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The Potential Impact Of 'Recall Fatigue'

Law360, New York (November 24, 2010) -- “Recall” means different things to different people. To a product manufacturer, “recall” conjures up thoughts of costly public relations nightmares followed by a tsunami of product liability litigation. “Recall” makes plaintiffs attorneys salivate at the mere thought of mass tort litigation, class actions and the pot of gold they hope will be waiting for them at the end of the litigation rainbow. However, to the general public, “recall” is beginning to mean nothing important or new at all.

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With an invigorated — some would even say activist — U.S. Food and Drug Administration, the number of medical device recalls has soared to previously unseen levels. While manufacturers and plaintiffs attorneys take great interest in the uptick in the number of recalls, consumers — the very target of a recall — seem to have become desensitized to the whole thing. The current environment may affect how manufacturers handle recalls and impact their defense strategies in any product liability litigation that ensues on the heels of a recall.

Rising Number of Recalls and Potential for Recall Fatigue

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According to FDA records, the number of Class I recalls of medical devices and other products has skyrocketed in recent years. For example, to date there have been around 414 Class I recalls in just this year, which is a 159 percent increase from last year’s total of 160 Class I recalls.[1]

The increase in recalls could be due in part to the desire of many companies to get ahead of a controversy before it spirals out of control. Transparency is the name of the game today. With corporations maintaining Twitter and Facebook accounts, company websites and other social media outlets, and their customers doing the same, a company should recognize the need to be totally transparent in its dealings with the public, or face the consequences. A recent article in Advertising Age explained:

"[M]arketing experts say companies these days are quicker to pull the trigger on a voluntary product recall both in the hopes of averting legal problems down the road and as they come to grips with conducting business in an ever-more transparent world where consumers air their grievances via Twitter and Facebook and government agencies are right there to listen."[2]

While some may applaud the increase in the number of recalls as a sign of increased dedication to the safety of product users, not everyone agrees. The increase in the number of recalls leads to what has been characterized as recall fatigue:

"Government regulators, retailers, manufacturers and consumer experts are concerned that recall notices have become so frequent across a range of goods — foods, consumer products, cars — that the public is suffering from 'recall fatigue.'

"In many cases, people simply ignore urgent calls to destroy or return defective goods.

"One recent study found that 12 percent of Americans who knew they had recalled food at home ate it anyway. After Hasbro recalled the iconic Easy Bake Oven in 2007 because about two dozen children had gotten fingers stuck in the door, the toymaker received 249 more reports of injuries over the following six months. One five-year-old girl was so seriously burned that doctors had to partially amputate a finger."[3]

At least one FDA official has expressed concern about the risk of oversaturation from the proliferation of recalls:

"'It's a real issue,' said Jeff Farrar, associate commissioner for food protection at the FDA, who said even his wife has complained about the difficulty of keeping pace with recalls. 'That number is steadily going up, and it's difficult for us to get the word out without oversaturating consumers.'" Id.

The tension between providing adequate safety information and avoiding overwarning is nothing new. See Mason v. Smithkline Beecham Corp., 596 F.3d 387, 392 (7th Cir. 2010) ("While it is important for a manufacturer to warn of potential side effects, it is equally important that it not overwarn because overwarning can deter potentially beneficial uses of the drug by making it seem riskier than warranted and can dilute the effectiveness of valid warnings."); Witty v. Delta Air Lines Inc., 366 F.3d 380, 385 (5th Cir. 2004) (Moreover, warnings by their nature conflict, in the sense that the import of one warning is diluted by additional warnings that might be imposed under state law."); accord Morales v. Trans World Airlines Inc., 504 U.S. 374, 390 (1992) ("As the FTC observed, '[r]equiring too much information in advertisements can have the paradoxical effect of stifling the information that consumers receive.'").

It is therefore no wonder that recall overload can have a deleterious effect on consumer compliance.

Recall Fatigue and the Product Liability Plaintiff

If recall fatigue has set in, how does it affect a manufacturer's litigation defense strategy? The answer is significantly.

Recall notices must contain certain information, including specific and detailed identification of the product, the manufacturer and the reasons for the recall. See 21 C.F.R. § 7.46. The FDA, for example, requires the format, content and extent of a recall communication to be commensurate with the hazard of the product being recalled. 21 C.F.R. § 7.49(a)-(c).

When the audience of a manufacturer's recall message is fatigued by reports of recalls involving everything from automobiles to eggs to breakfast cereal to any number of drugs and medical devices, the manufacturer may find it necessary to alter the message to attract the reader's attention. Does the need to get the message across mean that the manufacturer must overstate the risk or consequences of disregarding the notice? Only time will tell. But, because consumer and user safety should be the paramount objective of any recall communication, the manufacturer must always strive for clear, timely and accurate communication in spite of any perceived fatigue that has set in.

Make no mistake about it — the mere issuance of a recall communication increases the odds that a manufacturer will be involved in some type of product liability litigation. And when the litigation arises, a manufacturer that has complied with all applicable regulatory requirements governing recalls may rightfully expect consumers and users of the product at issue to abide by the instructions and to respond accordingly. Recall fatigue is no excuse for disregarding a recall notice or other safety message — quite to the contrary, inaction by the user or consumer can mitigate or defeat altogether the manufacturer's liability.

A handful of cases from across the country have addressed the effect of a plaintiff's noncompliance with a pre-injury safety notification from the manufacturer.

Most recently, the Eleventh Circuit addressed the issue under Alabama law in JHOC v. Volvo Trucks North Am. Inc., 303 Fed. Appx. 828, 2008 WL 5264666 (11th Cir. Dec. 18, 2008). In JHOC, a semi-truck tractor manufactured by Volvo and owned by JHOC, which does business as Premier Transportation, caught fire and was destroyed in August 2006. Everyone agreed that the cause of the fire was a defective condition in the exhaust gas recirculation pipes of the tractor. In January 2006, seven

months before the fire, Volvo e-mailed the plaintiff's director of maintenance informing him that a recall notice for the EGR would be issued; Volvo then issued the recall notice in March 2006. Concluding that JHOC unreasonably failed to comply with the recall notice, the district court granted Volvo's motion for summary judgment on contributory negligence/assumption of the risk grounds, and the Eleventh Circuit affirmed:

"Here, the district court found that Premier was contributorily negligent and assumed the risk by allowing nearly six months to pass without obtaining the repairs described in the safety recall as necessary to avoid potential fire. Premier behaved negligently because the recall notified Premier that a fire could occur if the EGR pipes were not repaired, and five and a half months is an unreasonable amount of time to avoid a needed safety repair, especially where the consequences association [sic] with the defect are so grave." Id. at 832-33, 2008 WL 5264666, at *3.

Because contributory negligence and assumption of the risk are complete bars to recovery, the courts dismissed the claims against Volvo.

Under Iowa law, however, noncompliance with safety notifications is not a complete bar to recovery, and simply operates to reduce the plaintiff's recovery. In Burke v. Deere & Co., 6 F.3d 497 (8th Cir.), reh'g and reh'g en banc denied (1993), the court considered the effect of the plaintiff's noncompliance with a post-sale decal issued by Deere after receiving reports of injuries involving a Deere combine. The court held that the plaintiff's noncompliance with original and supplemental warnings could be evidence of assumption of the risk that might reduce, but not bar altogether, the plaintiff's recovery. Id. at 505.

At least one court has held that a defendant may not even argue that noncompliance with a recall notice constitutes negligence or assumption of the risk. In Ceretti v. Flint Hills Rural Elec. Coop. Ass'n, 837 P.2d 330 (Kan. 1992), for example, a power company argued that the plaintiff's noncompliance with a sailboat manufacturer's recall notice about replacing an aluminum mast constituted assumption of the risk. One person died and another one suffered injury when the sailboat mast contacted a power line. Although the jury was instructed that the plaintiff had been warned of the hazard posed by an aluminum mast, the trial court prohibited the power company from arguing that the noncompliance with the recall notice was negligence or assumption of the risk. Id. at 372.

The Kansas Supreme Court affirmed and held that any error was harmless because the record contained testimony that the replacement mast would not have been available before the accident. Id. at 372-73.

As with most affirmative defenses premised upon the fault of the plaintiff, any defense based upon a plaintiff's noncompliance with a pre-injury safety notification will ordinarily be a question for a jury to decide, not one for a court to decide on a motion for summary judgment. In Springmeyer v. Ford Motor Co., 71 Cal. Rptr. 2d 190 (1998), Ford argued that Avis' failure to comply with a fan blade recall notice as a matter of law constituted a superseding cause that relieved Ford of liability for the plaintiff's injuries. (Although Springmeyer involves noncompliance by someone other than the injured plaintiff, it provides insight into how a California court may resolve the issue in the context of a plaintiff's noncompliance.)

Rejecting Ford's argument, the trial court submitted the issue of the effect of Avis' noncompliance to the jury, and the court of appeal affirmed. The court of appeal recognized that California case law is in a state of flux — some cases conclude that noncompliance severs the causal connection between the manufacturer's negligence (or product defect) and the accident, while other cases reach opposite conclusions. Compare Temple v. Velcro USA Inc., 196 Cal. Rptr. 531 (1983) (affirming summary judgment for the manufacturer when the plaintiff admitted that she received the post-sale warning but did not pay attention to it) with Balido v. Improved Machinery Inc., 105 Cal. Rptr. 890 (1972) ("Insofar as machinery dangerous to life and limb is involved, we think it a question of fact whether a manufacturer would reasonably anticipate that a wholesaler, a dealer, a retailer, an owner, or a user, may not positively respond to warnings of the need to correct a design deficiency.").

The courts in Springmeyer followed Balido and held that the effect of noncompliance is a question of fact for the jury: "Since there was evidence from which the jury could find that Ford could have foreseen (and actually did foresee) that many owners, like Avis, would fail to respond to the recall, we conclude that the issue of superseding cause was correctly treated as a question of fact in this case." 72 Cal. Rptr. at 200.

Conclusion

A strong argument could be made that with increased media attention and publicity about recalls of all shapes and sizes comes consumer recall fatigue that undermines and dilutes the efficacy of the recall message. Manufacturers must manage the potential for fatigue within the confines of governing regulations. Nonetheless, disregard of recall notices and communication from the manufacturer may support defenses to claims that the product at issue is defective. Recall fatigue may be a fact of life in today's society, but it does not permit a plaintiff to ignore or disregard recall notices sent for their own protection and safety.

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[1] See http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm; http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/default.htm.

[2] Rupal Parekh, Glut of Recalls Threaten to Desensitize Consumers, ADVERTISINGAGE (AUG. 30, 2010), HTTP://ADAGE.COM/ARTICLE?ARTICLE_ID=145621 (last visited Nov. 12, 2010).

[3] Lyndsey Layton, Officials Worry About Consumers Lost Among the Recalls, Washington Post (July 2, 2010), http://www.washingtonpost.com/wp-dyn/content/article/2010/07/01/AR2010070106504.html (last visited Nov. 12, 2010).

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