Supreme Court Decision Opens Door for Possible Implied Conflict Preemption of Over-the-Counter Drugs

By David B. Sudzus, B. Todd Vinson and Russell J. Chibe

The United States Supreme Court’s most recent pronouncement on federal preemption, decided in the context of generic prescription drugs, appears destined to be at the forefront in future battles over unsettled questions regarding preemption in the context of nonprescription, over-the-counter (OTC) drugs. In PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011), the Supreme Court held that federal law preempted state law failure to warn claims asserted against generic drug manufacturers. The Court’s preemption holdings, couched in terms of “impossibility” borne out of federal regulatory requirements of “sameness,” could arguably have similar applicability in the context of OTC drugs regulated under the FDA’s “monograph” regime.

The doctrine of federal preemption is based on the Supremacy Clause of the United States Constitution. The Supremacy Clause provides that federal law is “the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.” U.S. CONst. art. VI, cl. 2. As such, any state law that conflicts with the exercise of federal power is preempted and has no effect. See Maryland v. Louisiana, 451 U.S. 725, 747 (1981).

State law is preempted under the Supremacy Clause where Congress has expressly preempted state law. See, e.g., Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516, (1992). Preemption may also be implied to the extent that state law actually conflicts with federal law. English v. Gen. Elec. Co., 496 U.S. 72, 79 (1990). “Implied” or “conflict” preemption exists where (1) it is impossible for a private party to comply with both state and federal requirements; or (2) state law obstructs accomplishing and executing Congress’ full
purposes and objectives. See Mensing, 131 S. Ct. 2567 (citing Freightliner Corp. v. Myrick, 514 U.S. 280, 287 (1995)). In Mensing, the Supreme Court addressed implied preemption based on impossibility.

**Impossibility-Based Federal Preemption as Articulated by Supreme Court in Mensing**

Mensing involved state law failure to warn claims asserted against generic prescription drug manufacturers, and alleged the manufacturers failed to provide adequate warning labels. Plaintiffs claimed that state law required the manufacturers to use a different, safer label.

However, the Mensing Court determined that, under FDA regulations, generic drug manufacturers have an ongoing federal duty of "sameness" regarding their labels – namely, that the generic drug’s labeling must at all times be the same as the brand name drug’s labeling because the brand name drug is the basis for generic drug approval. Specifically, the Court found that the generic drug manufacturers could not strengthen their labels through the FDA’s “changes-being-effected” (CBE) process, as such action would constitute a unilateral change by the generic drug manufacturers violating federal regulations requiring a generic drug’s label to match its brand name counterpart. 131 S. Ct. at 2575.

The Court distinguished its prior 2009 decision in Wyeth v. Levine (holding that state law failure to warn claims were not preempted against a brand name prescription drug manufacturer) based on this difference in availability of the CBE process. The Court explained that Wyeth turned on its finding that it was not impossible for Wyeth to strengthen its product warnings because Wyeth could take advantage of CBE provisions applicable to brand name prescription drugs approved under the New Drug Application (NDA) procedure and change its labeling without first seeking FDA approval. Id. at 2581. Thus, the Mensing Court reasoned that, unlike the case before it, the availability of the CBE regulations permitted the brand name drug manufacturer to “unilaterally strengthen its warning” without prior FDA approval, and therefore “allowed the company, on its own volition, to strengthen its label in compliance with its state tort duty.” Id.

The Mensing plaintiffs nonetheless argued against a finding of impossibility by contending that, despite the federal requirement of “sameness” and lack of CBE availability, the generic drug manufacturers were still able to (or even were required to) propose stronger warning labels to the FDA if they believed such warnings were needed. Id. at 2575. The Mensing Court, however, reasoned that simply proposing label changes “would not have satisfied the requirements of state law,” but rather “federal law would permit the Manufacturers to comply with the state labeling requirements if, and only if, the FDA and the brand-name manufacturer changed the brand-name label.” Id. at 2578. This, according to the Court, “raise[d] the novel question of whether conflict preemption should take into account these possible actions by the FDA . . . .” Id. The Mensing Court held that it should not:

The question for “impossibility” is whether the private party could independently do under federal law what state law requires of it . . .
If these conjectures suffice to prevent federal and state law from conflicting for Supremacy Clause purposes, it is unclear when, outside of express preemption, the Supremacy Clause would have any force. We do not read the Supremacy Clause to permit an approach to preemption that renders conflict preemption all but meaningless . . .

To consider in our preemption analysis the contingencies inherent in these cases - in which the Manufacturer's ability to comply with state law depended on uncertain federal agency and third-party decisions - would be inconsistent with the *non obstante* provision of the Supremacy Clause . . .

Id. at 2579-80. The *Mensing* Court summarized the test for “impossibility” as follows:

> When a party cannot satisfy its state duties without the Federal Government’s special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for [preemption] purposes.

Id. at 2581.

**Impact of Mensing’s Test for Impossibility in Context of OTC Drugs Preemption**

The *Mensing* articulation of impossibility arguably provides compelling grounds for finding impossibility-based preemption in the context of failure to warn claims asserted against OTC drug manufacturers. Specifically, manufacturers of OTC drugs regulated under the FDA’s “monograph” system could persuasively argue that, similar to the generic prescription drug manufacturers in *Mensing*, their product labeling is subject to federal requirements of “sameness” that cannot be unilaterally changed without FDA permission and assistance.

**Lack of Express Preemption for OTC Drugs Does Not Foreclose Arguing Implied Preemption**

An initial hurdle facing OTC drug manufacturers asserting implied preemption lies in reconciling the fact that Congress specifically carved out state product liability claims (including presumably, failure to warn claims) from the reach of an express preemption clause applicable to OTC drugs. The Federal Food, Drug and Cosmetic Act (FDCA) governing OTC nonprescription drugs contains an express preemption clause, but then sets forth a “saving clause” stating that “[n]othing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.” 21 U.S.C. § 379r(a), (e).

Nevertheless, the Supreme Court has recognized that the existence of an express preemption provision and saving clause does not foreclose application of the doctrine of implied conflict preemption. In *Buckman v. Plaintiffs’ Legal Committee*, the Court recognized that “neither an express preemption provision nor a savings clause bars the ordinary working of conflict preemption principles.” 531 U.S. 341, 352 (2001) (citing *Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000)).
“Monograph” Regulation of OTC Drugs

The FDA regulates most OTC drugs under its “monograph” regime. A monograph is a set of regulations promulgated by the FDA through notice and comment rulemaking that describes the conditions under which a category of drugs may be marketed without a prescription.

The Final Monograph for a class of OTC drugs includes labeling requirements. The manufacturer of an OTC drug must use the warning language authored by the FDA. 21 C.F.R. § 330.1(c)(2). The FDA’s labeling requirements are designed to provide warnings reflecting known risks based on reliable scientific evidence. See generally 21 C.F.R. § 330.10(a) (procedure for establishing OTC monograph). Adequate warnings are those that, in the judgment of the FDA, are “clear and truthful in all respects, not misleading in any particular,” and that accurately communicate the benefit to risk ratio and the proper use of the product in terms “likely to be read and understood by the ordinary individual.” 21 C.F.R. § 330.10(a)(4)(v).

Compliance with the Final Monograph by the OTC drug manufacturer is mandatory. “Any product which fails to conform to an applicable monograph after its effective date is liable to regulatory action.” 21 C.F.R. § 330.10(b). Therefore, once a Final Monograph goes into effect, it is illegal to sell a drug described therein unless it conforms to the monograph. 21 U.S.C. §§ 332-334. If a drug is marketed without prior FDA approval or without complying with an applicable monograph, the United States may bring an enforcement action under the FDCA. Enforcement measures include seizure of the drug product, civil injunction against its sale and criminal penalties against the violator.

“Sameness” of Labeling Imposed on Final Monograph OTC Drugs

Mensing’s articulation of impossibility arguably provides compelling grounds for finding impossibility-based preemption in the context of failure to warn claims asserted against Final Monograph OTC drug manufacturers. Specifically, manufacturers of Final Monograph OTC drugs could persuasively argue that, similar to the generic prescription drug manufacturers in Mensing, their product labeling is subject to federal requirements of “sameness” that cannot be unilaterally changed without FDA permission and assistance.

Manufacturers of Final Monograph OTC drugs could persuasively argue that, similar to the generic prescription drug manufacturers in Mensing, their product labeling is subject to federal requirements of “sameness” that cannot be unilaterally changed without FDA permission and assistance.

Final Monograph OTC drug manufacturers could assert that federal regulations, providing for specific product labeling and making it illegal to sell an OTC drug unless it conforms to the monograph, make it impossible for the manufacturer to comply with the federal law and also provide the additional or different labeling sought under the state law failure to warn claims. Moreover, the OTC drug manufacturers would assert that the monograph regime does not contain any directly applicable CBE provision—a critical distinction made by the Mensing Court in distinguishing its holding from Wyeth.

Finally, the OTC drug manufacturers could argue that under Mensing, the fact that FDA regulations provide a mechanism to amend or repeal any final monograph based on consideration of new information related to the safety or effectiveness of OTC products in the category does not change the impossibility preemption result. As Mensing held, impossibility preemption does not take into account possible actions by the FDA. As such,
the OTC drug manufacturer could argue that the mechanism for potential amendment or repeal of a final monograph does not allow it to “satisfy its state duties without the Federal Government’s special permission and assistance, which is dependent on the exercise of judgment by a federal agency,” and thus it “cannot independently satisfy those state law duties for [preemption] purposes” through such means. 131 S. Ct. at 2581.

**Conclusion**

The law of federal preemption regarding claims against drug manufacturers—whether brand name or generic, prescription or over-the-counter—is constantly evolving, and promises to remain in flux in the immediate wake of *Mensing*. Key holdings in *Mensing* provide OTC drug manufacturers with plausible, though far from certain to prevail, impossibility-based preemption arguments to challenge failure to warn claims. Whether *Mensing* ultimately provides a path to preemption for OTC drug manufacturers should become more clear in the future as courts across the country begin to interpret *Mensing*’s impact in non-generic OTC drug contexts.

**About the Authors**

**David B. Sudzus**  |  [www.drinkerbiddle.com/dsudzus](http://www.drinkerbiddle.com/dsudzus)

David is a partner in the Products Liability and Mass Tort Practice Group. His practice focuses on products liability, medical device, complex and multi-district litigation.

**B. Todd Vinson**  |  [www.drinkerbiddle.com/tvinson](http://www.drinkerbiddle.com/tvinson)

Todd is a partner in the Products Liability and Mass Tort Practice Group. His practice focuses on civil litigation, including products liability and commercial litigation matters.

**Russell J. Chibe**  |  [www.drinkerbiddle.com/rchibe](http://www.drinkerbiddle.com/rchibe)

Russ is an associate in the Products Liability and Mass Tort Practice Group. He has worked on state and federal complex litigation matters at both the trial and appellate phases and has significant experience with multi-district litigation on behalf of major pharmaceutical companies.
Illinois Supreme Court Applies Risk-Utility Analysis in Negligent Design Case and Refuses to Expand A Manufacturer's Postsale Duty to Warn in Reversal of $43 Million Jury Verdict in Exploding Gas Tank Accident Case

By William V. Essig and Cason C. Clements

In a significant victory for product manufacturers, the Illinois Supreme Court reversed a $43 million jury verdict against defendant Ford Motor Company in a case involving a fatal accident in which the fuel tank of a 1993 Lincoln Town Car exploded. The court held that a defendant’s duty in a negligent design case is determined by application of the risk-utility test and that, as a matter of public policy, a manufacturer “is not required to guard against every conceivable risk, regardless of the degree of harm.” Jablonski v. Ford Motor Co., 955 N.E.2d 1138, 1157 (Ill. 2011). The court refused to expand postsale duties beyond those currently required by Illinois law and held that a manufacturer “is under no duty to issue postsale warnings or to retrofit its products to remedy defects first discovered after a product has left its control.” See id. at 1160 (citing Modelski v. Navistar International Transportation Corp., 302 Ill.App.3d 879, 890, 236 Ill.Dec. 394, 707 N.E.2d 239 (1999)).

John and Dora Jablonski were stopped at a stop sign in their 1993 Lincoln Town Car in 2003 when another car struck the Jablonskis’ car at between 55 and 65 mph. As a result of the crash, a large pipe wrench in the trunk of the Town Car penetrated the trunk and punctured the back of the car’s fuel tank. The car burst into flames, causing John’s death and Dora’s severe burns. See Jablonski, 955 N.E.2d at 1142. Plaintiffs brought suit in the Circuit Court of Madison County against Ford Motor Company, alleging negligent design of the 1993 Town Car’s fuel tank and willful and wanton conduct, seeking punitive damages.

Plaintiffs abandoned their strict liability claims after the close of evidence. The case was presented to the jury on several theories of negligent design and willful and wanton conduct, including (1) failing to locate the vertical-behind-the-axle fuel tank either over-the-axle or forward-of-the-axle, (2) failing to shield the fuel tank to prevent punctures by contents in the trunk, and (3) failing to warn of the risk of trunk contents puncturing the fuel tank. The jury was also presented with a fourth theory that had not been pled, that Ford failed to inform the Jablonskis of certain remedial measures taken by Ford after the manufacture of the vehicle, but prior to the accident. Jablonski, 955 N.E.2d at 1142-43. The jury returned a general verdict awarding a total of $28 million in compensatory damages and $15 million in punitive damages. Jablonski, 955 N.W.2d at 1142. The appellate court affirmed.

In a 5-0 opinion by Justice Theis, the Supreme Court clarified the duty analysis in negligent product design cases and adopted the risk-utility analysis, an analysis typically used to determine whether a product is unreasonably dangerous in a strict liability claim. The court explained that “the key question in a negligent-design case is whether the manufacturer exercised reasonable care in designing the product.” Jablonski, 955 N.W.2d...
at 1154 (citing Calles v. Scripto-Tokai Corp, 224 Ill.2d 247, 270, 309 Ill.Dec. 383, 864 N.E.2d 249 (2007)), and this exercise of reasonable care “encompasses a balancing of the risks inherent in the product design with the utility or benefit derived from the product.” See id. at 1154 (citing Restatement (Second) of Torts § 291, at 54 (1965)). Despite prior indication by the Court in Blue v. Environmental Engineering, Inc., 215 Ill.2d 78, 293 Ill. Dec. 630, 828 N.E.2d 1128 (2005) that the risk-utility test does not apply in negligent product design cases, the Jablonski court found otherwise. See Jablonski, 955 N.E.2d at 1154-55.

As a threshold matter in applying the risk-utility test to determine the duty in a negligent-product-design case, “the court must initially balance factors it finds relevant to determine if the case is a proper one to submit to the jury.” See Jablonski, 955 N.E.2d at 1155 (citing Calles, 224 Ill.2d at 266). “Once this threshold determination has been met, the issue is then for the fact finder to determine the weight to be given any particular factor . . .” Id. The court set forth a non-exhaustive list of factors that may be relevant to the risk-utility analysis including evidence of (1) the availability and feasibility of alternate designs at the time of the product’s manufacture; (2) the design used not conforming to the design standards in the industry, design guidelines provided by an authoritative voluntary organization, or design criteria set by legislation or governmental regulation; (3) the utility of the product to the user and to the public as a whole; (4) the safety aspects of the product including the likelihood that it will cause injury; and (5) the manufacturer’s ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility. Id. at 1154 (citing Calles 224 Ill.2d at 263-64).

Ford argued that it was entitled to judgment notwithstanding the verdict because its compliance with industry standards, alone, was dispositive of its duty in a negligent design claim. The court disagreed. The language in Blue upon which Ford relied was not binding. 955 N.E.2d at 1156 (citing Blue, 215 Ill.2d at 96). Evidence of industry standards is just one of the factors to be balanced in the risk-utility test. It is not dispositive.

After conducting its threshold review, the court found plaintiffs failed to present sufficient evidence that Ford breached the standard of care, reasonable conduct, for their first three negligent design theories. The court balanced several factors in its risk-utility analysis, including evidence of compliance with industry standards, availability and feasibility of alternate designs, and the relative risk of the design at issue. Id. at 1157-59. The court explained that plaintiffs were required to produce evidence that “the risk was foreseeable and that the risks inherent in the product design outweighed the benefits.” Id. at 1157. A manufacturer “is not required to guard against every conceivable risk, regardless of the degree of harm.” Id. Because the unrebutted evidence revealed that Ford complied with, and even exceeded, the industry standard set for fuel system integrity, the court required plaintiffs to present evidence that Ford’s conduct was otherwise unreasonable because the foreseeable risk posed by the vertical-behind-the-axle design of the Town Car’s fuel tank at the time of manufacture outweighed its utility. Id.

In seeking to establish Ford’s unreasonable conduct, plaintiffs presented evidence of alternative tank designs, but the court found that plaintiffs had failed to establish the designs were safer than the design Ford adopted. Plaintiffs must “show more than the technical possibility of an alternative design.” Id. at 1158. The court further indicated
that “[i]t is not sufficient that the alternative design would have reduced or prevented the harm suffered by the plaintiff if it would also introduce into the product other dangers of equal or greater magnitude.” See id. at 1158 (quoting Restatement (Third) of Torts, Product Liability §2, cmt. f, at 23 (1998)).

Plaintiffs also presented Ford’s internal recommendations from the late 1960s to early 1970s, regarding an over-the-axle location of the fuel tank as evidence for the risks involved with an under-the-trunk location. The court found this research irrelevant and inapposite since it occurred more than a decade before the vertical-behind-the-axle tank was introduced in “Panther platform” vehicles, such as the Mercury Grand Marquis, Ford Crown Victoria, Ford Crown Victoria Police Interceptor and Lincoln Town Car, in 1979. The jury could not conclude Ford’s conduct was unreasonable based on remote research on a different fuel tank location. Id. at 1158.

Likewise, the court found numerous accident reports irrelevant to prove Ford was aware of the potential for trunk contents to puncture the fuel tanks in the 1993 Lincoln Town Cars. Despite evidence that 11 Crown Victoria Police Interceptors had had trunk contents puncture the tank in high-speed rear-end collisions from 1997 to 2003, plaintiffs’ expert was unaware of any accident, occurring prior to 1993, which involved any vehicle made by any manufacturer where any object in any trunk had ever punctured a fuel tank. Plaintiffs also introduced 416 incidents involving the puncture of a fuel tank in various Ford models over a number of years, but none of the accidents reported involved a “Panther platform” or any other car as of 1993. Id. at 1158; see also id. at 1146.

Plaintiffs introduced, and the court also found insufficient, evidence related to gas tank shielding as a way to minimize the hazard. The court stated that, “although not required to develop a specific prototype, it was incumbent upon plaintiffs to present evidence that there was a shield that was feasible to prevent trunk contents from puncturing the tank in the 1993 Lincoln Town Car.” Id. at 1158. In other words, the shield design had to be feasible to prevent the particular occurrence from occurring in the car at issue. The “mock up” shield provided by plaintiffs’ expert was insufficient, as it had not been design tested. The evidence also showed that the trunk shields and shield alternatives for other cars would not have prevented the ruptures that occurred in the Jablonski accident. See id. at 1158-59.

The court concluded that, after balancing the foreseeable risks and utility factors, plaintiffs failed to present sufficient evidence from which a jury could conclude that Ford’s conduct was unreasonable at the time of manufacture. Accordingly, the court determined that there was insufficient evidence to justify the submission of plaintiffs’ first three claims of negligence to the jury. Id. at 1159.

The court next examined plaintiffs’ fourth theory of negligence, which was based upon a postsale duty to warn. Under this theory, the jury had been instructed that it could find Ford negligent for its failure to “inform of the existence of the Trunk Pack and/or Trunk Pack recommendations,” which Ford developed for a different car a decade after the sale of the 1993 Town Car. Id. at 1159. First, the court noted that plaintiffs’ claim was contrary to Illinois law. Under Illinois precedent, “when a design defect is present at the time of sale, the manufacturer has a duty to take reasonable steps to warn at least the purchaser of the risk as soon as the manufacturer learns or should have learned of the risk created by its fault.” Id. at 1159 (emphasis added). Further, a duty may be imposed
upon a manufacturer by a statute or administrative regulation that mandates the recall of the product, under circumstances where the dangerous characteristic of the product is not discovered until after the product has left the manufacturer’s control. Id. at 1160 n. 1. A manufacturer, however, is under no common law duty “to issue postsale warnings or to retrofit its products to remedy defects first discovered after a product has left its control.” Id. at 1160.

Plaintiffs argued that their postsale duty to warn theory was, in fact, premised upon a continuing duty to warn at the time the car was manufactured. The instructions submitted to the jury inappropriately reiterated section 10 of the Third Restatement of Torts, which has not been adopted by Illinois and which establishes a duty to warn of a product-related risk after the time of sale, whether or not the product is defective at the time of the original sale. See id. at 1160-61; and see Restatement (Third) of Torts: Products Liability § 10, cmt. a, at 192 (1998). The court held that the jury instructions imposed an inappropriate duty of care that failed to require the jury to find that Ford knew or should have known that the product was unreasonably dangerous at the time of the sale. Id. at 1161. The court found plaintiffs’ theory legally defective and improperly submitted to the jury, as it was premised upon a duty not recognized in Illinois at the time of trial. Id. at 1161.

The court also briefly addressed the voluntary undertaking doctrine, under which the intermediate appellate court found the postsale duty to warn cognizable. The instruction on the voluntary undertaking doctrine provided that a manufacturer who voluntarily undertakes to provide postsale warnings to some of its customers may be liable if it does not warn other customers. Id. at 1162 (citing Restatement (Second) of Torts. § 323 (1965)). The court found the instruction was not an accurate statement of the law; rather “[u]nder a voluntary undertaking theory of liability, the duty of care to be imposed upon a defendant is limited to the extent of the undertaking.” Id. at 1162-63 (quoting Frye v. Medicare-Glaser Corp., 153 Ill.2d 26, 32, 178 Ill.Dec. 763, 605 N.E.2d 557 (1992)). In other words, the voluntary undertaking doctrine is to be narrowly construed. Although Ford developed and provided a “Trunk Pack” for “Panther platform” police vehicles due to fuel tank punctures, because Ford’s undertaking in developing these “Trunk Packs” was directed specifically at improved police safety related to use of the Crown Victoria Police Interceptor this measure did not create a duty owed to civilians. Therefore, the court determined that the trial court erred in instructing the jury on a postsale duty to warn theory based on voluntary undertaking. Id. at 1163.

Conclusion

The Jablonski decision places some limits on a manufacturer’s liability under Illinois product liability law. The Illinois Supreme Court refused to make manufacturers absolute insurers of the safe use of their products: “A manufacturer is not required to guard against every conceivable risk, regardless of the degree of harm.” 955 N.E.2d at 1157. Although the court was unwilling to find evidence of compliance with industry standards dispositive, it applied the risk-utility analysis quite rigorously in this negligent product

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1 Further, the Court declined Plaintiffs’ invitation to adopt Section 10 of the Restatement (Third). The Court did not, however, foreclose the possibility that a postsale duty to warn could be recognized in the future in Illinois. Id. at 1161-62.
design case. Similarly, the court both refused to expand a manufacturer’s postsale duty to warn to include defects first discovered after a product has left the control of the manufacturer, and sought to limit the duty of care, under a voluntary undertaking theory of liability, to the extent of the specific undertaking.

### About the Authors


Bill is a partner in the Products Liability and Mass Tort Practice Group and a member of the firm’s Electronic Discovery and Data Management Task Force. His practice focuses on drug and medical device products liability litigation including mass torts, toxic tort litigation, e-discovery and data management, health care fraud and other white collar criminal defense, and commercial litigation.

**Cason C. Clements | [www.drinkerbiddle.com/cclements](http://www.drinkerbiddle.com/cclements)**

Cason is an associate in the Products Liability and Mass Tort Practice Group.
Plaintiffs’ Attempts to Hold Brand Manufacturers Liable for Harm Caused By Generic Products Thwarted Again Despite Mensing’s Glimmer of Hope

By Melissa A. Graff

The Conte decision is well known by brand and generic manufacturers alike. 85 Cal. Rptr.3d 299 (Cal.App. 2008). There, one panel of the California Court of Appeal allowed the plaintiff to pursue a claim against a brand manufacturer, even though the record was clear that she had taken only generic manufacturers’ products. At the time, counsel and our brand manufacturer clients questioned whether the decision signaled the beginning of the end of product identification requirements or whether the Conte decision would stand alone as an isolated incident of unfortunate reasoning.

In the three years following Conte, courts throughout the country rejected its reasoning and refused to find that brand manufacturers owe a duty to individuals who take generic bioequivalents.

Then came Pliva, Inc. v. Mensing, 131 S.Ct. 2567 (2011), and the glimmer of hope for plaintiffs for broader application of Conte doctrine. In Mensing, the United States Supreme Court held that federal law preempts state laws that require stronger warnings on the generic product’s label and therefore barred plaintiffs’ state tort claims against generic manufacturers. As a result of the Court’s decision, many brand name counsel and clients expected plaintiffs’ lawyers to rigorously pursue the argument that the brand manufacturers should be held liable for injuries caused by the use of generic products because their clients would be left without recourse simply because a pharmacy dispensed a generic product rather than a brand product.

The Sixth Circuit Court of Appeals quickly thwarted plaintiffs’ hopes. In Smith v. Wyeth, Inc., 657 F.3d 420 (6th Cir. 2011), the court explicitly rejected Conte and affirmed the district court’s dismissal of all claims against the brand manufacturer. Plaintiffs Lala Smith, Alice Wilson and Dennis Morris were prescribed Reglan, which is a medication used to treat gastroesophageal reflux. Id. at 422. Reglan was manufactured by Wyeth from 1989 to 2001 and by Schwarz Pharma. Inc. from 2002 to 2005. Id. Pursuant to Kentucky’s generic-substitution law, which requires pharmacies to fill prescriptions with generic products unless the prescribing physician specifically instructs otherwise, all three plaintiffs received generic metoclopramide, but never received Reglan manufactured by Wyeth or Schwarz. Id. As a result of their long-term use of metoclopramide, the plaintiffs claimed that they developed tardive dyskinesia, a neurological disorder that resembles Parkinson’s disease. Id.

Like the plaintiff in Conte, the plaintiffs brought state-law failure to warn claims against the generic manufacturers and asserted state-law fraud, fraudulent concealment and negligent misrepresentation claims against the brand manufacturers. Id. As to the brand manufacturers, the plaintiffs alleged that Reglan’s label “falsely and misleadingly represented the risks associated with long-term use of metoclopramide.” Id. The district court granted summary judgment to the brand manufacturers and held that “Kentucky law does not permit a cause of action for misrepresentation about a product against
anyone other than the product’s manufacturer or distributor.” *Id.* Additionally, the district court granted summary judgment to the generic manufacturers based on federal preemption. *Id.*

The Sixth Circuit affirmed the dismissal of the generic manufacturers, finding the decision compelled by the plain language of *Mensing*: “The Supreme Court held unequivocally . . . that federal law preempts state laws that impose on generic-drug manufacturers the duty to change a drug’s label, thus barring the plaintiffs’ state-law tort claims.” *Id.* at 423.

As to plaintiffs’ fraud-based claims against the brand manufacturers, the Court made the following unequivocal statement regarding product identification: “A threshold requirement of any product-liability claim is that the plaintiff assert that the defendant’s product caused the plaintiff’s injury.” *Id.* (citing *Holbrook v. Rose*, 458 S.W.2d 155, 157 (Ky. 1970)). The court concluded that plaintiffs’ theory of liability “fails to satisfy the threshold requirement of a products-liability action – that the defendant’s product have injured the plaintiff.” *Id.* (emphasis in original). The court specifically rejected the plaintiffs’ *Conte*-based arguments: “As have the majority of courts to address this question, we reject the argument that a name-brand drug manufacturer owes a duty of care to individuals who have never taken the drug actually manufactured by that company.” *Id.* at 424.

**Conclusion**

Of course, Kentucky does not stand alone in requiring plaintiffs to establish that the harm they complain of was caused by a product manufactured by the defendant. Indeed, product identification is widely accepted as a threshold requirement in product liability claims, although surprisingly this proposition is not often clearly stated in case law involving drugs and devices. Nonetheless, this decision by the Sixth Circuit in the post-*Mensing* and post-*Conte* environment hopefully will encourage other courts to likewise prevent recovery of damages from a brand manufacturer for harm allegedly caused by a product manufactured by one of its generic competitors, and will confirm that *Conte* remains an aberration.

**About the Author**

**Melissa A. Graff | www.drinkerbiddle.com/mgraff**

Melissa is an associate in the firm’s Products Liability and Mass Tort Practice Group. She specializes in representing pharmaceutical and medical device companies in complex civil litigation with an emphasis on products liability defense.
A Tried and True Summary Judgment Option in Pharmaceutical and Medical Device Failure to Warn Cases

By William A. Hanssen and Siobhan A. Cullen

Summary judgment is a manufacturer’s goal in almost every case. Often, it’s an uphill battle. For example, a recent Supreme Court decision has made summary judgment more difficult to obtain in prescription drug cases that allege a failure to adequately warn, by limiting the scope of the federal preemption defense.\(^1\) Thus, a Food and Drug Administration (“FDA”) decision that a particular risk need not be identified in the labeling is rarely a basis to preclude Plaintiffs from proceeding with litigation criticizing the FDA-approved labeling. Additionally, courts are reluctant to adjudicate, at the summary judgment stage, that labeling adequately warns of the risks at issue because this is perceived by many courts as a question for the jury.\(^2\)

Moreover, Plaintiffs’ lawyers can easily find “experts” to criticize labeling and to offer opinions that the labeling, albeit FDA-approved, should have disclosed additional or different risks, or disclosed them in a different manner. These expert opinions, even when weakly supported, are often enough to thwart a defense summary judgment motion in most state court actions.

But even when the alleged risk is not mentioned in the labeling, prescription drug and medical device manufacturers may still have a defense available in failure to warn cases. As set forth in a seminal California case on this subject, *Plenger v. Alza Corporation*, 11 Cal.App.4th 349 (1992), a manufacturer has no duty to warn of a risk that is well-known and well-appreciated by the medical community.\(^4\)

As set forth in a seminal California case on this subject, *Plenger v. Alza Corporation*, 11 Cal.App.4th 349 (1992), a manufacturer has no duty to warn of a risk that is well-known and well-appreciated by the medical community.

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4. *Plenger*, 11 Cal. App. 4th at 362 (“We are aware of no authority which requires a manufacturer to warn of a risk which is readily known and apparent to the consumer, in this case the physician.”); *see also Carlin*, 13 Cal. 4th at 1116 (1996).
to know about the risk, not the absence of a warning. In other words, no harm can be caused by failure to warn of a risk already known.\(^5\)

Courts outside of California have also recognized these defenses.\(^6\) For example, as explained in *Stanback v. Parke, Davis and Co.*, 657 F.2d 642 (4th Cir. 1981), there is no evidence of causation when it is firmly established that a more complete warning would not have changed the physician’s course of action in prescribing or administering a prescription drug. *Id.* at 645-46. In *Stanback*, Plaintiff brought suit against a pharmaceutical manufacturer for its alleged failure to warn of the risk of Guillain-Barre Syndrome allegedly associated with its influenza vaccine. The lower court granted the manufacturer’s motion for summary judgment holding that its alleged failure to warn was not the cause in fact of Plaintiff’s illness, given the administering physician’s testimony that he independently knew of the risk but chose to administer the vaccine anyway, without communicating the risk to the Plaintiff. *Id.* at 644. The appellate court affirmed, reasoning that the physician’s testimony conclusively demonstrated that his decisions and actions would not have been affected in the least by the communication of a different warning, therefore breaking the chain of causation that Plaintiff needed to prove in order to survive summary judgment. *Id.* at 646.

The no duty to warn and the lack of proximate cause defenses are available in several contexts. First, in cases involving older products and established classes of medication, where the risk profile of the medications is well-known, both prescribers and experts are likely to concede this point, especially when confronted at deposition with ample medical literature reporting the risk.\(^7\) Likewise, manufacturers may have success with this defense in cases involving off-label pediatric use of a product with a well-appreciated risk profile in adult patients. This defense may also be useful in cases where the alleged undisclosed risk had been the subject of

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\(^5\) See *Rosburg v. Minn. Mining & Mfg. Co.*, 181 Cal. App. 3d 726, 735 (1986). Plaintiff complained that the manufacturer of breast implants failed to adequately warn of the risk of spontaneous deflation. The Plaintiff’s physician testified that he already knew of the danger. The trial court concluded that “no harm could have been caused by failure to warn of a risk already known.” Judgment for the manufacturer was affirmed on appeal.

\(^6\) See generally *Proctor v. Davis*, 682 N.E.2d 1203, 1211 (Ill. App. Ct. 1997); *Wooten v. Johnson & Johnson Products, Inc.*, 635 F. Supp.799, 803 (N.D. Ill. 1986) (“[C]ourts have consistently held that a drug manufacturer is entitled to summary judgment where the prescribing physician is aware of the risks associated with a drug.”); *Sacher v. Long Island Jewish-Hillside Med. Ctr.*, 530 N.Y.S.2d 232, 232 (App. Div. N.Y.1988) (Generally no duty to warn users of products who are fully aware of the risks attendant to their use); *Tatum v. Schering Corp.*, 795 F.2d 925, 927 (11th Cir. 1986) (“Since the manufacturer’s goal in warning is to provide the physician with knowledge, when that physician has such knowledge, either from the manufacturer or independently, there can be no causal link between a failure to advise a physician of what he already well knows...”); *Kirsch v. Picker*, 753 F.2d 670, 671 (8th Cir. 1985) (“[Manufacturer’s] failure to warn Dr. Murphy could not have been the proximate cause of Kirsch’s injury if Murphy was already aware of the cancer risks associated with radiation therapy.”); *Strong v. E.I. DuPont de Nemours Co.*, 667 F.2d 682, 687 (8th Cir. 1981) (“In the realm of strict liability there is a... principle providing that a manufacturer has no duty to warn when the dangers of a product are within the professional knowledge of the user”); *Jones v. Minn. Mining & Mfg. Co.*, 669 F.2d 744, 748 (N.M. Cpt. App. 1983) (No duty to warn of dangers actually known to the user of the product; in the case of prescription drugs and devices, this rule applies to a manufacturer’s duty to warn a prescribing physician.); *Lindsay v. Ortho Pharmaceutical Corp.*, 637 F.2d 87, 92 (2d Cir.1980) (“No one needs notice of that which he already knows.”)

\(^7\) Physician co-defendants are also better served by acknowledging awareness of the benefits and risks of a medication and standing behind their prescribing decision and counseling strategy as opposed to claiming they were unaware of a well-known risk.
regulatory action or media attention, yet the risk had not yet been inserted in the labeling or did not appear as a Warning/Precaution at the time of use.8

Similarly, the no duty to warn defense is also appropriate in cases where the risk is ever-present (for example, infection followed by death as a result of a surgical procedure) as was the case in Plenger. In Plenger, Plaintiffs filed an action for wrongful death, alleging that the decedent died as a result of an infection caused by her use of an Intrauterine Device ("IUD") that was manufactured by Defendant. The trial court ruled that the IUD was a prescription device and that the warnings Defendant had given to the decedent’s physician were adequate to preclude liability. The trial court granted summary judgment and entered judgment in Defendant’s favor. The Court of Appeal affirmed, holding that although Defendant did not specifically advise of the risk of death that can result from a pelvic infection, the court held that there was no triable issue of fact on the adequacy of Defendant’s warning, since a manufacturer need not warn of a risk which is readily known and apparent to the consumer—in the case of prescription drugs, the prescriber. The Court explained:

We are aware of no authority which requires a manufacturer to warn of a risk which is readily known and apparent to the consumer, in this case the physician. Further, if the risk of death from untreated infection is universally known in the medical profession, the failure to warn the physician of that risk cannot be the legal cause of the decedent’s death.

Plenger, 11 Cal. App. 4th at 362 (citing Kirsch v. Picker Int’l, Inc., 753 F.2d 670, 671-672 (8th Cir. 1985)).

Manufacturers should not shy away from this defense in off-label cases. In Huntman v. Danek Medical, Inc., No. 97-2155-IEG RBB, 1998 WL 663362 (S.D. Cal. July 24, 1998), the Defendant obtained summary judgment in a case involving an alleged off-label use of bone screws. Plaintiff alleged the manufacturer improperly marketed and promoted its bone screws for pedicle fixation even though FDA had only approved the use of these screws for anterior fixation. Plaintiff alleged that “but for” the manufacturer’s illegal marketing, she would not have had the screws implanted. In support of its motion for summary judgment, the Defendant manufacturer provided the following evidence regarding the prior knowledge of Plaintiff’s surgeon, Dr. Thompson:

[P]rior to plaintiff’s surgery, Dr. Thompson had been a physician for over 30 years and had performed between 50–70 spinal fusions with pedicle screws. Dr. Thompson testified that he was aware of the risks involved

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8 According to FDA “[t]he WARNINGS AND PRECAUTIONS section is intended to identify and describe a discrete set of adverse reactions and other potential safety hazards that are serious or are otherwise clinically significant because they have implications for prescribing decisions or patient management. To include an adverse event in the section, there should be reasonable evidence of causal association between the drug and the adverse event, but a causal relationship need not have been definitively established.” See FDA GUIDANCE FOR INDUSTRY, Warnings and Precautions, Contraindication, and Boxed Warnings Sections of Labeling for Human Prescription Drugs and Biological Products – Content and Format (2011), available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075096.pdf (emphasis in original).
in these procedures based on his independent research which involved
(a) speaking with other physicians who were performing the procedure;
(b) reading physician-authored articles concerning the procedure; and,
(c) attending symposiums and conferences at which the pedicle screw
techniques were presented. Dr. Thompson further testified that (a) he was
generally aware of the lack of FDA approval for pedicle fixation from other
doctors and (b) defendant’s representative specifically informed him there
was no FDA approval for pedicle fixation.

Id. at *5 (citations omitted).

The District Court found that the uncontroverted testimony of Dr. Thompson
demonstrated he had independent knowledge of the risks of pedicle fixation. Thus,
the Court granted Defendant’s motion for summary judgment holding that the
adequacy of the warnings is immaterial where the doctor knows of the specific risks.

Conclusion

In summary, armed with medical literature and case reports in a failure to warn case
involving a prescription medication or medical device with a long history of use, well-
defined risks, or recent publicity and/or regulatory action, Defense counsel may well
be able to elicit deposition testimony from the prescriber which not only concedes
that the relevant risk is well-known in the medical community but also that he or
she was specifically aware of the risk. In those situations, the chance of obtaining
summary judgment based on lack of duty or proximate cause is increased. Likewise,
if the prescriber is not available for deposition or if a summary judgment motion
can be filed without prescriber testimony, a manufacturer may use expert testimony,
medical literature, and medical texts to demonstrate to a court’s satisfaction that a
risk was well-known in the medical community, thus negating any legal obligation for
the manufacturer to warn of the risk at issue.

About the Authors

William A. Hanssen | www.drinkerbiddle.com/whanssen
Bill is a partner in the Products Liability and Mass Tort
Practice Group and the Regional Partner In Charge of
the Los Angeles office. Bill concentrates his practice
on defending the pharmaceutical and medical device
industry.

Siobhan A. Cullen | www.drinkerbiddle.com/scullen
Siobahn is counsel in the Products Liability and Mass
Tort. Her practice is concentrated in complex litigation
and she has experience in the areas of pharmaceutical
and medical device liability and unfair competition/
consumer fraud.
Pennsylvania Adopts Significant Tort Reform Eliminating Joint and Several Liability: Fair Share Act Signed into Law

By Meredith N. Reinhardt

In our June 2011 Newsletter, we discussed the status of important pending legislation in Pennsylvania (the Fair Share Act) designed to eradicate the common law doctrine of joint and several liability. As of the date of that article, the Pennsylvania House of Representatives approved the Fair Share Act (H.B. 1), and the Act was before the Pennsylvania Senate for consideration. After extensive debate, the Senate ultimately approved a bill substantively identical to H.B. 1.

On June 28, 2011, Governor Tom Corbett signed the Fair Share Act into law, effective immediately. The Fair Share Act, (42 Pa. Cons. Stat. § 7102), provides for proportionate share liability among joint tortfeasors and eliminates the common law doctrine of joint and several liability in all but a few limited situations. Under the new law, each defendant is liable for “that proportion of the total dollar amount awarded as damages in the ratio of the amount of that defendant’s liability to the amount of liability attributed to all defendants and other persons to whom liability is apportioned under subsection (a.2).” 42 Pa. Cons. Stat. § 7102(a.1)(1). Joint and several liability still applies where there is an intentional misrepresentation, an intentional tort, a claim under section 702 of the Hazardous Sites Cleanup Act, a violation of section 497 of the Liquor Code or where a defendant is liable for 60% or greater of the total liability apportioned to all parties. 42 Pa. Cons. Stat. § 7102(a.1)(3).

The Fair Share Act is a significant victory for product manufacturers, insurance companies and other businesses who are often hauled into litigation because of their “deep pockets” even if they might be only minimally liable. Reactions from these groups has been overwhelmingly positive. Pennsylvania Chamber of Business and Industry Vice President Gene Barr commented that the Fair Share Act “restores fairness and predictability to the state’s legal system, encouraging business investment and job growth.” The Chairman of the Insurance Agents & Brokers of Pennsylvania further praised the new law: “The act is a win for consumers, businesses and the insurance industry, which all carry the financial burdens of such a litigious environment.”

Conclusion

As a practical matter, passage of the Fair Share Act will likely decrease the frequency "deep pocket" defendants with minimal liability are brought into litigation. Even if such defendants are joined in litigation, the Fair Share Act will reduce the possibility of inequitable judgments. As time passes, product manufacturers, insurance companies and other business who are often co-defendants in various litigations will continue to see the benefits of this significant tort reform.

About the Author

Meredith N. Reinhardt | www.drinkerbiddle.com/mreinhardt

Meredith is an associate in the firm’s Products Liability and Mass Tort Practice Group.
Update on California Civil Jury Instructions Concerning Products Liability Litigation

By Alan J. Lazarus, William A. Hanssen, and Siobhan A. Cullen

As reported in our June 2011 Newsletter, the Judicial Council of California in 2011 proposed revisions to California Civil Jury Instructions (known as CACI) related to the element of the foreseeability and effect of product misuse. The proposed instructions contravened well-settled public policy and precedential limitations on manufacturer liability, including, importantly, an essential element of a plaintiff’s products liability case—proof of reasonably foreseeable use. In our prior report, we explained that the proposed revisions, if adopted, would significantly impact litigation of product liability claims in California.

The Advisory Committee on Civil Jury Instructions (Advisory Committee) recommended approval of the proposed revisions in a report dated May 17, 2011.1 Despite objections from at least a dozen commentators, including Drinker Biddle & Reath LLP, the proposed revisions were approved by the Judicial Council on June 24, 2011.2

The revisions include changes to four strict products liability instructions by removing or minimizing the long-standing California requirement that the plaintiff prove he or she was injured while using or misusing the product in a reasonably foreseeable way.3 For example, see revised CACI No. 1205 which lays out the essential elements of a strict liability-failure to warn claim.5

1205. Strict Liability—Failure to Warn—Essential Factual Elements

[Name of plaintiff] claims that the [product] lacked sufficient [instructions] [or] [warning of potential [risks/side effects/allergic reactions]]. To establish this claim, [name of plaintiff] must prove all of the following:

1. That [name of defendants] [manufactured/distributed/sold] the [product];
2. That the [product] had potential [risks/side effects/allergic reactions] that were [known] [or] [knowable by the use of scientific knowledge available] at the time of [manufacture/distribution/sale];

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1 Rule 2.1050 of the California Rules of Court requires the Advisory Committee to update, amend, and add topics to CACI on a regular basis and submit its recommendations to the Judicial Council for approval. In its May 17 report, the Judicial Council stated “the proposed new and revised [products liability] instructions are necessary to ensure that the [jury] instructions remain clear, accurate, and complete; therefore, the Advisory Committee did not consider any alternative actions.”

2 The minutes from the June 24, 2011 Judicial Council meeting suggest that the proposed revisions were not the subject of discussion and were simply approved based on the Committee’s recommendation. See http://www.courts.ca.gov/jcmeetings.htm


4 See generally May 17, 2001 Civil Jury Instruction Advisory Committee Report to the California Judicial Council (herein Report), pgs. 18-48.

5 Revisions appear in redline font.
3. That the potential [risks/side effects/allergic reactions] presented a substantial danger to users of persons using or misusing the [product] in an intended or reasonably foreseeable way;

4. That ordinary consumers would not have recognized the potential [risks/side effects/allergic reactions];

5. That [name of defendant] failed to adequately warn [or instruct] of the potential [risks/side effects/allergic reactions];

6. That [name of plaintiff] was harmed while using the [product] in a reasonably foreseeable way; and

7. That the lack of sufficient [instructions] [or] [warnings] was a substantial factor in causing [name of plaintiff]’s harm.

In the documents posted on the Judicial Council website seeking comment on the proposed revisions, the Advisory Committee repeatedly cited Perez v. V.A.S., 188 Cal. App.4th 658 (2010), and this recent court of appeal case appeared to be the Advisory Committee’s primary motivation for proposing changes. Indeed, those commenting on the proposed revisions focused their comments in large measure on Perez.

In a May 17, 2011, Report to the Judicial Council, the Advisory Committee’s stated rationale for proposing the changes was not limited to Perez but included a purported several-year-long struggle by the Committee with inconsistent cases that required both parties to prove or disprove misuse and a 2009 revision to CACI No. 1245 Affirmative Defense-Product Misuse or Modification, which required manufacturers in products cases to prove that there was misuse that was not reasonably foreseeable. In the Report the Advisory Committee said:

The committee recognizes that manufacturers are not insurers of their products; they are liable in tort only if a defect in the manufacture or design of its product causes injury while the product is being used or misused in a reasonably foreseeable way. (Soule v. General Motors Corp. (1994) 8 Cal.4th 548, 560, 568 fn. 5; see also Wright v. Stang Mfg. Co. (1997) 54 Cal.App.4th 1218, 1235 [a manufacturer must foresee some degree of misuse and abuse of its product, either by the user or by third parties, and must take reasonable precautions to minimize the harm that may result from misuse and abuse]). But the question of where the burden of proof falls on product misuse is one that the committee has been considering for several years. The committee now proposes modifying the instructions to place the burden on the defendant to prove that the plaintiff’s injuries occurred while the product was being misused in an unforeseeable way.8

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6 CACI No. 1245. Affirmative Defense—Product Misuse or Modification (2009 version)

[Name of defendant] claims that [he/she/it] is not responsible for [name of plaintiff]’s claimed harm because the [product] was [misused/ or modified] after it left [name of defendant]’s possession. To succeed on this defense, [name of defendant] must prove that:

1. The [product] was [misused/ or modified] after it left [name of defendant]’s possession;
2. That the [misuse/ or modification] was not reasonably foreseeable to [name of defendant]; and
3. That the [misuse/ or modification] was the sole cause of [name of plaintiff]’s harm.

7 See Report, pg. 6.
8 Id. at pg. 5.
The alleged inconsistency in the cases and the revised instructions are not well described in the Advisory Committee’s May 17 Report. For example, the Report cites no cases which suggested a need to change the long-standing requirement that plaintiff’s *prima facie* burden include proof of reasonably foreseeable use. Nor was there any discussion of any cases in which courts and parties struggled with jury instructions and the case law on foreseeable use and misuse. Indeed, the Report describes only the Advisory Committee’s speculative concerns about the burdens of proof in products cases. In summary, it’s not clear why the Committee proposed that the burden of proof suddenly be placed on the defendant to prove unforeseeable misuse. Moreover, the Committee’s recommendation is especially difficult to reconcile given long-standing, consistent California jurisprudence holding that plaintiff must plead and prove reasonably foreseeable use (or misuse) to proceed.

As noted above, there were numerous objections to the proposed instructions and the changes to plaintiff’s burden regarding foreseeable use or misuse. One that is particularly noteworthy is the California Judge’s Association comment on the proposed revisions to CACI 1201:

> The legal basis for the change in these instructions appears to be based on an apparently incorrect reading of *Perez v. VAS* (2010) 188 Cal.App.4th 658 and *Saller v. Crown* (2010) 187 Cal.App.4th 1220. Neither case supports removal of the language: “while using the [product] in a reasonably foreseeable way.” (*Perez* quotes *Baker* as requiring evidence “that the plaintiff was injured while using the product in an intended or reasonably foreseeable manner…” (*Perez*, supra, 188 Cal.App.4th at p. 678.) It should also be noted that *Saller* directed that CACI 1203 be given without comment that the instruction should be modified in any way. (*Saller*, supra, 187 Cal.App.4th at p. 1237.)

It appears that the confusion results from the idea that misuse of a product is an affirmative defense, which it is, and therefore the burden shifts to the defense once the plaintiff establishes a prima facie case. Such is the status of the law…
In response to this comment, the Advisory Committee said “...[T]he plaintiff must establish a prima facie case to the court to avoid summary judgment or nonsuit. Once the case gets to the jury, misuse is an affirmative defense.”

The Advisory Committee’s response to the comments of the Judge’s Association is perplexing. Historically, plaintiffs have been required to demonstrate that the product was used properly or foreseeably as part of their burden, and only then was defendant required to prove the unforeseeable misuse defense. With the revised instructions, plaintiffs have to meet a very low standard to escape summary judgment and it appears defendants do not get to argue unforeseeable use or misuse until trial (and, as explained below, the revised instructions make use of those defenses questionable.) Defendants will now be put to the trouble and expense of trying a case that previously may have been appropriate for summary judgment. Worse yet, in a pre-trial settlement context, the view will now be that defendants are potentially liable for a host of unimaginable injuries arising out of unforeseeable product misuse modification, because the new instructions, in particular CACI No. 1205, suggest plaintiff gets a trial if he or she presents evidence of nothing more than use of the defendant’s product, a defect and a harm.

**Conclusion**

In summary, these revisions may well have a significant impact on products liability litigation in California from early law and motion practice through trial. As demonstrated in the table below relating to the failure to warn instruction concerning plaintiff’s prima facie case, the burden of proof for plaintiffs and defendants is markedly different with the new instructions.

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<tr>
<td>Defendant’s Product;</td>
<td>Defendant’s Product;</td>
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<tr>
<td>Potential dangers with use;</td>
<td>Potential dangers with use or misuse in an intended or reasonably foreseeable way;</td>
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<tr>
<td>Ordinary consumer would not recognize potential danger;</td>
<td>Ordinary consumer would not recognize potential danger;</td>
</tr>
<tr>
<td>Defendant failed to adequately warn of potential danger; and</td>
<td>Defendant failed to adequately warn of potential danger; and</td>
</tr>
<tr>
<td>Plaintiff injured while using the product in a reasonable foreseeable way.</td>
<td>Plaintiff injured while using the product.</td>
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14 Id.
The one piece of good news is that Perez and the revised instructions do not overrule the long line of California cases that require a plaintiff to prove proper use or foreseeable misuse as part of his or her case in chief, and manufacturers should rely on these cases at every turn, including when submitting proposed instructions.

About the Authors

**Alan J. Lazarus** | [www.drinkerbiddle.com/alazarus](http://www.drinkerbiddle.com/alazarus)

Alan is a partner resident in the San Francisco office and Vice Chair of the firm's Products Liability and Mass Tort Practice Group. He is a trial and appellate lawyer with experience defending a wide variety of product liability and toxic tort matters in trial and appellate courts.

**William A. Hanssen** | [www.drinkerbiddle.com/whanssen](http://www.drinkerbiddle.com/whanssen)

Bill is a partner in the Products Liability and Mass Tort Practice Group and the Regional Partner In Charge of the Los Angeles office. Bill concentrates his practice on defending the pharmaceutical and medical device industry.

**Siobhan A. Cullen** | [www.drinkerbiddle.com/scullen](http://www.drinkerbiddle.com/scullen)

Siobhan is counsel in the Products Liability and Mass Tort. Her practice is concentrated in complex litigation and she has experience in the areas of pharmaceutical and medical device liability and unfair competition/consumer fraud.

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15 See *e.g.*, *Anderson v. Owens-Corning Fiberglas Corp.*, 53 Cal.3d 987, 994, (1991) (“Strict liability, however, was never intended to make the manufacturer or distributor of a product its insurer. From its inception, strict liability has never been, and is not now, absolute liability. [U]nder strict liability the manufacturer does not thereby become the insurer of the safety of the product’s use”) (alterations and emphasis in original); *Romito v. Red Plastic Co.*, 38 Cal.App.4th 59, 63 (1995) (“We conclude as a matter of policy that despite the means to build a safer product, a manufacturer owes no duty to prevent injuries resulting from unforeseeable and accidental product misuse”); *Mendocino v. Club Car*, 81 Cal.App.4th 287 (2000) (Jury finding that product was not being used in reasonably foreseeable way was inconsistent with liability verdict); *Johnson v. American Standard, Inc.*, 43 Cal.4th 56, 70 (2008) (“Although manufacturers are responsible for products that contain dangers of which the public is unaware, they are not insurers, even under strict liability, for the mistakes or carelessness of consumers who should know of the dangers involved”).
Products Liability Update
May 2012

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A Delaware limited liability partnership
Jonathan I. Epstein and Andrew B. Joseph, Partners in Charge of the Princeton and Florham Park, New Jersey offices, respectively.
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Products Liability Update Editors

Krista L. Cosner
(415) 591-7594
Krista.Cosner@dbr.com
Benjamin J. Holl
(415) 591-7638
Benjamin.Holl@dbr.com

Practice Group Leaders

Michelle A. Childers
Chair
(415) 591-7527
Michelle.Childers@dbr.com
Daniel B. Carroll
Vice Chair
(973) 549-7296
Daniel.Carroll@dbr.com
Kenneth A. Murphy
Vice Chair
(215) 988-2837
Kenneth.Murphy@dbr.com
David B. Sudzus
Vice Chair
(312) 569-1498
David.Sudzus@dbr.com

Practice Group Partners and Counsel

Thomas F. Campion
(973) 549-7300
Thomas.Campion@dbr.com
Kenneth P. Conour
(415) 591-7530
Kenneth.Conour@dbr.com
Siobhan Cullen
(310) 203-4071
Siobhan.Cullen@dbr.com
John Dames
(312) 569-1499
John.Dames@dbr.com
William V. Essig
(312) 569-1497
William.Essig@dbr.com
Lauren D. Godfrey
(973) 549-7095
Lauren.Godfrey@dbr.com
William A. Hansen
(213) 253-2331
William.Hansen@dbr.com
Heidi E. Hilgendorff
(973) 549-7363
Heidi.Hilgendorff@dbr.com
Rodney M. Hudson
(415) 591-7545
Rodney.Hudson@dbr.com
Jennifer La Mont
(973) 549-7368
Jennifer.LaMont@dbr.com
Alan J. Lazarus
(415) 591-7551
Alan.Lazarus@dbr.com
Chris L’Orange
(415) 591-7517
Chris.LOrange@dbr.com
Jeffrey A. Peck
(973) 549-7360
Jeffrey.Peck@dbr.com
John J. Powers
(415) 591-7565
John.Powers@dbr.com
Thomas W. Pulliam Jr.
(415) 591-7570
Thomas.Pulliam@dbr.com
Lori J. Rapuano
(215) 988-2653
Lori.Rapuano@dbr.com
Tracie Militano Rosen
(415) 591-7558
Tracie.Rosen@dbr.com
Jodi Sydell Rosenzweig
(973) 549-7364
Jodi.Rosenzweig@dbr.com
Arthur M. Scheller III
(312) 569-1389
Arthur.Scheller@dbr.com
Steven M. Selna
(415) 591-7579
Steven.Selna@dbr.com
Susan M. Sharko
(973) 549-7350
Susan.Sharko@dbr.com
Todd B. Vinson
(312) 569-1496
Todd.Vinson@dbr.com
Michael C. Zogby
(973) 549-7209
Michael.Zogby@dbr.com
Vernon I. Zvoleff
(415) 591-7590
Vernon.Zvoleff@dbr.com
Sandra L. Weiherer
(310) 203-4073
Sandra.Weiherer@dbr.com

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Jonathan I. Epstein and Andrew B. Joseph, Partners in Charge of the Princeton and Florham Park, New Jersey offices, respectively.
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DrinkerBiddle
Products Liability & Mass Tort Practice Group
CALIFORNIA | DELAWARE | ILLINOIS | NEW JERSEY
NEW YORK | PENNSYLVANIA | WASHINGTON DC | WISCONSIN

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