wiley

NEWSLETTER

POM Juice's Failure to Meet Health Claim Substantiation Standards Leaves Legal Standards Unchanged

June 2012

A Federal Trade Commission (FTC) Administrative Law Judge (ALJ) recently rejected attempts to ratchet up the requirements for substantiating advertising claims while still finding the advertising at issue unlawful.

On May 21, 2012, ALJ Michael Chappell ruled that consumers could interpret some of POM Wonderful LLC's (POM) advertisements to impliedly claim that its juices and other products were clinically proven to treat, prevent, or reduce the risk of heart disease, prostate cancer, and erectile dysfunction. Because these claims were not properly substantiated under existing legal standards, they were deceptive and in violation of the FTC Act.

More important in the long run, however, the ALJ rejected the FTC's position that substantiation for all health-related efficacy claims requires double-blind, randomized, placebo-controlled human clinical trials (RCTs).

He found that neither the FTC Act nor relevant case law requires RCTs. Rather, case law has established that the required level of substantiation is a question of fact based upon numerous factors—including the nature of the product, the safety of the product, the overall context in which the transaction occurs, and what experts in the relevant field would consider sufficient to support the claim at issue. For claims that a product treats, prevents, or reduces the risk of a disease, the level of substantiation required is "competent and reliable scientific evidence," as defined by experts in the respective field. Although this standard requires clinical trials for safe food or food-derived products, it does not require RCTs such as those required under FDA standards for pharmaceuticals.

Applying this framework, Judge Chappell determined that POM's claims were not adequately substantiated. This finding was based on expert testimony that there was insufficient competent and reliable scientific evidence to support the implied claims.

He also rejected the FTC's argument that POM should be required to obtain FDA approval before it could make any future health claims. He characterized the FTC's proposed pre-approval requirement, which would hold food companies to the same standard as drug companies, as "unnecessarily overreaching." And he acknowledged that "no previous decision by the Commission or any court has required FDA pre-approval as

the required level of substantiation for disease claims, including for purposes of a cease and desist order." Rather, the competent and reliable evidence standard is "established precedent" and is "sufficiently clear and precise" to guide POM's future advertising practices.

Thus, the ALJ issued a 20-year injunction against POM and its parent company, Roll International Corp., which owns national brands such as Fiji Water, Cuties Tangerines, and Everybody's Nuts! Pistachios. The injunction bars the companies from making any representation about the "health benefits, performance, or efficacy" of POM products or any other food, drug, or dietary supplement, absent "competent and reliable scientific evidence to substantiate that the representation is true."

The ALJ's initial decision is subject to review by the full FTC, and both sides are expected to seek appeal. For now, the decision may force the FTC to reel in and reevaluate its current interpretation of what level of substantiation is required under the FTC Act.