Portfolio Media. Inc. | 860 Broadway, 6th Floor | New York, NY 10003 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Product Liability In 2014: What Did And Didn't Happen?

Law360, New York (December 22, 2014, 1:04 PM ET) --

Shagha Tousi

As the year comes to a close, we take a look back at Law360's "Product Liability Cases to Watch in 2014" to analyze how the courts ruled in five areas of litigation and the impact of these decisions on product liability law.

Washing Machine Defect Litigation

Whirlpool Corp. and Sears Roebuck & Co. petitioned for writ of certiorari in two cases alleging product liability claims against each of the two companies in connection with their front-loading washing machines. According to plaintiffs' claims in the two cases, these machines developed mold, mildew and an odor after use.

While the U.S. Supreme Court had instructed the circuits to reconsider their decisions to back class certification in light of its 2013 ruling in Comcast Corp. v. Behrend, the circuits nonetheless decided to reaffirm class certification. In October 2013, the companies petitioned the Supreme Court to review these rulings. Because the circuits' rulings allowed purchasers of the washing machines in question to be a part of the class even if the alleged mold defect did not exist in their machine, Law360 identified this as a "product liability case to watch" in 2014.

In February, the Supreme Court denied cert and refused to hear the appliance companies' challenge of the class certification decisions by the Sixth Circuit. In a rare turn of events, Whirlpool elected to try one of the cases in the class action and, following a jury trial in October, obtained a defense verdict. While a victory for Whirlpool, the Sixth Circuit's rulings and the Supreme Court's refusal to grant review of the class certification issue leaves open the possibility that defendants in class actions will be forced to defend claims against a class that potentially includes thousands of claimants who have suffered no real harm. The cost of defending such a case coupled with the uncertainty inherent in a jury trial will have an impact on the filing of broad class actions and the potential for settlement.

Potential Developments in Pharmaceutical and Medical Device Law

Law360 noted in its "Cases to Watch" that, in 2014, there could be clarifying rulings on the scope of liability for an industry highly regulated by the U.S. Food and Drug Administration — pharmaceutical and

medical device companies. Because each operate under a different regulatory regime, practitioners watch closely developing law under existing Supreme Court precedent.

Post-Bartlett Claims for Pharmaceuticals

In Mutual Pharmaceutical Co. Inc. v. Bartlett, the Supreme Court held that state design defect claims against generic drug manufacturers are preempted by federal law. After Bartlett and PLIVA Inc. v. Mensing, in which the Supreme Court decided that state law failure-to-warn claims against generic manufacturers are preempted, plaintiffs were seemingly precluded from suing a generic drug manufacturer on a claim of failure to warn or a state law design defect claim that turns on the adequacy of the drug's warning. However, in an "enigmatic footnote" in the Bartlett opinion, the court stated that it did not address design defect claims that "parallel the federal misbranding statute." In re Darvocet, Darvon and Propoxyphene Products Liability Litigation, 756 F.3d 917 (6th Cir. 2014).

Users of the generic versions of the painkiller Darvocet and Darvon were among the first plaintiffs to cite the Bartlett footnote in an attempt to overturn the dismissal of their claims. Plaintiffs argued that their claims that the drugs are misbranded under federal law because they were ineffective and dangerous when used as directed were not preempted and should be reinstated in light of the Bartlett footnote. On May 7, 2014, the Sixth Circuit issued its decision largely affirming the lower court's dismissal. Regarding the Bartlett footnote, the Sixth Circuit noted that even if a parallel misbranding exception to preemption for generic drugs exists after Bartlett, it did not need to decide the issue because plaintiffs had failed to plead such a claim sufficiently. More specifically, the Sixth Circuit found that plaintiffs had failed to allege sufficient facts to assert a parallel misbranding claim because they had not identified "new and scientifically significant information" that the generic manufacturers possessed that had not been provided to the FDA.

The Sixth Circuit's decision therefore accomplished two small victories for pharmaceutical defendants facing such claims: (1) its decision acknowledged doubt as to whether a parallel misbranding exception exists; and (2) even if such an exception exists, plaintiffs face a high bar for asserting such claims, as the allegations in this case were consistent with the level of detail typically provided by plaintiffs. Undoubtedly, plaintiffs will continue to pursue parallel misbranding claims and those cases will end up on our list of "product liability cases to watch" as we follow the progeny of Bartlett and its footnote four.

Post-Riegel Claims for Medical Devices

In Riegel v. Medtronic, the Supreme Court left open a narrow exception to express preemption of state law claims concerning pre-market approved medical devices; namely, when state duties "parallel," rather than add to, federal requirements. Lower courts have been wrestling with the meaning of "parallel" claims ever since. In 2014, a petition for certiorari pending before the Supreme Court held promise to provide some clarity.

In Stengel v. Medtronic, the plaintiff claimed that Medtronic failed to warn the FDA of known risks of its pain pump, which plaintiff claimed caused his paralysis. In January 2013, the Ninth Circuit held that plaintiff's state law failure-to-warn claim was not preempted by federal law, which raised new questions about the applicability of the Supreme Court's ruling in Buckman Co. v. Plaintiffs' Legal Committee, which held that claims of fraud upon the FDA were preempted. More specifically, the Ninth Circuit found that Arizona's state-law duty of care paralleled the federal-law duty imposed by the Medical Device Amendments and as such was not preempted. Medtronic petitioned the Supreme Court to

review the Ninth Circuit's ruling in May 2013.

At the court's invitation, the solicitor general filed an amicus brief arguing that the Medical Device Amendments only preempt claims related to specific FDA requirements and that the court should decline to hear the case. The Supreme Court agreed and denied Medtronic's petition for certorari. The Supreme Court's refusal to hear this case is significant for those awaiting clarification of the boundaries of "parallel claims" left open under Riegel v. Medtronic Inc., as an undefined avenue that remains for plaintiffs seeking to pursue state-law claims against medical device manufacturers.

"All Natural" Food Labeling Class Actions

Food labeling litigation saw a rise in 2013, with class actions being filed against food manufacturers attacking the "all natural" claims on product labels. In 2013, proposed class actions were filed against well-known brands, including Kellogg Co., General Mills Inc. and Campbell Soup Co.

In Cox v. Gruma Corp., plaintiffs in the putative class action argued that defendant's claims that its food products are "all natural" were false and misleading because those products contained genetically modified organisms in the form of corn grown from bioengineered seeds. On July 11, 2013, U.S. District Judge Yvonne Gonzalez Rogers stayed the proposed class action, asking the FDA "for an administrative determination" as to whether food products containing ingredients produced using bioengineered seed may be labeled "Natural," "All Natural" or "100% Natural." Other judges followed suit in hopes that the FDA would weigh in on the subject.

On Jan. 6, 2014, the FDA responded via a letter to Judge Gonzalez Rogers and other judges who had similarly requested a determination, declining to make a definitive decision regarding whether and under what circumstances food products containing ingredients produced using genetically engineered ingredients may or may not be labeled "natural." In its letter, the FDA cited its limited resources and the need to prioritize other, more critical issues, including the development of food safety regulations implementing the FDA Food Safety Modernization Act of 2011. The FDA's refusal to make the requested determination leaves in place the uncertainty that many food manufacturers hoped would be resolved, with litigation attacking manufacturers' labeling practices likely to continue. Particularly in light of the legislation being proposed and enacted in many states on the topic of labeling of food products containing genetically modified organisms, this area of product liability litigation will likely see critical developments in 2015.

CPSC Suit Against Buckyballs Maker CEO

In 2012, the Consumer Product Safety Commission initiated an administrative enforcement proceeding against Maxfield and Oberton Holdings LLC, the importer and distributor of Buckyballs, a magnetic toy initially marketed to children. The CPSC claimed the toys posed significant risks to the health of those who accidentally swallowed the small magnets. In 2013, the administrative law judge allowed the CPSC to add Craig Zucker, the company's CEO, as a respondent and to hold him personally liable for the product's defects. Zucker countersued in the District of Maryland, claiming the CPSC overreached in adding him as a respondent.

This case was included in Law360's "product liability cases to watch" because of the repercussions it could pose for all product manufacturers if the CPSC is ultimately successful in holding Zucker liable for any alleged defects. On May 9, 2014, the parties settled the case, ending both the CPSC's administrative enforcement proceeding against the company and Zucker as well as Zucker's civil action pending in

federal court against the commission. Since Zucker's claims against the CPSC were never adjudicated, the question of whether the commission's claims against the CEO exceeded its authority was never addressed. This leaves open the possibility that the CPSC or other government agencies can pursue executives or other individuals for claims of wrongdoing against their companies.

Conclusion and Thoughts for 2015

Looking back on 2014, one is reminded of the mantra "the more things change, the more they stay the same." It is interesting to note the level of judicial and administrative restraint on the areas of law discussed above. In all five areas examined in this article, the courts and regulators ultimately left unresolved critical underlying issues with potentially substantial legal repercussions, particularly in the areas of class certification and personal liability for product defects. In the pharmaceutical, medical device and food labeling areas, we can anticipate continued litigation given the remaining uncertainties in the law. As we consider "Product Liability Cases to Watch in 2015," companies and practitioners alike should be mindful that they may not always obtain the clarity they want from a complex and ever-changing legal system.

—By Shagha Tousi, David Ferrera, Rebecca Gallup and Alison Casey, Nutter McClennen & Fish LLP

Shagha Tousi is an associate in Nutter McClennen & Fish's Boston office. Tousi becomes a partner at the firm effective Jan. 1, 2015.

David Ferrera is a partner and chairman of Nutter McClennen & Fish's product liability and toxic tort litigation practice group in the firm's Boston office.

Rebecca Gallup and Alison Casey are associates in Nutter McClennen & Fish's Boston office.