The Future of Failure-to-Warn Claims

Evolving Theories of Liability Against Brand and Generic Drug Manufacturers

By Michael Bruyere and Tammara Tukloff

Until Congress addresses the concerns raised by the majority in *Mensing* and the dissent in *Bartlett* regarding remedies, creative litigation variations of failure-to-warn claims will continue to develop and judicial reasoning to deal with these claims will remain unsettled.

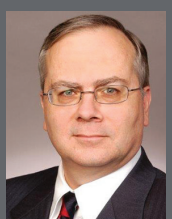
In 2011, the U.S. Supreme Court effectively barred failure-to-warn state law claims against generic drug manufacturers. *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). The court held that generic manufacturers have a duty of sameness. *Id.* In other words, the warnings for a generic drug *must* be identical to the warnings for the brand-name drug. The court held that it was impossible for a generic drug to vary the warnings from the brand and to comply with federal law at the same time. An individual who ingested a generic drug and was allegedly injured, therefore, could no longer pursue a state law-based failure-to-warn claim against the manufacturer of that product.

In the wake of *Mensing*, claimants mostly have failed to craft viable theories against generic manufacturers, including that a manufacturer should have stopped selling a drug and removed it from the market. But brand-name drug manufacturers still must defend claims that they should be liable for alleged injuries caused not by drugs that they manufactured, but by a corresponding generic drug maker's product.

Regardless of a drug's label, generic and brand-name drug manufacturers share an uncertain future as courts grapple with the breadth of *Mensing* and its impact on warning allegations.

The Litigation Landscape for Innovator Liability

Manufacturers of brand-name pharmaceuticals have different barriers to defeating failure-to-warn claims compared with manufacturers of generic pharmaceuticals. While the generic pharmaceutical industry makes up over 75 percent of the United States' prescription drug market, in the wake of *Mensing*, plaintiffs continue to assert claims of misrepresentation against manufacturers of brand-name pharmaceuticals despite never having ingested their products. The majority of jurisdictions have declined to accept such actions and have found that the Fourth Circuit holding



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in *Foster v. American Home Prods. Corp.*, 29 F.3d 165 (4th Cir. 1994), precludes imposing liability on brand-name manufacturers. In *Foster*, the plaintiffs sued Wyeth, the brand-name manufacturer of Phenergan syrup, under Maryland state law for strict liability, negligence, breach of warranty, and negligent misrepresentation following the death of their daughter, who ingested the generic version of the drug. The district court granted a summary judgment favoring Wyeth on the first three counts because Wyeth did not manufacture the ingested drug. Even though the district court allowed the action to proceed on the negligent misrepresentation claim, summary judgment was later granted on the grounds that the Fosters did not establish that the prescribing physician relied on representations made by Wyeth in his decision to prescribe the drug to their daughter. The Fourth Circuit Court of Appeals affirmed the order granting a summary judgment on the negligent misrepresentation claim, acknowledging the general principle that "there is no recognized cause of action based on negligent misrepresentation against one manufacturer for injuries" arising from the use of another manufacturer's product." However, the Fourth Circuit based the opinion on the premise that the generic manufacturer was fully capable under federal law of unilaterally providing stronger warnings, writing that

> "as an expert, a manufacturer of generic products is responsible for the accuracy of labels placed on its products. Although generic manufacturers must include the same labeling information as the equivalent name brand drug, they are also permitted to add or strengthen warning and delete misleading statements on labels, even without prior FDA approval.

Id. at 170.

The court also found that Wyeth owed no duty to the Fosters, and

> to impose a duty in the circumstances of this case would be to stretch the concept of foreseeability too far. The duty required for the tort of negligent misrepresentation arises when there is 'such a relation that one party has the right to rely for information upon the other, and the other giving the information owes a duty to give it with care.'

Id. at 171 (citations omitted).

No real deviation from the *Foster* opinion occurred until *Conte v. Wyeth, Inc.* 168 Cal. App. 4th 89 (Cal. Ct. App. 2008), was decided by a California Court of Appeals. In *Conte*, a user of the generic form of Reglan sued the brand-name manufacturer of the drug, Wyeth, Inc., under California state law for fraud, fraud by concealment, and negligent misrepresentation. A summary judgment was granted in favor of Wyeth because the plaintiff failed to establish that the physician relied on Wyeth's warnings, and also because Wyeth owed no duty to individuals who took the generic form of the product.

The California appellate court reversed, finding that

> the common law duty to use due care owed by a brand name manufacturer when providing products warnings extends not only to consumers of its own product, but also to those whose doctors foreseeably rely on the name-brand manufacturer's product information when prescribing a medication, even if the prescription is filled with the generic version of the prescribed drug.

Id. at 94–95.

The court noted however, that if the plaintiff sought recovery under a theory of strict product liability against Wyeth, then the fact that the plaintiff had ingested a generic version of the drug would be relevant. Because the plaintiff based her claims for liability against Wyeth on intentional or negligent misrepresentations concerning the safety of the drug, its long-term use, and the likelihood of serious side effects, the allegations did not implicate strict liability doctrine.

The California appellate court analyzed whether Wyeth had a duty of care and whether it was foreseeable that Wyeth knew, or should have known, that doctors would rely on its Reglan warnings in prescribing the generic form of the drug and held that Wyeth did have a duty of care in this case: "[w]e hold that Wyeth's duty of care in disseminating product information extends to those patients who are injured by generic metoclopramide as a result of prescriptions written in reliance on Wyeth's product information for Reglan." *Id*. at 315. The *Conte* opinion analyzes *Foster*'s consideration of the foreseeability issue but contends that *Foster* failed to address that the information disseminated about the brand-name version of the drug should have some significance in considering whether a duty of care arises. The *Conte* court also found the policy considerations in *Foster* unpersuasive; namely that it would be unfair to allow misrepresentation actions to proceed against brand-name manufacturers for injuries caused by generic drugs because the brand-name manufacturers bear the expense of developing, testing, and formulating labeling information for new medications, while the generic manufacturers simply ride on their coattails. The California Supreme Court declined to hear the issue, and the author has not uncovered any pending appeals before the California Supreme Court on this issue.

Not long after *Conte* was decided, a district court in Vermont came to a similar conclusion. In *Kellogg v. Wyeth,* 762 F. Supp. 2d 694 (D. Vt. 2010), the district court held that Kellogg's claims for negligent misrepresentation, fraud, and fraud by concealment were not strict liability claims in disguise but were independently actionable under Vermont common law. Wyeth questioned the scope of its duty under Vermont common law to provide warnings to users of the generic version of Reglan to no avail. The district court refused to follow the holding in *Foster*, instead finding no reason under Vermont law to limit Wyeth's duty of care because it was reasonably foreseeable that a physician would rely on a brand-name manufacturer's representations about the side effect of the drug regardless of whether a pharmacist filled a prescription with the generic form of the product. *Id*. at 708–09.

Conte and *Kellogg* were anomalies until the Alabama Supreme Court recently issued an opinion in *Wyeth v. Weeks,* 2013 Ala. Lexis 2 (Ala. Jan. 11, 2013). In *Weeks*, the Alabama Supreme Court joined the *Conte* and *Kellogg* courts in finding that the law permits imposing liability on a brand-name manufacturer for fraud and misrepresentation in warnings even when a plaintiff only ingested a generic form of a corresponding product. In reaching this decision, the court found that since the U.S. Food and Drug Administration (FDA) requires the generic drug labeling to be identical to the corresponding brand-name labeling, the brand-name manufac-

turers have a continuing duty to update their labels and strengthen their warnings because they can foresee that a user of a generic product might be injured as a result of deficiencies in the generic product labeling. The Alabama Supreme Court relied on both *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), and *Mensing*. In *Levine*, the plaintiff, Levine, sued Wyeth for failing to warn of the risks associated with administering the drug Phenergan intravenously. Wyeth argued that Levine's claims were preempted by federal drug labeling regulations because the FDA had approved the labeling that Levine contended was inadequate and that it was impossible for Wyeth to comply with both federal and state labeling requirements. The U.S. Supreme Court disagreed, finding that Wyeth had failed to establish preemption and that under federal regulations, a brand-name manufacturer has a continuing duty to revise and strengthen its warnings. The Alabama Supreme Court in *Wyeth v. Weeks* acknowledged that the holding was not consistent with *Foster*, but it reasoned that because of the duty of sameness articulated in *Mensing*, *Foster* may no longer be good law. The Alabama Supreme Court also concluded in *Wyeth v. Weeks* that a brand-name manufacturer may owe a duty to plaintiffs for fraudulent representations made to a prescribing physician based on reasonable reliance on the brand-name information by that physician. Wyeth requested reconsideration of this ruling, and on June 13, 2013, the Alabama Supreme Court scheduled the oral argument for September 2013. While a reversal seems unlikely, Wyeth still appears to have a chance to sway the Alabama Supreme Court to follow the national consensus and *Foster*.

The death knell sounded for the "stop selling" theory when the U.S. Supreme Court overturned the First Circuit ruling in *Bartlett*.

Despite these developments, the majority of courts have declined to find that *Mensing* overturned *Foster*, or that *Foster* is no longer good law. Rather, strict liability claims against brand-name manufacturers related to ingestion of another manufacturer's product remain defensible. As this article was written, the Eighth Circuit Court of Appeals issued a decision in *Bell v. Pfizer, Inc.,* No. 12-1674 (8th Cir. June 14, 2013), following the decision in *Foster* and finding that the brand-name manufacturer could not be held liable for Bell's injuries caused by ingesting a generic form of the brand-name drug under Arkansas state law. The court further held that Bell failed to establish that the brand-name defendants "owed her a duty of care necessary to trigger liability" under Arkansas state law. *Id*. at 7. Similarly, despite the holdings in *Conte*, *Kellogg,* and *Weeks*, claims against brand-name manufacturers for misrepresentation related to ingestion of another manufacturer's product are defensible in most courts. The *Bell* court held consistent with this argument, finding that the premise "stretches the concept of foreseeability too far." (quoting *Foster*).

Unfortunately, the plaintiffs' bar has chosen California as its venue of choice for pharmaceutical mass torts due to the liberal rules on pleading, misjoinder, and forum non convenens, which makes it imperative that brand-name defendants seek choice of law determinations early in litigation to ensure that courts do not apply *Conte* in cases when plaintiffs are not residents of California.

Plaintiffs Attempt to Improve Their "Unfortunate Hand"

Manufacturers of generic drugs received a strong legal shield from the U.S. Supreme Court decision in *Mensing*. In a five-to-four decision, the *Mensing* court held that plaintiffs' state law failure-to-warn claims were preempted by federal regulations because if the generic manufacturers had independently changed their labels to satisfy a state law duty to attach safer labels to their drugs, they would have violated the federal regulation that generic labels be the same as the corresponding brand-name drug labels. Thus, it was impossible for a generic manufacturer to comply with both state and federal law.

The Court did, however, voice concern regarding the far-reaching effect of the decision. Writing for the majority, Justice Thomas noted "the unfortunate hand that federal drug regulation has dealt Mensing, Demahy and others similarly situated. But it is not this Court's task to decide whether the statutory scheme established by Congress is unusual or even bizarre." *Mensing*, 131 S. Ct. at 2581 (internal quotes and citation omitted).

Not surprisingly, generic drug manufacturers rely heavily on *Mensing* to obtain dismissals of myriad failure-to-warn and other claims. Plaintiffs that have ingested generic drugs pursue other legal theories to avoid *Mensing*. And legislators, supported by public interest groups, have attempted through legislation to overcome it as well.

Legal Theories to Avoid Mensing Have Been Largely Unsuccessful

Perhaps the most frequent anti-*Mensing* theory that plaintiffs pursue is strict liability for design defects. Plaintiffs typically claim that a generic drug manufacturer *should* have designed or manufactured its product differently. Courts almost universally have dismissed such claims based on *Mensing*, noting that these claims were "all based on the allegedly defective design of the drugs, which the Generic Defendants, bound by their 'ongoing federal duty of sameness,' were powerless to change." *See*, *e.g.*, *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, 2012 WL 718618 (E.D. Ky. 2012); *Lyman v. Pfizer, Inc*., 2012 WL 368675 (D. Vt. 2012) (holding that *Mensing*'s logic precluded the plaintiffs' claims that generic defendants' drugs should have been designed or manufactured differently due to federal preemption).

Unable to succeed on strict liability, the "just don't sell it" theory gained some traction after the First Circuit decision in *Bartlett v. Mut. Pharm. Co*., 678 F.3d 30 (1st Cir. 2012), *cert. granted*, 133 S. Ct. 694 (2012), *reversed by Mut. Pharm. Co. v. Bartlett*, 2013 U.S. Lexis 4702. (U.S. June 24, 2013). The plaintiff, Karen Bartlett, was prescribed a generic form of sudilinac (Clinoril) to treat her shoulder pain. Bartlett suffered an acute case of toxic epidermal necrolysis. The effects were "horrific." As described in the decision, "[s]ixty

to sixty-five percent of the surface of [the plaintiff's] body deteriorated, was burned off, or turned into an open wound. She spent months in a medically induced coma, underwent 12 eye surgeries, and was tube-fed for a year. She is now severely disfigured, has a number of physical disabilities, and is nearly blind." Slip op. at 4.

On appeal from a $21 million verdict, the First Circuit declined to find that federal law preempted a no-alternative design-defect claim. The court reasoned that since the generic manufacturer had the option of removing its product from the market, state law could impose liability on the manufacturer.

But the "stop selling" theory has gained little traction elsewhere. For example, in an unpublished decision, the Fifth Circuit considered and rejected the theory that no warnings for the drug metoclopramide would have been sufficient and that the drug should not have been sold at all. *See Morris v. PLIVA, Inc.*, ___ F.3d ___, 2013 WL 563506, slip op. (5th Cir. Feb. 14, 2013). Not persuaded by the First Circuit reasoning in *Bartlett*, the Fifth Circuit noted that "while this type of claim has been recognized by the First Circuit, it has been rejected by this one." *Id.* (citing *Demahy v. Schwarz Pharma, Inc.*, 702 F.3d 177, 186–87 (5th Cir. 2012) (per curiam)). The court noted that metoclopramide "has legitimate therapeutic uses, *as evidenced by* the FDA's approval of Reglan in the first place." *Id.* (emphasis added). Thus, state law claims based on the theory that the manufacturer should have provided different labels or ceased manufacturing the drug were preempted. *Id. See also, In re Darvocet, Darvon & Propoxyphene Products Liability Litigation*, 2012 WL 2457825, slip op. (E.D. Ky. June 22, 2012); *Johnson v. Teva Pharmaceuticals USA, Inc.*, 2012 WL 1866839 (W.D. La. May 21, 2012); *Cooper v. Wyeth, Inc.*, 2012 WL 733846, slip op. (M.D. La. March 6, 2012); *In re Darvocet, Darvon & Propoxyphene Products Liability Litigation*, 2012 WL 718618, slip op. (E.D. Ky. March 5, 2012); *Moretti v. Mut. Pharm. Co.*, 852 F. Supp. 2d 1114 (D. Minn. 2012); *Coney v. Mylan Pharmaceuticals, Inc.*, 2012 WL 170143, slip op. (S.D. Ga. Jan. 19, 2012); *Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011)(rejecting the theory that a responsible manufacturer would have suspended selling the product); *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654, 659 (D. Md. 2011) (such a claim "would directly conflict with the federal statutory scheme in which Congress vested sole authority with the FDA to determine whether a drug may be marketed in interstate commerce").

The death knell sounded for the "stop selling" theory when the U.S. Supreme Court overturned the First Circuit ruling in *Bartlett*. *Mutual Pharmaceutical Co. v. Bartlett*, No. 12-142, slip op. (U.S. June 24, 2013):

> The Court of Appeals' solution—that [the defendant] should simply have pulled [the drug] from the market in order to comply with both state and federal law—is no solution. Rather, adopting the Court of Appeals' stop-selling rationale would render impossibility pre-emption a dead letter and work a revolution in this Court's pre-emption case law.
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> *Mutual Pharmaceutical Co. v. Bartlett*, No. 12-142, slip op. at 2 (U.S. June 24, 2013).
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> We reject this 'stop-selling' rationale as incompatible with our pre-emption jurisprudence. Our pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability. Indeed, if the option of casing to act defeated a claim of impossibility, impossibility pre-emption would be all but meaningless.
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> *Id.* at 15.
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> * * * *
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> The incoherence of the stop-selling theory becomes plain when viewed through the lens of [the Court's] previous cases. *In every instance* in which the Court has found impossibility pre-emption, the 'direct conflict' between federal- and state-law duties could easily have been avoided if the regulated actor had simply ceased acting. Adopting the First Circuit's stop-selling rationale would mean that not only [*Mensing*], but also the vast majority—if not all—of the cases in which the Court has found impossibility pre-emption, were wrongly decided. Just as the prospect that a regulated actor could avoid liability under both state and federal law by simply leaving the market did not undermine the impossibility analysis in [*Mensing*], so it is irrelevant to our analysis here.

Id. at 16 (emphasis added).

Bartlett is the nail in the coffin to the "stop selling" theory of liability and supports the lower court decisions based on *Mensing*.

Perhaps in recognition of *Mensing*'s bar of standard failure-to-warn claims against generic drug manufacturers and in anticipation of the U.S. Supreme Court ruling in *Bartlett*, plaintiffs have begun alleging a variation on that theme: failure to update. Such claims typically allege that a manufacturer became aware of adverse reactions to its products and therefore should have updated or changed the warnings. *See*, *e.g.*, *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578 (6th Cir. 2013).

In *Fulgenzi*, the plaintiff took a generic form of Reglan periodically over several years. The plaintiff developed tardive dyskinesia and sued the generic manufacturer for claims based, in part, on the failure of the generic manufacturer to update the warnings. Shortly after the plaintiff began using the drug, the FDA had approved a change to the brand-name labeling that indicated that the drug should not be taken for more than 12 weeks in duration. The generic manufacturer did not update its label.

The generic manufacturer successfully argued to the district court that *Mensing* dictated that the court must find that federal law preempted the plaintiff's claims, including the failure-to-update claim. However, the Sixth Circuit did not agree. The court noted that "generic-drug manufacturers *must* maintain labeling consistent with their branded counterpart or else the FDA may withdrawal approval." *Id.* at 581 (citing 21 C.F.R. §314.150(b)(10)) (emphasis added). Since Reglan's label had been updated, the Sixth Circuit found that the generic manufacturer could have updated its label without violating its duty of sameness; therefore, it was not only possible to meet the duty of sameness to the branded label, it was required. In other words, *Mensing*'s impossibility methodology did not apply because the Federal Food, Drug, and Cosmetic Act (FDCA) required updating.

The Sixth Circuit found that a failure-to-update claim based on state negligence was not a disguised claim for private enforcement of the FDCA. *Fulgenzi*, 711 F.3d at 588–89. Notably the FDCA does not create a private enforcement right of action. 21 U.S.C. §337(a); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001). Thus, there exists in the Sixth Circuit an exception, albeit narrow, to *Mensing*. *See also Phelps v. Wyeth Inc.*, 2013 WL 1403060, slip op. (D. Or. April 2, 2013) (denying a summary judgment request based on failure-to-update claims); *Smith v. Wyeth*, 657 F.3d 420 (6th Cir. 2011).

Another variation on failure to warn being advanced by plaintiffs is failure to communicate FDA-approved or required warnings adequately, such as the failure to send a "dear doctor" letter. Courts have concluded that no such state law claim exists, that this is just a recharacterization of failure-to-warn claims, and that the FDCA does not provide a private right of enforcement for a failure to comply with federal labeling obligations. *See, e.g.*, *Kellogg v. Wyeth*, No. 2012 WL 368658 (D. Vt. 2012) ("state tort law demands an adequate warning; it does not require a drug manufacturer to educate the healthcare profession"); *Brinkely v. Pfizer, Inc.*, 2012 WL 1564945 (W.D. Mo. 2012) ("[T]here is no state law requiring Pliva to communicate such a warning… [T]his claim appears to be nothing more than a failure to warn claim"); *Bell v. Pliva, Inc.*, 2012 WL 640742 (E.D. Ark. 2012) ("It is also clear that [the plaintiff] does not have a federal private cause of action against Pliva for its alleged failure to include the strengthened 2004 warning on the products dispensed to Bell in 2008"); *Guarino v. Wyeth*, ___ F.3d ___, No. 12-13263, slip op. (11th Cir. June 25, 2013) (rejecting both failure to communicate theory via "dear doctor" letters and alleged liability for a brand-name manufacturer when the plaintiff took only the generic drug).

Legislative Attempts to Overturn Mensing

Perhaps due in part to the characterization by Justice Thomas of *Mensing* as dealing an "unfortunate hand" in April 2012, Senator Patrick Leahy introduced S. 2295, the Patient Safety and Generic Labeling Improvement Act. Senator Leahy described *Mensing* as creating a "troubling inconsistency" in law governing prescription drugs. Senate Bill 2295 and its companion H.R. 4384 would have nullified *Mensing* and allowed generic manufacturers to provide additional warnings about their drugs in the same manner that the FDA allows brand-name manufacturers to do so. Senate Bill 2295 purportedly would "promote consumer safety by ensuring that generic drug companies can improve the warning information for their products in the same way that brand manufacturers can under existing law."

The bill would have amended FDCA ¶ (11)(A)(j) to add the following language to the statute:

> 11(A) Notwithstanding any other provision of this Act, the holder of an approved application under this subsection may change the labeling of a drug so approved in the same manner authorized by regulation for the holder of an approved new drug application under subsection (b).
>
> (B) In the event of a labeling change made under subparagraph (A), the Secretary may order conforming changes to the labeling of the equivalent listed drug and each drug approved under this subsection that corresponds to such listed drug.

The proposed change received backing from various attorneys general and public interest groups. See Patient Safety and Generic Labeling Improvement Act, S. 2295, Money Trail, Open Congress, http://www.opencongress.org/bill/112-s2295/money (last visited Aug. 7, 2013). In Congress, support fell mostly along party lines and the bill died in committee. It would be naïve, however, to assume that legislators will not revive these legislative attempts during the next session of Congress, particularly in light of Bartlett's limitation on generic manufacturers' liability. And the likelihood of success of similar legislation will depend on the political landscape after the midterm elections.

Attempts by Public Interest Groups to Change FDA Regulations

In August 2011, Public Citizen, a "public interest group" that supported S. 2295—filed a petition with the FDA for regulation changes that would allow generic manufacturers to use the changes-being-effected (CBE) procedure and to *require* generic drug companies to warn about serious side effects caused by their medications. The petitioner based the request on these chief factors and arguments: (1) generic drugs are a majority of prescription drugs sold in the United States; (2) post-approval monitoring is essential to the safety of drugs and is a shared responsibility of the FDA and manufacturers; and (3) generic manufacturers' alleged lack of responsibility for ensuring the post-approval adequacy of product labeling threatens patient safety. *See* Citizen Petition (Aug. 29, 2011). The FDA has not taken any actions on the citizen petition, but on the same day that *Bartlett* was announced, Public Citizen renewed its request to allow for generic manufacturers to change the labeling of their products.

The FDA wasted no time signaling a changing regulatory landscape post-*Bartlett*. In July 2013, the FDA announced that it would issue a Notice of Proposed Rulemaking titled Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products. According to the abstract posted regarding the rulemaking

> [t]his proposed rule would amend the regulations regarding new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologics license applications (BLAs) to revise and clarify procedures for changes to the labeling of an approved drug to reflect certain types of newly acquired information in advance of FDA's review of such change. The proposed rule would describe the process by which information regarding a "changes being effected" (CBE) labeling supplement submitted by an NDA or ANDA holder would be made publicly available during FDA's review of the labeling change. The proposed rule also would clarify requirements for the NDA holder for the reference listed drug and all ANDA holders to submit conforming labeling revisions after FDA has taken an action on the NDA and/or ANDA holder's CBE labeling supplement. These proposed revisions to FDA's regulations would create parity between NDA holders and

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As this article went to press, the government had not yet published the notice.

The Crystal Ball Remains Clouded

Mensing brought a sea change to failure-to-warn claims in drug litigation. It appears doubtful that the attempts to simply relabel these claims will succeed. With the decision in *Bartlett*, the U.S. Supreme Court has further limited theories of recovery available to claimants against generic manufacturers. At the same time, courts reject the assault on brand-name manufacturers for the generic products produced by others.

Justice Thomas's characterization of the regulatory scheme as dealing an "unfortunate hand" has focused attention on failure-to-warn claims and the impossibility of a generic manufacturer varying its warnings from the corresponding brand-name drug and still complying with FDA requirements. Whether the means through which this dilemma is resolved, legal, regulatory, or judicial, remains to be seen.

In the weeks after the Court released the *Bartlett* decision, the renewed efforts for regulatory reform saw the most activity. But after the 2013 congressional summer recess, it is likely that the legislative efforts to deal with liability issues related to generic drugs will intensify. Until Congress addresses the concerns raised by the majority in *Mensing* and the dissent in *Bartlett* regarding remedies, creative litigation variations of failure-to-warn claims will continue to develop and judicial reasoning to deal with these claims will remain unsettled. FD