

## Noteworthy Product Liability Decisions Of 2012: Part 1



*Law360, New York (January 09, 2013, 11:50 AM ET)* -- The end of the calendar year brings forth from many critics a list of their favorite movies of the year as well as this list of our favorite product liability decisions of the year. From a defense perspective (because that's what we do), 2012 arguably did not produce many momentous product liability decisions. But there were plenty of interesting decisions that, with a little shoehorning, even parallel those top-10 movie lists. In chronological order, here are the first five items decisions:

### **1. O'Neil v. Crane Co., 53 Cal.4th 335, 266 P.3d 987 (Cal. Jan. 12, 2012)**

The California Supreme Court held that a product manufacturer is “the master” of only its own product and thus may not be held liable in strict liability or negligence for harm caused by another manufacturer’s product, unless the defendant’s own product contributed substantially to the harm, or the defendant participated substantially in creating a harmful combined use of the products.

The defendants made valves and pumps used in Navy warships, and they were sued here for a wrongful death allegedly caused by asbestos released from external insulation and internal gaskets and packing, all of which were made by third parties and added to the pumps and valves post-sale.

It is undisputed that defendants never manufactured or sold any of the asbestos-containing materials to which plaintiffs’ decedent was exposed. The plaintiff claimed that the defendants should be held strictly liable and found negligent because it was foreseeable that workers would be exposed to and harmed by the asbestos in replacement parts and products used in conjunction with their pumps and valves.

The court rejected that theory, noting that from the outset, strict products liability in California has always been premised on harm caused by deficiencies in the defendant’s own product. The reach of strict liability is not limitless; strict liability does not extend to harm from entirely distinct products that the consumer can be expected to use with, or in, the defendant’s nondefective product.

Instead, the courts require proof that the plaintiff suffered injury caused by a defect in the defendant’s own product. Mere foreseeability of harm, standing alone, is not a sufficient basis for imposing liability on the manufacturer of a nondefective product.

From a policy perspective, a manufacturer cannot be expected to exert pressure on other manufacturers to make their products safe and is not able to share the costs of ensuring product safety with these other manufacturers. It would be unfair to require manufacturers of nondefective products to shoulder a burden of liability when they derived no economic benefit from the sale of the products that injured the plaintiff.

Such an expanded duty could also undermine consumer safety by inundating users with excessive warnings. "To warn of all potential dangers would warn of nothing." An important re-emphasis of duty and causation principles in a busy jurisdiction.

## **2. Lofton v. McNeil Consumer & Specialty Pharmaceuticals, 672 F.3d 372 (5th Cir. Feb. 22, 2012)**

In *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the U.S. Supreme Court held that federal drug and medical device laws preempt a state tort-law claim based on failure to properly communicate with the U.S. Food and Drug Administration. Yet, while the Supreme Court has never so limited this rule, a few courts have limited their application of *Buckman* to direct "fraud on the FDA" causes of action. See *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006).

The issue arises particularly as several states have adopted the important tort-reform measure that presumes the adequacy of a warning on a medical product label that has undergone FDA review and approval, with an exception for warnings that arise from "fraud on the FDA."

In *Lofton*, the Fifth Circuit gave *Buckman* a broad reading that cannot be avoided by plaintiffs pulling pleading tricks out of their "Silver Linings Playbook." The court concluded that it makes no difference for preemption purposes that fraud on the FDA had become only an "element" of traditional tort claims because of the state statute.

Under the Texas provision, a plaintiff must establish a violation of the FDA's required disclosures. In so doing, the plaintiff necessarily retreats on the FDA's administrative ground. The Supreme Court was concerned that "disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court." *Buckman*, 531 U.S. at 351.

Since the statute requires a Texas plaintiff to prove fraud on the FDA to recover for failure to warn, this requirement invoked federal law supremacy according to *Buckman*.

## **3. Strudley v. Antero Resources Corp., No.2011-cv-2218 (Col. Dist. Ct. Denver Cty. May 9, 2012)**

While extracting natural gas from shale rock promises to provide cleaner, abundant energy for the United States, hydraulic fracturing, like any technology, carries potential risks. This has caught the attention of the plaintiffs' bar and advocacy groups that are openly speculating about everything from gas leaks and fires to environmental groundwater impacts and from the problems of large tanker trucks on small rural roadways to earthquakes (even to "Skyfall?").

In this case, the plaintiffs sued a gas exploration company and drilling equipment contractor, alleging that the hydraulic fracturing contaminated their well water. The U.S. District Court for the City and County of Denver, Colo., dismissed the claim, relying on a Lone Pine order. See *Lore v. Lone Pine Corp.* (N.J. Super. Ct. Nov. 18, 1986). The central issue was whether defendants caused plaintiffs' vaguely described "health injuries."

Cognizant of the significant discovery and cost burdens presented by a case of this nature, the court endeavored to invoke a more efficient procedure, requiring plaintiffs, before opening full two-way discovery, to make a prima facie showing of exposure and causation. The court further determined that the prima facie-showing requirement should not prejudice plaintiffs because ultimately, they would need to come forward with this data and expert opinion on exposure and causation to establish their claims.

Specifically, the case management order (CMO) required plaintiffs to identify each hazardous substance from defendants' activities to which she was exposed and which caused her injury; evidence of whether any and each of these substances could cause the type(s) of disease or illness that plaintiffs claimed (general causation); the dose or other quantitative measurement of the concentration; timing and duration of her exposure to each substance; a medically recognized diagnosis of the specific disease or illness from which each plaintiff allegedly suffers or is at risk for, such that medical monitoring is purportedly necessary; and a conclusion that such illness was in fact caused by such exposure (specific causation).

Plaintiffs were given several months to comply with the CMO. After that, the plaintiff expert's mere temporal association of symptoms and industrial production was insufficient. His conclusion that "sufficient environmental and health information exists to merit further substantive discovery" was simply the request for further discovery that the CMO was meant to curtail.

Neither sufficient data nor expert analysis stated that a causal connection in fact existed between the alleged injuries and exposure to the defendants' drilling activities. The case reflects an effective use of the Lone Pine order and may be a useful model for other fracking toxic tort suits.

#### **4. Pom Wonderful LLC v. Coca-Cola Co., 679 F.3d 1170 (9th Cir. May 17, 2012)**

The court confronted the clash of two federal statutes and the choice of the appropriate forum for a claim about food-product labeling. Just as the lead character in "Wreck-It Ralph" escaped his proper video game, the Ninth Circuit found that the plaintiff could not escape the appropriate forum for the complaint here: the FDA.

The plaintiff alleged that the defendant misled consumers with the naming and labeling of its juice product because of the relative percentages of various juices in the product. The Lanham Act prohibits false advertising, but the Food, Drug and Cosmetic Act (FDCA) also regulates food and beverage labeling. Specifically, FDA regulations address the naming of beverages and the language that may be included in labeling.

While the Ninth Circuit noted that courts should try to give as much effect to both statutes as possible, it was most significant that the FDCA does not include private plaintiff enforcement. Thus, allowing plaintiffs to sue under the Lanham Act to enforce the FDCA or its regulations would undermine Congress' decision to limit the FDCA's enforcement to the federal government. Therefore, the court concluded that the FDCA and its regulations barred pursuit of both the name and labeling aspects of this Lanham Act claim.

Once Congress and the FDA have spoken to what content a label must bear, so as not to mislead consumers, it is not the place of the courts to displace these requirements. The FDA could have required more explicit juice content labeling but did not. Under these circumstances, the appropriate forum for the plaintiff's complaints was the FDA — a useful precedent in the growing food-marketing litigation realm.

## 5. Centocor Inc. v. Hamilton, 372 S.W.3d 140 (Tex. June 8, 2012)

Texas had been a significant jurisdiction lacking state supreme court precedent adopting the learned intermediary rule in prescription drug cases. No longer seeing the “Perks of Being a Wallflower” on this issue, the Texas Supreme Court held that a prescription drug manufacturer fulfills its duty to warn by providing an adequate warning to the prescribing physician, noting that the underlying rationale for the validity of the learned intermediary doctrine remains viable today.

Patients can obtain prescription drugs only through their prescribing physician, and the “learned intermediary” is best suited to weigh the patient’s individual needs in conjunction with the risks and benefits of the prescription drug.

Almost as importantly, the case reversed the lower court's adoption of a direct-to-consumer (DTC) exception to the learned intermediary rule, concluding that even patients who seek prescription drugs based solely on DTC advertising will obtain them only when the prescribing physician has evaluated the potential risks and benefits for the particular patient.

The court also recognized the role of causation in this context: When the prescribing physician is aware of the product’s risks and decides to use it anyway, any inadequacy of the product’s warning, as a matter of law, is not the producing cause of the patient’s injuries — a major jurisdiction joining the majority view.

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