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You've Been Warned: Pleading and Proving Failure to Warn Claims

BIGSTOCK

Failure to warn claims have long been a staple of tort litigation, particularly in the mass tort and product liability arena. Claims that the defendant knew more than it told the buying public, or failed to convey adequate information or instructions for the plaintiff to properly size up the risks of a dangerous product, are the stuff of investigative journalism, breaking news headlines and, of course, legal filings. While failure to warn claims are common in a variety of contexts, there are pitfalls regarding these claims for the unwary practitioner. In the past few years, New York federal and state courts have continued to grapple with thorny issues posed by warning claims, particularly at the motion to dismiss and summary judgment stages. Whether you are bringing a failure to warn claim on behalf of a plaintiff, or defending such a claim, it is essential to stay on top of recent developments in this area. Don't say you haven't been warned!

Pleading Failure to Warn

The U.S. District Court for the Southern District of New York recently addressed the level and type of proof needed for a plaintiff to overcome a motion to dismiss a failure to warn claim in *Goldin v. Smith & Nephew*, 2013 U.S. Dist. LEXIS 58811 (S.D.N.Y. April 24, 2013). In the course of granting both the defendant's motion to dismiss and the plaintiff's motion for leave to amend her complaint, the court stressed the plaintiff's burden to specify how and why an allegedly defective product's warnings are inadequate.

Goldin stemmed from the voluntarily recalled R3 Constrained Acetabular Liners by Smith & Nephew. Id. at *4. The plaintiff went through a series of hip replacements and revisions culminating in conversion to the R3 Constrained Liner, which had been marketed to patients at high risk of dislocation. See id. at *1-3. Ultimately, this procedure also allegedly proved a failure, and the plaintiff was rushed to the hospital after experiencing "excruciating pain in her right hip." Id. at *3. Smith & Nephew subsequently issued the voluntary product recall, "warning of the risk of intra-operative and post-operative dislocation." Id. at *4. The plaintiff sued Smith & Nephew alleging, inter alia, failure to warn, and the defendant moved to dismiss. The court noted that to prevail on a failure to warn claim in New York, "a plaintiff must prove that (1) a manufacturer has a duty to warn (2) against dangers resulting from foreseeable uses about which it knew or should have known, and (3) that failure to do so was the proximate cause of the harm." Id. at *13 (citation and internal quotation marks omitted). The court further pointed out that there are two circumstances under which a manufac-

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turer has no duty to warn of known or foreseeable dangers: "[F]irst, where the dangers are obvious; and second, where the user is fully aware of those dangers." Id. at *13-14 (citation and internal quotation marks omitted).

The court ruled for the defendant dismissing the claim because the plaintiff did "not identify the allegedly defective warnings, nor [did] she allege facts in support of her claim that these warnings were, in fact, defective." Id. at *14. Moreover, the plaintiff did not identify the promotional materials upon which she or her surgeon relied, and she failed to explain "what warnings those materials contained and how those materials breached a legal obligation." Id. Her allegations coupled only with "the bare fact that Plaintiff suffered an injury after using a product that had been promoted for patients in her situation does not render the warnings inadequate." Id. *Goldin* highlights the peril for plaintiffs at the pleading stage in failing to fully and specifically set forth why the allegedly defective warnings are deficient, and the opportunity for defendants when plaintiffs fail to meet their burden.

Proximate Cause

Proximate cause is another essential element of such a warning claim. In *Mussara v. Mega Funworks*, 952 N.Y.S.2d 568 (App. Div. 2012), the court addressed this issue in the context of injuries sustained in a 50-foot-long "splash pool" after exiting a water slide in an inner tube. The defendant operators of a water park installed a new water slide and implemented a number of safeguards. See id. at 570-71. A "200-pound weight limitation, a height restriction, and [an] instruction to pull back on the [inner tube] handles were placed on several warning signs to the ride." Id. at 571. Lifeguards were also stationed at the top of the ride "to make sure the rider was sitting in the tube correctly, holding the handles, and was supposed to tell the rider to hold the handles and to pull back on them when entering the splash pool to slow down." Id. The plaintiff (who weighed in excess of the 200-pound weight limit) and his son rode the slide, and the plaintiff was injured after traversing the entire length of the splash pool. Id. The plaintiff "checked the warning sign to see if his son was tall enough to qualify for the ride, but did not read the rest of the warnings." Id.

The court granted the defendants motion for summary judgment as to the plaintiffs' failure to warn claims, holding that the plaintiffs had not established the necessary element of proximate cause linking the injuries and the warnings. Id. at 572.

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The appellate court affirmed the lower court's ruling as to the failure to warn claim. "Insofar as the…cause of action… based upon a failure to warn, any failure to warn was not a proximate cause of the alleged injuries, as the injured plaintiff admitted that he read the height restriction on the warning sign but failed to read the rest of the warnings. In opposition, the plaintiffs failed to raise a triable issue of fact…." Id.

Similarly, in *Fredette v. Town of Southampton*, 944 N.Y.S.2d 206 (App. Div. 2012), the Appellate Division found proximate cause lacking in the plaintiff's failure to warn claim. The plaintiff in *Fredette* sued several defendants, including the manufacturer of a motorcycle, for injuries sustained in a motor vehicle accident. The trial court denied the manufacturer's motion for judgment as a matter of law, but the appellate court reversed, finding that the plaintiff failed to raise a triable issue of fact. See id. at 207-08. "The plaintiff conceded in his deposition testimony that he had 'just looked through' the motorcycle's manual without recalling any particular pages or entries." Id. at 208. Despite this testimony, the plaintiff's affidavit in opposition to the manufacturer's motion for judgment as a matter of law asserted a different position: "that he had seen the manual's front cover many times and read pages 2 through 7 and most of the service and maintenance section at pages 11 through 31." Id. at 209. The court rejected the affidavit, finding that it had been "tailored to avoid the consequences of the plaintiff's earlier deposition testimony." Id. at 209. The court did note, however, that "even where a plaintiff fails to read warnings altogether, there may still be a viable cause of action based on the inadequacy of the warnings themselves, as the sufficiency of warnings is not limited to what is warned but also includes consideration of the intensity of the language used and the prominence of its display." Id. But under the specific facts of this case, the plaintiff failed to raise a triable issue of fact as to the adequacy of the warnings regarding avoidance of hazards, the rider's positioning on the motorcycle, and the pre-inspection of riding areas. Id.

In contrast to the Fredette and Mussara cases, *Monell v. Scooter Store*, 895 F. Supp. 2d 398 (N.D.N.Y. 2012), demonstrates how a plaintiff can survive a motion for summary judgment even when she has not read the warnings provided by the manufacturer. In *Monell*, the plaintiff, a 93-year-old woman with limited mobility, suffered injuries when her scooter tipped over. Id. at 403. The plaintiff sued the manufacturer of the scooter alleging, inter alia, that the defendant failed to provide adequate warnings. In moving for summary judgment, the defendant argued that "Plaintiff did not read the Owner's Manual that accompanied the Go-Go Scooter or the marketing literature about the product…and, therefore, there

is no basis for any claim that the incident was proximately caused by the failure to provide adequate warnings." Id. at 413.

The district court was not persuaded by the defendant's arguments, and found that the plaintiff should be allowed to proceed to trial on her failure to warn claim. The court first noted that "the New York State Court of Appeals has described the standard for evaluating failure-to-warn liability as intensely fact-specific, including but not limited to such issues as… proximate cause. Given this fact-intensive inquiry, as the Second Circuit has emphasized, the adequacy of the instruction or warning is generally a question of fact to be determined at trial and is not ordinarily susceptible to the drastic remedy of summary judgment." Id. at 414 (citation and internal quotation marks omitted). With this in mind, the court found that "the fact that neither Plaintiff nor [the purchaser the scooter for plaintiff] read the Owner's Manual or the other material that came with the scooter is not dispositive under New York law in connection with a failure to warn claim." Id. The plaintiff challenged both the substance and the conspicuousness of the warnings, "including the failure to include such a warning in the marketing material and on the scooter itself." Id. at 415. "While it is true that, in many cases, a plaintiff who admits that he failed to read a warning that was issued with the product will have failed to show that any deficiency in that warning was the proximate cause of his injuries, plaintiff's failure to read an insufficiently conspicuous or prominent warning will not necessarily defeat the causation element of a failure to warn claim." Id. (citation and internal quotation marks omitted).

For plaintiffs' attorneys, the message is clear: Evidence of failure to read a warning may well doom your client's failure to warn claim. However, in cases where conspicuousness of the warning is at issue, courts, like *Monell*, may be hesitant to grant summary judgment despite evidence a warning was not read. In such cases, the nature of the actual warning given may be the key to whether such a claim survives summary judgment. Plaintiffs and defendants will need to tailor discovery to gather evidence supporting their side of the "failure to read" divide. Finally, defense counsel should investigate early on in a case whether their clients have undertaken adequate pre-marketing testing, where appropriate, before designing and implementing warnings when introducing a product into the market.

Generic Drugs

New York courts have also addressed failure to warn claims in the context of generic prescription drugs in light of the U.S. Supreme Court's decisions in *Wyeth v. Levine*, 555 U.S. 555 (2009), and *PLIVA v. Mensing*, 131 S. Ct. 2567 (2011). The Fosamax MDL involves claims, including failure to warn, that the drug Fosamax, or its generic equivalent, caused osteonecrosis of the jaw (ONJ). *In re Fosamax Prods. Liab. Litig.*, 2013 U.S. Dist. LEXIS 115667 (S.D.N.Y. Aug. 15, 2013). The manufacturers of the generic drug moved for judgment on the pleadings, arguing that the plaintiffs' claims were preempted under *Mensing*. See id. at *1-2. The Supreme Court in *Mensing* held that a plaintiff's state-law failure to warn claims were preempted, because federal regulations require generic drug manufacturers to keep their labels the same as the brand-name equivalent. See id. at *4-5.

The plaintiffs in *Fosamax* tailored their failure to warn claims in two ways to attempt to evade the Mensing holding. First, they alleged a "failure to update" the generic label for a year after the brand-name manufacturer updated its label. Id. at *7. While this was an issue of first impression in the Second Circuit, the court followed the "majority of other jurisdictions in finding that 'failure to update' claims against [generic manufacturers] are not preempted." Id. at *8. The court reasoned that "it was possible for the [generic manufacturer] to comply with their federal duty to match their labels to the Fosamax label, while also satisfying their state tort law duty to adequately warn the consumers [of the generic version of the drug]. Indeed, its obligations under federal law were coextensive with state law requirements." Id. at *9.

Second, the plaintiff alleged a "failure to communicate" label changes to physicians and consumers through other methods such as "Dear Doctor" letters. Id. at *12. The Fosamax plaintiffs argued "that *Mensing* held only that generic manufacturers could not send 'Dear Doctor' letters that contained new or additional warnings, and the Supreme Court did not consider whether a generic manufacturer could use such letters or other methods to apprise health care professionals of information appearing in approved labeling." Id. The court rejected that argument, finding that the term "labeling is so broadly defined that it encompasses nearly every form of communication with medical professionals," and holding that such a claim is preempted under *Mensing*. Id. at *13 (citation and internal quotation marks omitted). These failure to warn issues specific to generic drugs continue to play out in courts across the country.

Conclusion

New York litigators should be aware of the current state of failure to warn law. Both plaintiffs' attorneys representing individuals harmed by a product, and defense lawyers representing the manufacturers of those products, must be careful to carefully examine all of the essential elements of these very common causes of actions. While dismissal for failure to state a claim or summary judgment may properly lie in some cases, in other instances courts will be hesitant to dismiss such claims before trial. Finally, specific warning standards will apply with regard to generic drugs and other products regulated by the FDA.