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A Bitter Loss For POM Signals More FTC Scrutiny

Law360, New York (March 12, 2013, 12:40 PM ET) -- On Jan. 17, the Federal Trade Commission released its much-anticipated decision in In the Matter of POM Wonderful LLC, FTC Docket No. 9344 (Jan. 2013), upholding a May 2012 decision by an administrative law judge that POM Wonderful, the maker of POM Wonderful pomegranate juices, POMx pills and POMx Liquid, deceptively advertised its pomegranate juice and POMx supplements.

The decision is the latest in the long-running battle between the FTC and POM over the company's advertising claims. Last year, the FTC brought an administrative proceeding against POM regarding a variety of aggressively phrased disease- and health-related claims and the implication that these claims were supported by scientific evidence, including, for example, "Floss Your Arteries," "Cheat Death," "Amaze your cardiologist" and "Your New Health Care Plan."

In the underlying administrative proceeding, the FTC argued that POM should be required to obtain the U.S. Food and Drug Administration's preapproval for future disease claims and substantiate all claims with randomized, double-blind, placebo-controlled human clinical trials. POM challenged these requirements as illegal and a departure from the FTC's settled course of substantiation standards.

With the battle lines thus drawn, the FTC's move toward more stringent substantiation requirements for food and health products was called into question.

In his May 2012 decision, Administrative Law Judge D. Michael Chappell held that the appropriate level of substantiation for a safe food or food-related product (not being offered as a substitute for medical treatment) that treats, prevents or reduces the risk of disease is competent, and reliable scientific evidence was established through clinical studies, rejecting a heightened standard of double-blind, randomized, placebo-controlled clinical trials sought by the FTC.

However, the ALJ found that even in light of the traditional substantiation standard, POM did not substantiate some of its implied claims. Following the ALJ decision, both parties appealed.

The latest unanimous decision and final judgment against POM presents the FTC's view regarding what it considers is the appropriate level of substantiation for certain food and food-, disease- and health-related claims.

Even though the FTC's opinion makes clear that it is not setting a new rule regarding the level of substantiation required to support all disease- and health-related claims, and the commission chose only to address the POM claims at hand, the decision sends a strong cautionary signal to marketers of food, beverage and wellness products.

Specifically, the commission unanimously held that POM is barred from making any claims that a food or food-related product is "effective in the diagnosis, cure, mitigation, treatment or prevention of any disease," unless that claim is substantiated by two double-blind, statistically significant, randomized and controlled human clinical trials.

The FTC further held that any claims about the "health benefits, performance, or efficacy" of a product must be supported by competent and reliable scientific evidence, which includes "test, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified personas and are generally accepted in the profession to yield accurate and reliable results."

In its final judgment, the commission applied these substantiation requirements to all POM products as well as to any future food, drug or dietary supplements sold by the companies or individuals involved. The commission justified these broad "fencing-in" requirements because, it noted, the marketing techniques used for POM's products are easily transferable to other products and the respondents, who "have a demonstrated propensity to misrepresent to their advantage the strength and outcomes of scientific research" and sell, and have sponsored research on, Wonderful Pistachios and FIJI Water.

However, the commission's final judgment fell short of imposing the FTC staff's sought requirement, which would have required POM to obtain FDA preapproval for disease-related claims. On this point, the commission agreed with the ALJ determination that preapproval for disease-related claims was not warranted and reasoned that requiring two randomized, well-controlled human clinical trials would offer many of the same benefits as an FDA preapproval, "including a clear, bright line standard that would be easy to enforce and at the same time, provide certainty for Respondents."

Given the impact of this ruling on the marketing of all current and future products that may be sold by POM or its owners, and statements to the press made by POM following the decision, it appears likely that POM will file an appeal of the commission's decision and order with a U.S. Circuit Court of Appeals. The federal appeals court must accept the commission's findings of fact if they are supported by substantial evidence; the commission's legal findings will be reviewed de novo.

Although the commission's opinion explicitly notes that the substantiation requirements imposed on POM apply only to the specific products and claims before it, the opinion sends a strong signal that the FTC may begin requiring a heightened standard of substantiation for marketers of food and food-related products that make health- and disease-related claims.

It has been common for such marketers to rely on studies of individual ingredients and on single studies of product performance. In light of the POM decision, this may no longer be adequate. An industry-wide application of the POM decision's substantiation standard by the FTC will make it far more difficult and expensive to market products with claimed health benefits.

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