

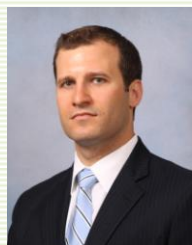
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The Ever-Shifting Landscape in Prescription Drug Design Defect Litigation

Aside from preemption, it is quite possible that no legal doctrine has caused more angst to both sides of the pharmaceutical product liability bar, and in turn, the courts, than the interplay of negligence v. strict liability and the viability of a design defect claim against manufacturers of FDA-approved prescription drugs. At the heart of this debate is "comment k" of the Restatement (Second) of Torts, a provision written almost 50 years ago by the American Law Institute (ALI). See Restatement (Second) of Torts § 402A, comment k (1965).

In the past eight months, two much-anticipated decisions, one from the US Supreme Court and one from the Supreme Court of Pennsylvania, stand at opposite ends of the spectrum on the viability of design defect claims against manufacturers of prescription drugs. In June 2013, the US Supreme Court decided *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013), holding that state law design defect claims against generic manufacturers of prescription drugs are preempted under federal law. This past month, the Pennsylvania Supreme Court – the highest court in Pennsylvania – decided *Lance v. Wyeth*, 2014 Pa. LEXIS 205 (Pa. Jan. 21, 2014), holding that design defect claims grounded in negligence can proceed against manufacturers of prescription drugs, side-stepping 20 year old precedent barring strict liability design defect claims under Pennsylvania law.

This article reviews the impact of these decisions, and what may lie ahead.

I. Background

Looking beyond the prescription drug context, under hornbook law, there are three types of product liability cases: (1) manufacturing defects; (2) design defects; and (3) warnings defects (more commonly called "failure to warn" claims). These defect cases have been pursued under theories of negligence and strict liability.

The genesis for strict liability claims is Restatement (Second) of Torts § 402A, which imposes strict liability on a seller who markets a product "in a defective condition unreasonably dangerous" to the consumer.

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However, comment k carves out an exception to the strict liability rule for products characterized as “unavoidably unsafe.” Comment k reads in part:

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs.... Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous.... The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement (Second) of Torts §402A, comment k (1965).

In the context of prescription drugs (and medical devices), some courts have relied on the interplay of comment k and the learned intermediary doctrine to properly find that the only available remedies to plaintiffs are grounded in manufacturing defects or failure to warn claims. These courts provide all prescription drugs categorical immunity from strict liability design defect claims. *See, e.g., Young for Young v. Key Pharms., Inc.*, 922 P.2d 59, 64 (Wash. 1996); *Hahn v. Richter*, 673 A.2d 888, 889-90 (Pa. 1996); *Grundberg v. Upjohn Co.*, 813 P.2d 89, 94-95 (Utah 1991); *Brown v. Superior Court*, 751 P.2d 470, 482-83 (Cal. 1988); *Stone v. Smith, Kline & French Labs.*, 447 So.2d 1301, 1303-04 (Ala. 1984); *McKee v. Moore*, 648 P.2d 21, 23 (Okla. 1982); *Lindsay v. Ortho Pharm. Corp.*, 637 F.2d 87, 90-91 (2d Cir. 1980) (applying New York law); *see also Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068, 1077 n.41 (2011) (“Though it is not pertinent to our analysis, we point out that a large number of courts . . . say that manufacturers did not face strict liability for side effects of properly manufactured prescription drugs that were accompanied by adequate warnings.”) (collecting cases).

“In the context of prescription drugs (and medical devices), some courts have relied on the interplay of comment k and the learned intermediary doctrine to properly find that the only available remedies to plaintiffs are grounded in manufacturing defects or failure to warn claims.”

Other courts, however, permit a plaintiff to bring a design defect claim against a prescription drug (or medical device) manufacturer, and they shift the burden to the defendant to raise comment k as an affirmative defense, meaning that the defendant must prove, on a case-specific basis, that its product is unavoidably unsafe and that the drug was labeled adequately. *See Moss v. Wyeth*, 872 F. Supp. 2d 162,

169-71 (D. Conn. 2012); *see also Hill v. Searle Labs.*, 884 F.2d 1064, 1068 (8th Cir. 1989) (applying Arkansas law); *Weiss v. Fujisawa Pharm. Co.*, 2006 WL 3533072 at *3 (E.D. Ky. Dec. 7, 2006); *Freeman v. Hoffman–La Roche, Inc.*, 618 N.W.2d 827, 836 (Neb. 2000); *Bryant v. Hoffmann–La Roche, Inc.*, 585 S.E.2d 723, 728 (Ga. 2003); *Adams v. G.D. Searle & Co.*, 576 So.2d 728, 732-33 (Fla. App. 1991); *Castrignano v. E.R. Squibb & Sons, Inc.*, 546 A.2d 775, 781 (R.I. 1988); *Toner v. Lederle Labs.*, 732 P.2d 297 at 308-09 (Idaho 1987); *Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652, 657 (1st Cir.1981) (applying New Hampshire law).

As one court adopting comment k as an affirmative defense noted, “defendant’s burden to prove the adequacy of the warning in a comment k defense is the mirror image of the plaintiff’s burden to prove the inadequacy of the warning in a warning defect claim.” *Moss*, 872 F. Supp. 2d at 172. Reliance on such burden shifting, coupled with the common law approach in many states that “the standard for warning defects effectively merges with the standard for negligent failure to warn,” *id.* at 173-174, demonstrates the logic and reasoning behind providing prescription drugs with immunity from design defect claims.

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II. *Mutual Pharmaceutical v. Bartlett* and Its Potential Impact

To fully appreciate *Bartlett*, it is important to understand that in 2011 the US Supreme Court held that state-law claims against generic manufacturers based on the failure to provide different warnings than the brand-name drugs are preempted under federal law. *See PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). Without wading knee-deep into preemption jurisprudence, the lynchpin for the *Mensing* decision is that federal law prohibits generic pharmaceutical manufacturers from independently changing the labeling of their drugs — the labeling must be the same as the labeling for the brand-name drug to which the generic is equivalent. *Id.* at 2574-78; *see also 21 C.F.R. §§ 314.94(a)(8)(iii), 314.150(b)(10)*. Accordingly, the court held that because “it was impossible for the [generic] manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same,” plaintiffs’ failure-to-warn claims were preempted. *Id.* at 2578.

With *Mensing* precluding plaintiffs from recovering against generic manufacturers under a failure to warn theory, plaintiffs proceeded to press their claims under a design defect theory.

In *Bartlett*, the plaintiff argued that under Section 402A of the Restatement (Second) of Torts, which was the applicable state law in New Hampshire, where the case originated, defendants should be liable under a claim of design defect because they caused harm by selling a “product in a defective condition unreasonably dangerous to the user or consumer,” even though they may have “exercised all possible care in the preparation and sale of the product.” *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2473 (2013), citing Restatement (Second) of Torts § 402A (1965), at 347–348. The Supreme Court agreed that

under the applicable state law, manufacturers had a duty to “ensure that the products they design, manufacture, and sell are not ‘unreasonably dangerous’... [and] that this duty can be satisfied either by changing a drug’s design or by changing its labeling.” *Bartlett* at 2474.

The court concluded that “redesign was not possible for two reasons.” *Id.* at 2475. First, if the manufacturer were “to change the composition of its” drug “the altered chemical would be a new drug that would require its own NDA to be marketed in interstate commerce.” *Id.* citing 21 C.F.R. § 310.3(h) (giving examples of when the FDA considers a drug to be new, including cases involving “newness for drug use of any substance which composes such drug, in whole or in part”). “Second, because of [the drug’s] simple composition, the drug is chemically incapable of being redesigned.” *Id.* Having already found in *Mensing* that “federal law prevents generic drug manufacturers from changing their labels, *id.* at 2476, the court held that “New Hampshire’s warning-based design-defect cause of action is preempted with respect to FDA-approved drugs sold in interstate commerce.” *Id.* at 2477.

Notably, the court did not limit its holding explicitly to FDA-approved *generic* drugs. What remains to be seen is if courts will extend the rationale of *Bartlett* – the impossibility and incapability of redesigning a prescription drug – to preempt state design-defect claims against branded pharmaceutical companies, or recognize that applying comment k as an affirmative defense simply masquerades a failure to warn claim as a design defect claim with shifting burdens. Either approach is consistent with the cases noted above, which limit plaintiffs’ claims against manufacturers of prescription drugs to: (a) manufacturing defect claims; and (b) failure to warn claims. Interestingly, while the majority, *Bartlett* at 2476 n.2, and Justice Sotomayor, in dissent, *id.* at 2487 n.3, discussed comment k in *Bartlett*, the argument was academic, because the defendant withdrew its comment k defense “for purposes of the trial of this matter,” and without any further explanation. *Id.* at 2476 n.2. As a result, the Supreme Court has yet to settle the precise effect of comment k – whether it provides blanket immunity from design defect claims in the pharmaceutical product arena, or whether it is applicable as an affirmative defense on a case by case basis.

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III. *Lance v. Wyeth* and Its Potential Impact

Just a few months after the *Bartlett* decision, the Pennsylvania Supreme Court decided *Lance*, in which Justice Saylor, speaking for the majority, noted that “[t]he dissent posits that we presently are creating a new cause of action, *i.e.*, ‘negligent design defect’ . . . against pharmaceutical companies.” *Lance v. Wyeth*, 2014 Pa. LEXIS 205 (Pa. Jan. 21, 2014) at *80 (quoting Dissenting Opinion at *83).

The plaintiff in *Lance* alleged that her daughter ingested Redux, a diet drug manufactured by Wyeth, which caused her to develop primary pulmonary hypertension, which ultimately caused her death. Plaintiff pled in her complaint that Wyeth was negligent when it “introduce[d] onto the market a drug that was unreasonably dangerous,” that it “failed to exercise ordinary care in the design, research,

development, manufacture, sale, testing,... and/or distribution of” Redux, and that Redux was so “defective in design that it should never have been on the market.” *Lance* at *5.

The trial court granted Wyeth’s motion for summary judgment, which was premised on the Pennsylvania Supreme Court’s “refusal to extend strict liability to prescription drug manufacturers” in *Hahn*, 543 Pa. at 560, “consistent with the treatment for ‘unavoidably unsafe products’ reflected in comment k.” *Lance* at *5. Wyeth argued that plaintiff “had failed to assert a cognizable cause of action because “the only allegations which would support liability against a pharmaceutical company based upon adverse effects from the use of a prescription drug” were those based on claims of manufacturing defects and/or inadequate warnings. *Id.* at *6. On appeal, Wyeth argued, *inter alia*, that any design defect theory, sounding in negligence or strict liability, was a “non-starter... as applied to pharmaceutical companies” because of the “considerations set forth in comment k” that a drug could not have a safer alternative design. *Id.* at *21.

“The court concluded that its ‘adoption of comment k in the strict-liability context’ did not preclude a negligence cause of action concerning the design of a prescription drug.”

Writing for the majority in a 4-2 decision, Justice Saylor repeatedly emphasized that based on the procedural posture of the case below, the court “will accept that the company did precisely what [plaintiff] alleges, namely, that it manufactured and tendered Redux into the marketplace, although it had actual or constructive knowledge that the risks of adverse health effects exceeded the drug’s benefits to any class of patients” and that “factually, Redux was so dangerous that no reasonable physician, appropriately apprised, would have prescribed it.” *Id.* at *44-45. Accepting these allegations, and numerous other inferences, as true, the court found that “[u]nder Pennsylvania law, pharmaceutical companies violate their duty of care if they introduce a drug into the marketplace, or continue a previous tender, with actual or constructive knowledge that the drug is too harmful to be used by anyone.” *Id.* at *82. Rejecting Wyeth’s arguments, the court held that there was “no supported presentation here which would persuade us to immunize companies from the responsibility to respond in damages for such a lack of due care resulting in personal injury or death.” *Id.*

The court concluded that its “adoption of comment k in the strict-liability context” did not preclude a negligence cause of action concerning the design of a prescription drug. *Lance* at *48. It reasoned that because comment k “is premised on the assumption that all products within its scope carry some net benefit (relative to risks) for some class of consumers,” it does not “encompass the scenario . . . [of plaintiff’s] central claim – that a pharmaceutical company’s lack of due care resulted in the dissemination of a product which is not apparently useful and desirable, but rather, is effectively useless and dangerous.” *Id.* at *49.

The extent to which the holding in *Lance* can be extended beyond the narrow, and unique, facts of the case are very much up for debate. As the court itself noted:

We recognize that the application of [plaintiff's] theory of liability would present more difficult questions in a circumstance in which a prescription drug maintained its FDA approval, it remained on the market, and US doctors continued to prescribe it. The assertion that no reasonable physician would prescribe the drug (knowing what the manufacturer knew or should have known) is capable of gaining greater traction when, as here, the inquiry is more in the nature of a post-mortem.

Lance at *68, n.33.

IV. Restatement (Third) of Torts

Lance brings back into focus another potential driver in the ongoing tug-of-war over design defect claims: The Restatement (Third) of Torts: Products Liability (1998). While the court in *Lance* was clear that “this appeal does not present the opportunity for [it] to consider adoption of an approach or approaches favored by the American Law Institute [ALI] in the Restatement Third,” the court did “credit [plaintiff's] position, however, that Pennsylvania law at the very least overlaps or intersects with the Restatement Third principle that a manufacturer marketing a prescription drug which it knows or should know is too dangerous *for anyone* to use violates the standard of due care and may be held liable under fault-based tort law.” *Lance* at *75-76 (citing *Restatement (Third) of Torts: Prods. Liab.* § 6(c) (1998)(emphasis added).

The ALI introduced the Restatement Third in 1998, recognizing that “[n]o one can seriously argue that the law of products liability in any jurisdiction has evolved in a straight line from § 402A of the Restatement Second.” See Foreword to Restatement (Third) of Torts: Prods. Liab. (1998). In order to “put[] this body of law much straighter,” *id.*, the ALI introduced Section 6 of the Restatement (Third), entitled “Liability of Commercial Seller or Distributor for Harm Caused by Defective Prescription Drugs and Medical Devices,” which applies the principles of Sections 1 and 2 to the prescription drug and medical device context. The relevant part of Section 6 provides:

(a) A manufacturer of a prescription drug or medical device who sells or otherwise distributes a defective drug or medical device is subject to liability for harm to persons caused by the defect.

(b) For purposes of liability under Subsection (a), a prescription drug or medical device is defective if at the time of sale or other distribution the drug or medical device: (1) contains a manufacturing defect as defined in § 2(a); or (2) is not reasonably safe due to defective design as defined in Subsection (c); or (3) is not reasonably safe due to inadequate instructions or warnings as defined in Subsection (d).

(c) A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, *would not prescribe the drug or medical device for any class of patients.*

Restatement (Third) of Torts: Prods. Liab. § 6 (1998)(emphasis added)(omitting subsections (d) and (e).

The ALI was clear that Section 6(c) of the Third Restatement only applies to the rarest of design defect cases: “Thus, a prescription drug or medical device that has usefulness to **any** class of patients is not defective in design even if it is harmful to other patients.” *Id.*, comment b. (emphasis added).

Currently, few jurisdictions follow Restatement (Third) of Torts § 6(c) (1998). Compare *Madsen v. Am. Home Prods. Corp.*, 477 F. Supp. 2d 1025, 1037 (E.D. Mo. 2007); *D'Agnese v. Novartis Pharms. Corp.*, 2013 U.S. Dist. LEXIS 92757 *21 n.7 (D. Ariz. 2013) with *Dunn v. Zimmer, Inc.*, 2005 U.S. Dist. LEXIS 5347 *21 n.2 (Conn. 2005); *Johnson v. Zimmer, Inc.*, 2004 U.S. Dist. LEXIS 6007 *25 n.6 (Minn. 2004); *Jones v. Sofamor, S.N.C.*, 1999 U.S. Dist. LEXIS 6421 *16 n.6 (N.D. Ga. 1999); *Mele v. Howmedica, Inc.*, 808 N.E.2d 1026, 1039 (Ill. App. Ct. 1st Dist. 2004); *Bryant v. Hoffmann-La Roche, Inc.*, 585 S.E.2d 723, 727-28 (Ga. Ct. App. 2003).

In conclusion, if the path through the design defect confusion is broader acceptance of the *Restatement (Third) of Torts: Prods. Liab. § 6(c) (1998)*, then courts must adhere to the clear direction, and common sense, of comment b.