2011 Product Liability Cases: Year in Review

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This year produced several significant rulings, but three decisions stood out because of their potential to significantly impact future product liability cases.

PLIVA, Inc. v. Mensing, 131 S. Ct. 2657 (June 23, 2011): In 2009, the U.S. Supreme Court in *Wyeth v. Levine* held that approval by the Food and Drug Administration of a brand name drug did not pre-empt state law failure to warn cases. But what about generic drugs? In a 5-4 decision, the Supreme Court in *PLIVA v. Mensing* held that failure to warn cases against generic drug manufacturers were pre-empted.

In *PLIVA*, plaintiffs were prescribed the generic version of metoclopramide (brand name "Reglan"), a drug to treat digestive problems. After several years of taking the generic drug, both women developed a neurological condition called tardive dyskinesia.

Plaintiffs sued the generic drug manufacturers, alleging that the manufacturers failed to warn that long-term use of metoclopramide could cause tardive dyskinesia. The manufacturers argued federal law pre-empted these state law tort actions because "federal statutes and FDA regulations required them to use the same safety and efficacy labeling as their brand-name counterparts." Therefore, it was impossible for them to comply with both the federal regulations dictating sameness and state tort law requiring a different label. Rejecting the manufacturers' arguments, the 5th and 8th U.S. Circuits Court of Appeals held that plaintiffs' claims were not pre-empted.

The Supreme Court consolidated the cases and reversed the 5th and 8th Circuits on the basis of federal preemption, agreeing with the manufacturers' arguments. Deferring to the FDA's interpretation of its own regulations, the Court categorically rejected plaintiffs' arguments that the manufacturers could have utilized the FDA's changes-being-effected (CBE) process to unilaterally strengthen their warning labels, and the manufacturers could have sent "Dear Doctor" letters to convey additional warnings about their drugs. Now, a generic drug manufacturer cannot be held liable under state tort law for failing to independently change its label to include new risk information.

Howell v. Hamilton Meats and Provisions, 52 Cal.4th 541 (Aug. 18, 2011): When calculating a plaintiff's past medical expenses, should the recovery be the amount billed or paid? In a 6-1 decision, the state Supreme Court in *Howell* held that a plaintiff's recovery for past medical expenses is limited to the amount paid by plaintiff or his or her insurer, not the amount that was originally billed by the medical provider.

In *Howell*, plaintiff was injured in an automobile accident involving a driver employed by Hamilton Meats and Provisions. Defendant conceded liability and the necessity of plaintiff's medical treatment, contesting only the amount of plaintiff's economic and non-economic damages.

At trial, plaintiff provided evidence that the total amount billed for her medical care was approximately $190,000. The jury returned a verdict for the full billed amount as damages for her past medical expenses. By post trial motion, defendant sought to reduce the award by more than $130,000—to the amount actually paid by plaintiff or her insurer—because plaintiff's

medical care providers had written off charges as part of a pre-existing contract between plaintiff's health insurer and medical provider. The trial court reduced the judgment by the requested amount. The appellate court reversed, holding that the reduction violated the collateral source rule.

The state Supreme Court reversed the appellate court, and concluded that "an injured plaintiff whose medical expenses are paid through private insurance may recover as economic damages no more than the amounts paid by the plaintiff or his or her insurer for the medical services received or still owing at the time of trial." The Court found that the collateral source rule did not apply, recognizing that the rule "has no bearing on amounts that were included in a provider's bill but for which the plaintiff never incurred liability because the provider, by prior agreement, accepted a lesser amount as full payment." Therefore, "such sums are not damages the plaintiff would otherwise have collected from the defendant," and "[b]ecause they do not represent an economic loss for the plaintiff, they are not recoverable in the first instance."

The Court acknowledged that the new rule presented "an element of fortuity to the compensatory damages the defendant pays" because a "tortfeasor who injures a member of a managed care organization may pay less in compensation for medical expenses than one who inflicts the same injury on an uninsured person treated at a hospital." Accepting this scenario as "a fact in the life of litigation," the Court declined to reach a decision that would require "one defendant to pay damages for an economic loss the plaintiff has not suffered merely because a different defendant may have to compensate a different plaintiff who *has* suffered such a loss."

In addition, the Court held that evidence of the amount a medical care provider has—by contract with a health insurer—accepted as payment for plaintiff's care, is "relevant to prove the plaintiff's damages for past medical expenses and, assuming it satisfies other rules of evidence, is admissible at trial." It further concluded that "evidence of the full billed amount is not itself relevant on the issue of past medical expenses," however, the Court "express[ed] no opinion as to its relevance or admissibility on other issues, such as noneconomic damages or future medical expenses."

Wal-mart Stores Inc. v. Dukes, 131 S.Ct. 2541 (June 20, 2011): Though decided in the context of a Title VII gender discrimination suit, the U.S. Supreme Court's decision in *Wal-mart* has the potential for broad application in all class actions, including product liability consumer class actions. In a 5-4 decision, the Supreme Court held that certification of a nationwide plaintiff class of female employees was inconsistent with Federal Rule of Civil Procedure 23(a), which requires the party seeking class certification to prove that the class has common questions of law or fact. The Court further held that the plaintiffs' claims for backpay were improperly certified under Federal Rule of Civil Procedure 23(b)(2) because claims for monetary relief cannot be certified under that provision when monetary relief is not incidental to the requested injunctive or declaratory relief.

In *Wal-Mart*, plaintiffs filed a putative class action against the retail giant, alleging systematic discrimination against women. The district court certified a nationwide class against Wal-Mart of approximately 1.5 million current and former female employees. The 9th U.S. Circuit Court of Appeals affirmed the class certification order, which the Supreme Court reversed.

Writing for the majority, Justice Antonin Scalia noted that "[t]he crux of this case is commonality—the rule requiring a plaintiff to show that 'there are questions of law or fact common to the class.'" The Court noted, however, that "[this] language is easy to misread, since [a]ny competently crafted class complaint literally raises common questions." It made clear that determining commonality will "frequently" require consideration of "the merits of plaintiff's underlying claim." In this case, plaintiffs were required to present "significant

proof that Wal-Mart operated under a general policy of discrimination." The Court concluded that plaintiffs failed to meet that threshold and had "not identified a common mode of exercising discretion that pervades the entire company" through any of the evidence they presented: statistical, anecdotal, or sociological. The Court noted that "[w]ithout some glue holding the alleged reasons for all those decisions together, it will be impossible to say that examination of all the class members' claims for relief will produce a common answer."

The Court further held that claims for backpay could not be certified under Rule 23(b)(2). Instead, it opined, the claims belong in Rule 23(b)(3), which contains the "procedural protections" afforded to a (b)(3) class such as "predominance, superiority, mandatory notice, and the right to opt-out."

This heightened commonality test potentially impacts certification of product liability consumer class actions as well. Such an impact could occur, for example, in drug or medical device class actions. Courts, in determining commonality for a putative class of patients who took the same drug or used the same medical device, may now place more weight on the individualized role medical care providers play in prescribing patient-specific treatments.

Only time will tell how trial and appellate courts at both the federal and state level will work to apply the broad principles of *Mensing*, *Howell*, and *Dukes* in a variety of contexts.

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