ARNOLD & PORTER LLP

Product Liability Litigation Update

Recent Developments in the Law

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Consumer Products: FTC Sends Cautionary Signal to Food and Dietary Supplement Manufacturers Making Health Benefit Claims

On January 10, 2013, the FTC issued a Decision and Final Order in *In the Matter of POM Wonderful LLC*, FTC Docket No. 9344 (Jan. 10, 2013), which has been closely watched in the hope it would shed light on whether randomized and controlled human clinical trials ("RCTs") are needed for food and dietary supplement manufacturers to make disease efficacy claims about their products.

The FTC has trended towards imposing a two-RCTs requirement in consent decrees—a rigorous standard that mirrors the FDA standard for evaluating new drug applications. But an administrative law judge ("ALJ") in the *POM Wonderful* case had ruled that, as a manufacturer of safe food products that were not offered as substitutes for medical treatment, POM Wonderful needed only clinical studies but not RCTs in order to meet the "competent and reliable scientific evidence" standard of substantiation. In its recent Decision, the full Commission reversed the ALJ and held that POM Wonderful was in fact required to substantiate its disease efficacy claims with RCTs. It declined, however, to set a bright line rule as to the number of RCTs required, or even to hold that RCTs would be needed whenever a manufacturer makes an efficacy claim concerning a food or dietary supplement.

Because it was limited to the facts of the case, the Decision failed to bring much-desired clarity to the level of substantiation required for disease efficacy claims made by manufacturers of food and dietary supplements. POM Wonderful has already expressed an intent to appeal the Decision and Order.

Preemption: Ninth Circuit Widens Circuit Split on Medical Device Preemption

In *Stengel v. Medtronic Inc.*, No. 10-17755, 2013 WL 106144 (9th Cir. Jan. 10, 2013), the U.S. Court of Appeals for the Ninth Circuit sitting en banc unanimously held that the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act do not preempt state law failure-to-warn claims premised on a medical device manufacturer's failure to report adverse information to the FDA.

The en banc court first construed *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) narrowly: "the plaintiffs in *Buckman* alleged no state-law claim and were concerned exclusively with alleged fraud on the FDA that had occurred as part of [the premarket] approval process." 2013 WL 106144, at *4. In contrast, the court held, the Stengels' claim under Arizona law that defendant had failed to report adverse events to FDA was a "state-law claim that is independent of the FDA's pre-market approval process that was at issue in *Buckman*." *Id*. at *8. In addition, that state law claim was "parallel" to federal duties and therefore not expressly preempted under the Supreme Court's decision in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). *Id*.

The Ninth Circuit thus joined the Fifth Circuit in holding that Buckman does not preempt claims premised on a failure to report adverse events to FDA. *See Hughes v. Boston Scientific Corp*., 631 F.3d 762 (5th Cir. 2011). This holding is at odds with the Eighth Circuit's decision in *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*, 623 F.3d 1200 (8th Cir. 2010), making Stengel a case to watch for possible Supreme Court review.

An in-depth Advisory on *Stengel* published by Arnold & Porter attorneys is available here.

Brand-Name Manufacturer Liability: Alabama Supreme Court Holds That Brand-Name Drug Manufacturers Can Be Liable for Injuries Caused by Generic Drug

In *Wyeth Inc. v. Weeks*, No. 1101397, --- So. 3d ---, 2013 WL 135753 (Ala. Jan. 11, 2013), the Alabama Supreme Court held that a plaintiff who took only the generic equivalent of a drug could hold the brand-name drug manufacturer liable for misrepresentations made in the drug's label.

Defendant had argued that there is an insufficient causal connection to hold a brand name manufacturer liable for injury caused by another company's product. The Alabama Supreme Court reasoned, however, that "an omission or defect in the labeling for the brand-name drug would necessarily be repeated in the generic labeling, foreseeably causing harm to a patient who ingested the generic product. . . . A brand-name manufacturer could reasonably foresee that a physician . . . would rely on the warning drafted by the brand-name manufacturer even if the patient ultimately consumed the generic version of the drug." *Weeks*, 2013 WL 135753, at *15. This holding relied heavily on the Supreme Court's recent opinion in *Pliva v. Mensing*, 131 S. Ct. 2567 (2011), which had held that claims against generic manufacturers were preempted because only branded companies have authority to change labeling, which generic manufacturers are then compelled to adopt.

The Alabama Supreme court's decision departed from a number of cases interpreting Alabama law, as well as the predominant post-*Mensing* view which rejects such expansion of branded drug manufacturers' liability. Defendants have applied for rehearing, arguing that the court read *Mensing* too broadly and improperly expanded state tort law.

For questions or comments on this newsletter, please contact the Product Liability group at product@aporter.com.

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