah County, 9705-03957).

[8] *Id.* at 828.

[9] *Williams v. Philip Morris USA Inc.*, 51 P.3d 670 (Or. App. Aug. 7, 2002), *cert. granted*, 540 U.S. 801 (2003).

[10] *See Philip Morris USA*, *Inc.*, 540 U.S. 801 (2003) *citing State Farm*, 538 U.S. 408. On April 7, 2003, the Supreme Court issued its 6-3 opinion in the landmark case *State Farm*, 538 U.S. 408. (Legal scholars and litigators, alike, hailed the decision for providing guidance toward a framework for evaluating the constitutionality of punitive awards.)

[11] *Williams v. Philip Morris USA*, 92 P.3d 126 (Or. App. June 9, 2004).

[12] *Williams v. Philip Morris USA.*, 127 P.3d 1165 (Or. Feb. 2, 2006)

[13] *State Farm*, 538 U.S. at 425 (indicating that a single-digit ratio of punitive damages to compensatory damages is the appropriate demarcation of a constitutionally acceptable punitive judgment).

[14] The 14th Amendment bars states from depriving "any person of life, liberty, or property, without due process of law." U.S. CONST., AMEND XIV.

[15] *See State Farm*, 538 U.S. at 425 (indicating that a single-digit ratio of punitive damages to compensatory damages is the appropriate demarcation of a constitutionally acceptable punitive judgment).

[16] *See id.* Justice Anthony Kennedy delivered the Court's 6-3 opinion in which then-Chief Justice Rehnquist, Justices John Paul Stevens, David H. Souter, Stephen G. Bryer, and then-Justice Sandra Day O'Connor joined. Justices Antonin Scalia, Clarence Thomas and Ruth Bader Ginsberg filed dissenting opinions.

[17] *Philip Morris USA.*, 127 S. Ct. at 1065.

[18] *See infra* notes 3-4.

[19] In *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996), the Court set forth three constitutional guideposts for punitives: (1) the degree of reprehensibility of the defendant's misconduct; (2) the disparity between the actual or potential harm suffered by the plaintiff; and, (3) the difference between the punitive damages awarded by the jury and the civil penalties authorized or imposed in comparable cases. Justice John Paul Stevens wrote the majority opinion in which Justices Anthony Kennedy, David H. Souter, Stephen G. Breyer, and then-Justice Sandra Day O'Connor joined. Justices Antonin Scalia and Clarence Thomas did not agree with the majority's due process analysis. Justice Ruth Bader Ginsberg and then-Chief Justice Rehnquist dissented on federalism grounds.

[20] *See Philip Morris USA.,* 127 S. Ct. at 1064. (emphasis added).

[21] *Id.* (emphasis added).

[22] *Id.* at 1065.

[23] 538 U.S. at 425.

[24] *Id.*

[25] *Id.*

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"Advances in Technology May Spur Class Action Lawsuits Arising from Foodborne Illness Outbreaks" – *cont'd from page 1*

The CDC estimates that foodborne diseases cause approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths in the United States each year. Thus, contaminated food products cause more deaths each year than the combined total of all 15,000 products regulated by the U.S. Consumer Products Safety Commission.

Listeria in the past few years. For example, on Dec. 13, 2006, the CDC reported that 71 people had become ill after eating at Taco Bell restaurants in five states.[2] The CDC confirmed that at least 48 of the 71 patients tested positive for a single strain of E. coli that was traced to the restaurants. Just two months earlier, the CDC announced that 199 people had been infected with another strain of E. coli bacteria that was traced to the consumption of tainted spinach.[3] In another notable case, three people died and 555 contracted Hepatitis A after consuming green onions at a single restaurant in Pennsylvania in 2003.[4]

Despite the often large numbers of people impacted in similar ways by these and other outbreaks, courts have generally been reluctant to certify personal injury claims arising from food contamination as class actions. This article will examine the rationale behind these decisions and whether the development of new technology may lead courts to reexamine their reluctance to certify class actions following future outbreaks.

Food Contamination in the United States is a Significant Issue

The CDC estimates that foodborne diseases cause approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths in the United States each year.[5] Thus, contaminated food products cause more deaths each year than the combined total of all 15,000 products regulated by the U.S. Consumer Products Safety Commission.[6] Foodborne illnesses now account for approximately 1 percent of all hospitalizations and 1 out of every 500 deaths in the United States.[7]

In 2001, the U.S. Department of Agriculture, Economic Research Service, issued a report that sought to identify and analyze every jury verdict, in both state and federal courts, that involved a foodborne illness from 1988 to 1997.[8] The report identified 178 such cases and demonstrated the challenges that plaintiffs in these cases faced. For example, more than two-thirds (68.6 percent) of the plaintiffs in these foodborne illness cases failed to recover any damages whatsoever.[9] In the 55 cases in which plaintiffs did prevail, the median award was just $25,560.[10] Moreover, the average time between the incidents that resulted in the plaintiffs' illnesses and the jury verdicts for the cases examined in the report was 3.1 years.[11]

The Department of Agriculture report noted that none of the cases that resulted in a jury verdict was a class action. Nonetheless, the report noted that the authors had observed an increase in class actions involving foodborne illnesses, perhaps because of the widespread media coverage surrounding the class action brought against Jack in the Box. Following an outbreak of E. coli O157:H7 in 1993 that was blamed on undercooked hamburgers and that sickened more than 600 people, the class action against Jack in the Box was settled for $12 million.[12]

Causation Issues Are a Significant Hurdle to Class Certification

Plaintiffs in federal court must satisfy the requirements of Rule 23 of the Federal Rules of Civil Procedure before a class action may be certified. The Advisory Committee's comments to Rule 23, however, suggest that class actions are not ordinarily appropriate to resolve claims arising from mass accidents such as outbreaks of foodborne illness:

> A 'mass accident' resulting in injuries to numerous persons is ordinarily not appropriate for a class action because of the likelihood that significant questions,

> not only of damages but of liability and defenses of liability, would be present, affecting the individuals in different ways. In these circumstances an action conducted nominally as a class action would degenerate in practice into multiple lawsuits separately tried.[13]

One of the first cases to consider the certification of a class action under Rule 23 to an outbreak of foodborne illness was *Hernandez v. Motor Vessel Skywards*.[14] *Hernandez* involved a class action complaint brought on behalf of 655 passengers, most of whom allegedly became ill after consuming contaminated food or water on their cruise ship. Among other things, the complaint raised claims for negligence in exposing the plaintiffs to contaminated food and water and for breach of the implied warranty of fitness of the food and water.

In its consideration of the plaintiffs' motion for class certification, the *Hernandez* court distinguished between those issues that were "subject to a uniform determination" and those that the court believed to be more individual in nature.[15] As a result, the court granted certification of the class only on the question of whether the defendants were negligent in preparing either the drinking water or food that was made available to the passengers. Conversely, the court found the remaining issues—most notably the proximate cause of each passenger's illness—to be individual in nature, and therefore, not subject to class treatment.[16] For example, the court noted that the symptoms exhibited by some of the passengers may have been caused by seasickness or some other issue unrelated to the alleged contamination.[17] *See also*, *Bentkowski v. Marfuerza Compania Maritima*[18] (certifying a class solely on the issue of negligence in another case involving food poisoning on a cruise ship).

Similarly, a Pennsylvania trial court recently declined to certify a class of individuals who were sickened after eating at a local swim club, in part because of the court's conclusion that causation could not be proved on a class-wide basis. *Kennedy v. Cannuli Bros., Inc*.[19] The *Kennedy* court reasoned that there may have been intervening and possibly superseding causes of the plaintiffs' illnesses because their symptoms did not become apparent for several days after the meal at issue.[20]

Nonetheless, a few courts have found that causation issues may be resolved in a foodborne illness case on a class-wide basis. In *Farrenholz v. Mad Crab, Inc*.[21] the Ohio Court of Appeals affirmed the trial court's decision to certify a class action arising from food contamination at a Strongsville, Ohio, restaurant. The plaintiff's motion for class certification incorporated an affidavit from a supervisor of the local board of health who reported that the board had concluded the likely source of the contaminated food was the restaurant.

The three judges in *Farrenholz* disagreed as to whether the issue of proximate causation could be proved on a class-wide basis so as to warrant class certification. The majority opinion concluded that class certification was proper because the "common question here is causation, which has to be proven on a class-wide basis. Whether damages may differ among the claimants is not a reason to deny class certification."[22] The dissent, however, argued that because the trial court would need to resolve several fact questions regarding causation for each plaintiff, including the presence or absence of any pre-existing conditions, the case was not appropriate for class treatment.[23]

Scientific Advances May Alleviate Concerns About Causation

New advances in technology may now enable plaintiffs to more fully prove causation issues in class action cases involving foodborne illnesses. For example, "DNA fingerprinting" has been used to trace the sources of contamination in more recent outbreaks. In its Oct. 6, 2006 update on the outbreak of *E. coli* from fresh spinach, the CDC reported that that stool samples from a 2-year-old child who died Sept. 20 contained *E. coli* O157 with a "DNA fingerprint" pattern that matched the outbreak strain.[24] The same update also reported *E. coli* O157 was isolated from 13 packages of spinach that was supplied by patients living in 10 states. The "DNA fingerprints" of all 13 of these *E. coli* matched that of the outbreak strain.[25] The CDC reports that DNA fingerprinting is now routinely done at public health laboratories in all states as part of the network of public health laboratories that sub-type bacteria.[26]

To the extent that it is available following a given outbreak, companies involved in food preparation, processing, and packaging should anticipate that class action plaintiffs will attempt to rely on DNA fingerprinting to prove causation on a class-wide basis following outbreaks of foodborne illness. Consequently, defendants in such cases will need to become familiar with the capabilities and limitations of DNA fingerprinting and other techniques, depending on the circumstances of each case. ■

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[1] U.S. Centers for Disease Control and Prevention, *Salmonellosis—Outbreak Investigation*, February 2007, updated Feb. 22, 2007, available at *http://www.cdc.gov/ncidod/dbmd/diseaseinfo/salmonellosis_2007/outbreak_notice.htm*.

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[2] U.S. Centers for Disease Control and Prevention, *Multistate Outbreak of E. coli O157 Infections, November-December 2006*, Updated Dec. 13, 2006, available at *http://www.cdc.gov/ecoli/2006/december/121306.htm*.

[3] U.S. Centers for Disease Control and Prevention, *Update on Multi-State Outbreak of E. coli O157:H7 Infections From Fresh Spinach*, updated Oct. 6, 2006, available at *http://www.cdc.gov/foodborne/ecolispinach/100606.htm*.

[4] U.S. Centers for Disease Control and Prevention, *Hepatitis A Outbreak Associated with Green Onions at a Restaurant—Monaca, Pennsylvania, 2003*, updated Nov. 28, 2003, available at *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5247a5.htm*.

[5] U.S. Centers for Disease Control and Prevention, *Food-Related Illness and Death in the United States*, Paul S. Mead, *et al.*, available at *http://www.cdc.gov/ncidod/eid/vol5no5/mead.htm*.

[6] U.S. Department of Agriculture, Economic Research Service, *Product Liability and Microbial Foodborne Illness*, *Buzby*, *et al.* (2001), available at *http://www.ers.usda.gov/publications/aer799/aer799.pdf*.

[7] *Id.*

[8] The average recovery in those 55 cases was somewhat higher—$133,280—because of a few large awards, including two that were in excess of $1 million. *Id.*

[9] *Id.* at 14.

[10] *Id.*

[11] *Id.*

[12] *http://www.marlerclark.com/news/jackbox10.htm*.

[13] Advisory Committee's Note to Rule of Civil Procedure 23.

[14] 61 F.R.D. 558 (S.D. Fla. 1974), *aff'd,* 507 F.2d 1278 (5th Cir. 1975).

[15] *Id.* at 561.

[16] *Id.*

[17] *Id.*

[18] 70 F.R.D. 401 (E.D. Pa. 1976).

[19] 2003 WL 22309584 (Pa. Com. Pl. 2003).

[20] *Id.*

[21] 2000 WL 1433956 (Ohio Ct. App. 2000).

[22] *Id.*

[23] *Id.* at *11.

[24] U.S. Centers for Disease Control and Prevention, *Update on Multi-State Outbreak of E. coli O157:H7 Infections From Fresh Spinach*, updated Oct. 6, 2006, available at *http://www.cdc.gov/foodborne/ecolispinach/100606.htm*.

[25] *Id.*

[26] U.S. Centers for Disease Control and Prevention, *Multistate Outbreak of Salmonella Tennessee Infections, August 2006 – January 2007*, updated Feb. 15, 2007, available at *http://www2a.cdc.gov/HAN/ArchiveSys/ViewMsgV.asp?AlertNum=00258*.

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