ARNOLD & PORTER LLP

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Recent Developments in the Law

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Supreme Court: Competitors May Bring False Advertising Claims Involving FDCA-Regulated Food and Beverage Labels Under Lanham Act

In *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228 (2014), the Supreme Court unanimously held that competitors may bring false advertising claims under the Lanham Act challenging food and beverage labels regulated under the Federal Food, Drug, and Cosmetic Act (FDCA).

The Supreme Court's decision in *POM* was greatly anticipated by some observers in heavily regulated industries (e.g., pharmaceuticals) because of the potential for a statement on preemption or the primary jurisdiction doctrine. Certain district courts have relied on the Ninth Circuit's *POM* reasoning to find state law consumer fraud and false advertising claims preempted under the primary jurisdiction doctrine. *See, e.g., Astiana v. Hain Celestial Grp. Inc.*, 905 F. Supp. 2d 1013 (N.D. Cal. 2012). A decision by the Supreme Court affirming the Ninth Circuit could have provided additional ammunition for defendants asserting a primary jurisdiction defense in the product liability or other contexts. But instead the Supreme Court decided the issue on different grounds.

In *POM*, petitioner, which produces and markets a pomegranate-blueberry juice, filed a Lanham Act suit alleging that the name, labeling and advertising of Coca-Cola's "Pomegranate Blueberry" juice misleads consumers into believing that it consists predominantly of pomegranate and blueberry juice, thereby causing decreased sales for petitioner. 134 S. Ct. at 2235. The lower courts held that the FDCA and the FDA's regulations precluded petitioner's suit under the Lanham Act. *Id*. at 2235-36. The Supreme Court reversed, finding first that this was not a preemption case because it did not raise the question of whether state law is preempted by federal law. Rather, the action concerned a question of preclusion between two federal statutes that hinged on statutory interpretation. *Id*. at 2236. The Court noted that neither the Lanham Act nor the FDCA expressly forbids Lanham Act claims challenging labels regulated by the FDCA, finding this to be "powerful evidence that Congress did not intend FDA oversight to be the exclusive means" of regulating food and beverage labeling. *Id*. at 2237. The Court further found that the structures of the two statutes reinforced the conclusion drawn from the text. The two statutes are complementary – while both touch on food and beverage labeling, the Lanham Act protects commercial interests and the FDCA protects health and safety. *Id*. at 2238. Moreover, because the FDCA's enforcement is largely committed to FDA and the Lanham Act allows private enforcement, "[a]llowing Lanham Act suits takes advantage of synergies among multiple methods of regulation." *Id*. at 2239. For these reasons, the Court stated that "[a] holding that the FDCA precludes Lanham Act claims challenging food and beverage labels would not only ignore the distinct functional aspects of the FDCA and the Lanham Act but would also lead to a result that Congress did not likely intend." *Id*.

Because the Supreme Court expressly stated that its decision was about statutory interpretation rather than preemption, the decision does not undermine the potential defense of primary jurisdiction in cases involving heavily regulated industries. But it did not yield the strong opinion on primary jurisdiction that some had hoped for. The *POM* decision does ensure that the Lanham Act remains a viable option for businesses in the food and beverage industry seeking to protect their commercial interests even when those interests involve a product that is regulated under the FDCA.

New York: Plaintiffs Not Required To Produce Medical Reports Establishing Causation Before Medical Examination By Defendants

In *Hamilton v. Miller*, --- N.E.3d ---, Nos. 113, 114, 2014 WL 2608461 (N.Y. June 12, 2014), the New York Court of Appeals held that plaintiffs were not required to produce medical reports establishing causation prior to medical examinations by defendants.

Plaintiffs in two cases consolidated for appeal brought personal injury actions against their respective former landlords seeking damages arising from childhood exposure to lead-based paint as a child. Each plaintiff filed a bill of particulars in which they listed several dozen injuries that they claimed were caused by the purported exposure. Although each of the plaintiffs disclosed certain medical records in the course of discovery, those records did not substantiate all of the alleged injuries, nor did they causally relate those injuries to lead exposure. Defendants noticed medical examinations and requested that plaintiffs produce, pursuant to 22 NYCRR 202.17(b)(1), medical reports establishing all of plaintiffs' alleged injuries and linking those injuries to their purported cause. After plaintiffs refused to produce the requested reports, defendants moved to compel. In each case, the Supreme Court held that plaintiffs must provide medical evidence of each injury and the cause thereof, or otherwise be precluded from offering evidence of that injury at trial. The Appellate Division affirmed.

On appeal, the Court of Appeals held that plaintiffs cannot be required to produce, prior to medical examination by defendants, a medical report *causally relating* plaintiffs' injuries to lead paint exposure or be precluded from offering proof of such injuries at trial. However, the court also held that the rule does require plaintiffs to provide comprehensive reports, detailing any injuries diagnosed or treated, from their treating and examining medical providers, regardless of whether such reports previously had been drafted. Therefore, while reports on causation are not required at that phase of the litigation, plaintiffs must have their medical providers draft reports setting forth any injuries or conditions as to which testimony will be offered at the trial.

While the *Hamilton* decision may limit defendants' ability to obtain reports on causation from plaintiffs' medical providers in the early stages of personal injury actions in New York, it does require plaintiffs to affirmatively obtain from their doctors reports that detail the injuries or conditions as to which testimony will be offered at trial. In addition, the Court of Appeals suggested an alternative route available to defendants who wish to challenge plaintiffs' causation evidence early in a case – moving for expedited expert discovery. "Should plaintiffs fail to produce any evidence of causation" in response to such an order, then defendants "can move for and obtain summary judgment" at that point.

FDA Offers Industry Draft Guidance On Certain Social Media Uses

In a June 18, 2014 *Federal Register* notice, the Food and Drug Administration (FDA) announced the availability of two documents providing draft guidance on industry use of internet and social media platforms with character space limitations and correction of third-party misinformation about prescription drugs and medical devices.

The first draft guidance document – *Internet/Social Media Platforms with Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices* – encapsulates FDA's current thinking on how the industry should use digital platforms with character space limitations, such as Twitter or sponsored links, to promote drugs or medical devices. When using such platforms, a company presenting information on the benefits of a product must also provide balanced risk information, including the most serious risks associated with the product and a link to more complete risk information. Companies should also communicate the indicated use and name (brand and established) of a product. If a company concludes that the required information cannot be communicated within the character space limitations, it should reconsider using the platform for the promotional message.

A second guidance document – *Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices* – advises how the industry should respond to product misinformation disseminated by independent third parties on the internet or social media regardless of whether that information appears on a company's own forum or an independent forum or website. Misinformation is defined as "positive or negative incorrect representations or implications about a firm's product." The FDA guidance makes clear that the industry generally has no obligation to correct misinformation propagated by independent third parties. Should a company choose to correct faulty statements, however, it

may provide truthful and non-misleading corrective information or, alternatively, a reputable source from which to obtain the correct information. A firm need not correct all misinformation on a forum, but must correct both positive and negative misinformation in a clearly defined portion of the forum it identifies. FDA recommends that companies keep records of any corrections they make to assist in any questions that FDA might have.

FDA is still working to finalize these guidance documents and has requested comments by September 16, 2014. While not ground breaking, these documents are useful in providing insight into FDA's thinking and the attendant risks for companies engaging in online promotional and corrective activities.

An in-depth Advisory on FDA's new online media draft guidance documents published by Arnold & Porter attorneys is available here.

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

arnoldporter.com