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The Top Product Liability Cases Of 2016: Year-End Report

By **Emily Field**

Law360, New York (December 9, 2016, 10:49 AM EST) -- The Second Circuit opened up New GM to a potential flood of claims when it undid a bankruptcy liability shield that protected it from ignition switch claims against its prebankruptcy entity, while courts also tackled the labeling of "natural" foods and generic drugs.

Here, Law360 takes a look at some of the most significant product liability rulings of the past year.

In re: Mirena IUD Products Liability Litigation

The decision of U.S. District Judge Cathy Seibel in late July to wipe out 1,200 suits alleging harm from Bayer Healthcare's intrauterine device Mirena due to the absence of expert testimony underscored its importance.

Judge Seibel had reached her decision to grant summary judgment to Bayer "reluctantly," as it doomed hundreds of cases in the multidistrict litigation alleging that Bayer failed to warn women that Mirena could perforate the uterus after and unrelated to insertion. But, she said, she refused to be the first court to hold that a company's admissions would be a sufficient stand-in for expert testimony.

The Mirena is a T-shaped, hormone-releasing insert used to prevent pregnancy. Its label has long warned about the risk of perforation of the uterus, "most often during insertion," but said nothing about post-insertion risks during the 2008-2014 period covered by the roughly 1,200 lawsuits. Bayer denies that perforation after and unrelated to insertion is possible.

In early March, the judge had barred most of the plaintiffs' expert witnesses for the first two lawsuits to go to trial, citing qualification issues, reliability issues, or both.

"If this sort of analysis becomes widespread, then it has the potential to make product liability needlessly more time-consuming for courts and expensive for parties, because defendants will inevitably deny everything, even basic scientific facts that are apparent in their own documents," said Max Kennerly, of counsel at plaintiffs firm Tor Hoerman Law. "Defendants are entitled to raise meritorious defenses, but they're not entitled to make courts waste their time watching plaintiffs reinvent the wheel by proving again something the defendant already acknowledged when they weren't being coached by their lawyers."

The women said in August that they plan to appeal the judge's decision to the Second Circuit.

The plaintiffs were represented by Diogenes Kekatos of Seeger Weiss LLP, Matthew McCauley of Parker Waichman LLP, James Ronca of Anapol Weiss, Fred Thompson III of Motley Rice LLC, and Michael Johnson, Kenneth Pearson and Rolf Fiebiger of Johnson Becker PLLC.

Bayer was represented by Shayna Cook, Brian O'Donoghue and Christopher Cook of Goldman Ismail Tomaselli Brennan & Baum LLP, Paul Schmidt, Phyllis Jones and Michael Imbroscio of Covington & Burling LLP, E. James Shepherd of Shook Hardy & Bacon LLP and William Harrington of Bleakley Platt & Schmidt LLP.

The case is In re: Mirena IUD Products Liability Litigation, case number 7:13-md-02434, in the U.S. District Court for the Southern District of New York.

Brazil v. Dole

The Ninth Circuit in September delivered a mixed win to food makers facing a rising stream of "natural" label claims, when it reversed in part a lower court's ruling that "all natural fruit" labeling on Dole Foods Co. Inc. products isn't likely to deceive consumers.

The three-judge panel sided with consumer Chad Brazil, saying a jury should hear his arguments that although Dole labeled its frozen berry and other mixed fruit products as "all natural," the fruit is packed in two man-made, mass-produced ingredients, citric acid and ascorbic acid, and that the versions used by Dole aren't found anywhere in nature.

But the panel also found that the lower court didn't err in decertifying the class, finding that damages were correctly limited to the difference between the prices consumers paid and the value of the fruit they bought.

Since Brazil hadn't proven that Dole's products were valueless — which would mean that consumers could be awarded full refunds of their purchases — recovery would be limited to the premium paid under the misunderstanding that the products were indeed all-natural.

"That headliner takeaway there, it's very favorable for the defense on the issue of commonality of damages for class certification," said Perkins Coie LLP's David Biderman.

Brazil's case is one of a number of food labeling suits that the Ninth Circuit is currently mulling.

In one appeal, Jones v. ConAgra, consumers claim the company's Hunt's, Pam and Swiss Miss products are falsely labeled, and are challenging a denial of class certification. That case also involves some natural-food label claims.

"We don't know how the court is going to go, but there is now becoming a circuit split," Biderman said. "At some point in time, depending on the president-elect, the Supreme Court may take up that ascertainability issue."

Brazil was represented by Charles Barrett of Charles Barrett PC, Colin H. Dunn of Clifford Law Offices PC, Ben F. Gore of Pratt & Associates and Brian K. Herrington of Herrington Law PA.

Dole was represented by William L. Stern, Claudia M. Vetesi, William Tarantino and Lisa A. Wongchenko of Morrison & Foerster LLP.

The case is Brazil v. Dole Food Co. Inc. et al., case number 14-17480, in the U.S. Court of Appeals for the Ninth Circuit.

Bristol-Myers Squibb Co. v. Superior Court

The California Supreme Court **in August** gave the go-ahead for nearly 600 non-Californians who have filed suit in the state alleging injuries from their use of Bristol-Myers Squibb Co.'s blood-thinner Plavix to proceed with their suits, finding that state courts have jurisdiction over their claims.

The state's high court said that given the company's extensive contacts with California — such as its marketing and distribution of the drug, as well as research and development facilities located there — the state courts have specific personal jurisdiction over the nonresidents' claims.

A court may have specific jurisdiction when the litigation in question arises out of obligations that are connected to a company's activities in that state, the high court said.

At issue in the ruling are eight separate complaints filed in San Francisco in March 2013 by 86 Californians and 592 residents of 33 other states, according to the opinion. Each one has the same allegations — including negligence, false or misleading advertising and strict product liability claims — according to the ruling.

In its decision, the state high court pointed to the U.S. Supreme Court's ruling in Daimler AG v. Barbara Bauman, which set out limits on general jurisdiction.

In that 2014 ruling, the nation's highest court said that California courts couldn't hear a suit against the German automaker over an Argentine subsidiary's union-busting activities and human rights violations committed in collaboration with the Argentine government.

However, the California Supreme Court said the question of whether a court has specific jurisdiction over a defendant who isn't a resident of the state involves three factors: whether that defendant has "purposefully directed" its activities" at that state, whether the claims are related to those activities, and whether exercising jurisdiction would be reasonable.

And both the Californians' and non-Californians' claims are based on the same allegedly defective drug and allegedly misleading marketing of that drug, the state high court said.

"The case has tremendous significance across a variety of claims: Can corporations overturn International Shoe and effectively destroy specific jurisdiction, or will we continue to use the rules that have guided us for 70 years?" Kennerly said, referring to the 1945 U.S. Supreme Court ruling in International Shoe v. Washington. "Big corporate defendants have taken the Humpty Dumpty approach to jurisdiction: Car manufacturers say specific jurisdiction doesn't apply where the plaintiff was injured, while drug manufacturers say specific jurisdiction applies only where the plaintiff was injured."

A petition to the U.S. Supreme Court is currently pending in the case.

Bristol-Myers Squibb was represented by Jerome B. Falk, Sean SeLegue, Steven G. Reade, Maurice A. Leiter and Anand Agneshwar of Arnold & Porter LLP and Jon B. Eisenberg of Horvitz & Levy LLP.

The plaintiffs were represented at the time by Kelly Ann McMeekin, then with the now-defunct Napoli Bern Ripka Shkolnik & Associates LLP, William Audet of Audet and Partners LLP, Hunter J. Shkolnik, John Lytle, Jennifer Liakos and Shayna E. Sacks of Napoli Shkolnik PLLC and Stuart B. Esner of Esner Chang & Boyer.

The case is Bristol-Myers Squibb Co. v. Superior Court, case number S221038, in the Supreme Court of the State of California.

In re: Motors Liquidation Co.

The bankruptcy decisions that shielded General Motors from liability related to ignition switch defects were unraveled by the Second Circuit in July, which found that the 2009 sale of the automaker's assets that provided the company with legal cover violated potential victims' due process rights.

The federal appeals court reversed parts of a 2015 ruling by U.S. Bankruptcy Judge Robert Gerber, who found that the sale order could be used to enjoin claims related to the ignition switch defect. The decision examines the limits to which the new GM entity that was formed upon the completion of the bankruptcy sale is shielded by "free and clear" provisions in Chapter 11.

GM did not reveal the ignition switch issue during the bankruptcy; the company began recalling cars because of the defect in February 2014. The timing of the disclosure by GM effectively denied plaintiffs the right to weigh in on the sale and therefore they cannot be bound by the provisions of the sale order that shield the company from litigation, the Second Circuit said.

The appeals court also ruled that the 2009 sale order does not cover so-called independent claims arising from misrepresentations by the new GM entity, referred to in the litigation as New GM, of vehicles made prior to the Chapter 11 sale. Similarly, the Second Circuit said the order does not halt claims based on the lost economic value of GM vehicles due to various defects.

No comment was made on the merits of the claims themselves in the panel's ruling.

GM has said that it intends to appeal the decision to the U.S. Supreme Court by the end of the year.

"I think they'll argue first it's not a due process violation, that sufficient process was afforded," said Barry Boise of Pepper Hamilton LLP.

"It's a question of constitutional due process. ... Would [the plaintiffs] have received anything anyway at the time and does the Bankruptcy Code even permit such claims to be brought against the purchaser?" Boise said.

GM was represented before the Second Circuit by Arthur Jay Steinberg of King & Spalding LLP.

Various plaintiffs' groups were represented by William P. Weintraub of Goodwin Procter LLP, Steve W. Berman of Hagens Berman Sobol Shapiro LLP, Alexander H. Schmidt of Wolf Haldenstein Adler Freeman & Herz LLP and Georgetown Law Professor Gary Peller.

The appeal is In Re: Motors Liquidation Company, case numbers 15-2844, 15-2847 and 15-2848, in the U.S. Court of Appeals for the Second Circuit.

In re: Reglan Litigation

The New Jersey Supreme Court found in August that state law claims alleging generic-drug manufacturers didn't adequately warn of neurological risks for Reglan aren't preempted by federal law.

The New Jersey high court ruled that in order for generic-drug manufacturers to find a safe harbor from state law failure-to-warn claims in the Food Drug and Cosmetic Act's requirement that a drug's labeling must match its brand-name counterpart's, they must be reasonably diligent to monitor for updates to the brand-name maker's labeling.

In affirming a lower court's decision to let consumers continue with their claims that generic-drug makers tarried in changing their labels for metoclopramide products, the state high court took a different tack than the Fifth Circuit in a similar case three years ago.

The New Jersey case centers on a label warning that the U.S. Food and Drug Administration approved for Reglan in July 2004 that advised therapy should not last beyond 12 weeks, as well as a related "black box warning" that treatment with metoclopramide can cause tardive dyskinesia, which the regulator approved in 2009.

Hundreds of consumers in the multicounty litigation have accused the generic Reglan makers of delaying label updates that would adequately warn of the risk of tardive dyskinesia, a neurological disorder characterized by involuntary, repetitive body movements.

The New Jersey high court's ruling put the onus on generic manufacturers to look out for the FDA's brand-name labeling updates, attorneys noted, whereas the circuit rulings stated that the generic company's duty to update labels is triggered once the brand-name manufacturer changes its label.

The ruling widens an appellate court split on the issue of whether labeling claims against generics makers are preempted.

The generics manufacturers are represented by Kirkland & Ellis LLP, Ulmer & Berne LLP, Goldberg Segalla LLP, McElroy Deutsch Mulvaney & Carpenter LLP, Harris Beach PLLC, Goodwin Procter LLP and Archer & Greiner PC.

The consumers are represented by Louis M. Bograd of Motley Rice LLC and Theodore Oshman and Jason L. Pullman of Oshman & Mirisola LLP.

The case is In re: Reglan Litigation, case number 075269, in the Supreme Court of the State of New Jersey.

--Editing by Mark Lebetkin and Rebecca Flanagan.
