Advertising Law

May 22, 2012

SPECIAL FOCUS: FTC Judge Rules POM Lacked Competent and Reliable Evidence for Health Benefit Claims

On May 21, 2012, the Federal Trade Commission announced that its Chief Administrative Law Judge ("ALJ") had issued a much anticipated ruling on the FTC's administrative complaint against POM Wonderful, its sister corporation Roll International Corp., and three of its principals, Stewart Resnick, Lynda Resnick and Matthew Tupper (hereafter "POM"). In a 335-page ruling, Judge D. Michael Chappell held that POM Wonderful lacked competent and reliable scientific evidence for a number of its advertising claims that pomegranate juice and supplements can treat or prevent heart disease, prostate cancer and erectile dysfunction. As such, he ordered POM Wonderful to cease and desist making these health benefits claims about its products.

However, with regard to the FTC's proposed order, which would have required that POM obtain the FDA's approval before making any future health claims about its products, Judge Chappell ruled in favor of POM, noting that such requirements would be "over-reaching." The judge also rejected the FTC's claim that studies involving food, beverages and supplements must comply with the same double-blind, randomized, placebo-controlled requirements imposed on pharmaceuticals. The ALJ's decision thus represents a significant setback to the FTC's much-debated tightening of substantiation standards for certain health claims.

The decision now proceeds to full review before the Commission, at which time it will decide whether to adopt or reject the findings. As further judicial review of the Commission decision is possible, the battle will likely continue for quite some time before a final resolution is reached.

Summary of Decision

The *POM* case dates to September 2010 when POM filed a declaratory judgment action against the FTC to set aside the FTC's new substantiation standard requiring that food marketers obtain FDA approval before making certain health claims. The FTC moved to dismiss the case and filed an administrative complaint that same month, alleging that POM violated the FTC Act by making deceptive claims that its products aid in the prevention and treatment of heart disease, prostate cancer and erectile dysfunction. According to the complaint, the claims at issue "appeared in national publications such as *Parade, Fitness, The New York Times,* and *Prevention* magazines; on Internet sites such as pomtruth.com, pomwonderful.com, and pompills.com; on bus stops and billboards; in newsletters to customers; and on tags attached to the product." The FTC provided the following examples in its September 27 press release:

- "SUPER HEALTH POWERS! ... 100% PURE POMEGRANATE JUICE. ...

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ABA Section of Litigation's 2nd Annual Food & Supplements Workshop
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Speaker: Ivan Wasserman
Downers Grove, IL
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Topic/Speaker: "Developing a Strategy to Combat the Uptick in Litigation Challenging the Marketing and Labeling of Food Products," Linda Goldstein
New York, NY
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July 24–27, 2012
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Topic: "NBJ State of the Industry"
Speaker: Ivan Wasserman
Dana Point, CA
For more information

Awards

Backed by $25 million in medical research. Proven to fight for cardiovascular, prostate and erectile health."

- "NEW RESEARCH OFFERS FURTHER PROOF OF THE HEART-HEALTHY BENEFITS OF POM WONDERFUL JUICE. 30% DECREASE IN ARTERIAL PLAQUE ... 17% IMPROVED BLOOD FLOW ... PROMOTES HEALTHY BLOOD VESSELS ... "
- "Prostate health. Prostate cancer is the most commonly diagnosed cancer among men in the United States and the second-leading cause of cancer death in men after lung cancer.
- Time pill. Stable levels of prostate-specific antigens (or PSA levels) are critical for men with prostate cancer. Patients with quick PSA doubling times are more likely to die from their cancer. According to a UCLA study of 46 men age 65 to 70 with advanced prostate cancer, drinking an 8 oz glass of POM Wonderful 100% Pomegranate Juice every day slowed their PSA doubling time by nearly 350%. ... 83% of those who participated in the study showed a significant decrease in their cancer regrowth rate."
- "You have to be on pomegranate juice. You have a 50 percent chance of getting [prostate cancer]. Listen to me. It is the one thing that will keep your PSA normal. You have to drink pomegranate juice. There is nothing else we know of that will keep your PSA in check. ... It's also 40 percent as effective as Viagra." The FTC's administrative complaint against POM Wonderful alleges that these claims are false and unsubstantiated:
- Clinical studies prove that POM Juice and POMx prevent, reduce the risk of, and treat heart disease, including by decreasing arterial plaque, lowering blood pressure, and improving blood flow to the heart;
- Clinical studies prove that POM Juice and POMx prevent, reduce the risk of, and treat prostate cancer, including by prolonging prostate-specific antigen doubling time;
- Clinical studies prove that POM Juice prevents, reduces the risk of, and treats, erectile dysfunction.

According to the FTC, these claims were not supported by competent and reliable evidence because the scientific studies failed to show that consuming POM products "prevents or reduces the risk of" or "treats" heart disease, prostate cancer and erectile dysfunction. The complaint also alleged that POM's studies were not competent and reliable, because they were not double-blinded, adequately controlled, and in some cases failed to show the product outperformed placebos.

The FTC's request for relief included an order which, if adopted, would have prohibited POM from making any health-related claim about a food, drug or dietary supplement without competent and reliable scientific evidence, and would have required FDA preapproval of all future claims that POM's pomegranate-based products could cure, prevent or treat any disease.

While POM generally denied making false claims and asserted that its scientific evidence was adequate, it attacked most strongly (as it had in the federal declaratory judgment complaint) the allegedly "new" requirement that health and safety claims for food and dietary

supplements, as with pharmaceutical products, must be substantiated with two randomized, double-blinded, placebo controlled studies. POM further alleged that the FTC lacked the authority to require that the FDA preapprove its future health-related claims.

In an administrative trial before Judge Chappell, both the FTC and POM were permitted to present witness testimony and submit documents in support of their claims. Extensive briefing and evidence were submitted.

Based on a review of the evidence before him, Judge Chappell generally upheld the FTC complaint, and ruled that POM "violated federal law by making deceptive claims in some advertisements that their POM Wonderful 100% Pomegranate Juice and POMx supplements (POM products) would treat, prevent, or reduce the risk of heart disease, prostate cancer, and erectile dysfunction." The judge found that the "preponderance of the evidence shows that some of the Challenged Advertisements disseminated by Respondents would reasonably be interpreted by consumers to contain an implied claim that the POM Products treat, prevent, or reduce the risk of heart disease, prostate cancer, or erectile dysfunction, and further…that these effects were clinically proven, as alleged in the complaint." The judge concluded that POM could not support the claims with competent and reliable scientific evidence. "The weight of the persuasive expert testimony demonstrates that there was insufficient competent and reliable scientific evidence to support the implied claims…that the POM Products treat, prevent or reduce the risk of heart disease, prostate cancer or erectile dysfunction, or were clinically proven to do so." Accordingly, the judge ordered POM to cease claims about the "health benefits, performance, or efficacy" of POM products and/or any other food, drug, or dietary supplement "unless the representation is not misleading, and the POM respondents possess 'competent and reliable scientific evidence . . . to substantiate that the representation is true.'" The order further prohibits POM from misrepresenting "the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research." If adopted by the Commission, the ruling will place POM under a 20-year order that requires scientific research to back up health benefit claims.

The judge also addressed the FTC's contention that it had the authority to require POM to substantiate future health and safety claims for pomegranate products with at least two double-blind, randomized placebo controlled clinical studies, equivalent to the substantiation standard used by the FDA for pharmaceuticals. According to the judge, while "claims that a food or food-derived product treats, prevents or reduces the risk of a disease" must be based on "competent and reliable evidence" which "must include clinical studies," the studies are not required to be "double-blind, randomized, placebo-controlled clinical trials." In reaching his conclusion, the judge credited testimony from POM's experts that double-blind, placebo controlled studies are not necessarily the gold-standard for evidence of efficacy for dietary substances whose effects over time are subtle, gradual, and population-based. Thus, in a portion of the opinion touted by POM in press releases, the judge rejected the FTC's attempt to impose an FDA preapproval requirement on the basis that such a requirement "would constitute unnecessary overreaching."

Responding to the ruling, Craig Cooper, chief legal officer for POM

Wonderful LLC, stated, “Through its lawsuit against POM, the FTC tried to create a new, stricter industry standard, similar to that required for pharmaceuticals, for marketing the health benefits inherent in safe food and natural food-based products. They failed." As such, “while we are still analyzing the ruling, it is clear that we will be able to continue to promote the health benefits of our safe, food products without having our advertisements, marketing or public relations efforts preapproved by the FDA and without having to rely on double-blind, randomized, placebo-controlled studies, the standard required for pharmaceuticals. We consider this not only to be a huge win for us, but for the natural food products industry."

As mentioned, this decision is subject to full review, a step the FTC will likely undertake. After Commission review, the Commission decision is subject to judicial review.

To read the FTC press release on the September 2010 complaint, click here.

To read the FTC press release on the May 17, 2012 initial decision, click here.

To review Judge Chappell’s 335-page initial decision, click here.

Why it matters: The natural foods industry has at least temporarily achieved a measure of comfort, knowing that it may promote the health benefits of foods without having to obtain preapproval by the FDA or conduct two, randomized, double-blind, placebo-controlled studies for every claim. Nonetheless, that the FTC went to the mat against POM indicates that the Commission will continue to monitor the market and will impose the strictest standard possible for health claims. Thus, while marketers may share information regarding the health benefits of foods with consumers that are supported by scientific evidence, they must exercise care not to say or suggest that consumption of such healthy foods is a substitute for professional medical care or that consuming such foods can treat, cure or mitigate a disease.