

PUBLICATION

FTC Ruling Not So Wonderful For POM or The First Amendment

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On January 16, 2013, the U.S. Federal Trade Commission (FTC) issued a final ruling in a case about the advertisements for POM Wonderful LLC's 100% Pomegranate Juice and POMx supplements. These ads, 43 in total, made various claims about the general health benefits of POM products, as well as their abilities to treat or prevent certain diseases.

The FTC upheld Chief Administrative Law Judge (ALJ) D. Michael Chappell's decision that the advertisements deceptively advertised the products, because POM did not have adequate scientific support for claims that the products could treat, prevent or reduce the risk of heart disease, prostate cancer and erectile dysfunction. The FTC noted that no clinical studies had been done on the products' effectiveness, so there was no clinical proof they could work as the advertisements suggested.

The FTC's opinion actually went beyond the ALJ's initial opinion. The commission found that POM made deceptive claims in 36 of 43 separate advertisements and promotional materials, whereas ALJ Chappell only found that 19 of the 43 challenged items were false or deceptive.

The commission's final order bars POM from claiming that its drinks and supplements are "effective in the diagnosis, cure, mitigation, treatment, or prevention of any disease," including heart disease, prostate cancer and erectile dysfunction, "unless the claim is supported by two randomized, well-controlled, human clinical trials." The order also prohibits misrepresentations regarding any test, study or research, and requires competent and reliable scientific evidence to support claims about the "health benefits, performance, or efficacy" of any food, drug or dietary supplement.

The commission's opinion was important because, for the first time, the FTC found that a health claim need not include the words "established" or "clinically proven" in order to be held to standards that require two randomized, well-controlled, human clinical trials. The opinion suggests that two randomized, controlled trials (RCTs) are now required to support any kind of disease prevention or treatment claims. The opinion strongly suggested that at least one such RCT is required for more general claims of healthfulness.

One issue that the FTC opinion did not seriously address was POM's First Amendment rights to make health-related claims. The commission held that because it had determined that the ads were misleading, no analysis under the U.S. Supreme Court's rulings on commercial speech, including the factors from *Central Hudson Gas & Electric Corp. v. Public Service Commission*, was necessary.

Importantly, the opinion ignored the Supreme Court's recent *U.S. v. Alvarez* decision where it held that it "has never endorsed the categorical rule the Government advances: that false statements receive no First Amendment protection." Even if they determine that the speech is misleading, courts across the country will generally continue to apply all of the *Central Hudson* factors to determine if the commercial speech at issue is prohibited, even if they do so while applying more strict scrutiny. Not surprisingly then, on March 8, 2013, POM filed a petition for review of the FTC's decision in the D.C. Circuit Court of Appeals, arguing primarily that the FTC's order unconstitutionally violates POM's First Amendment rights.

Given the remaining uncertainties of POM's available First Amendment defenses, and the resolution of the D.C. Circuit appeal, advertisers and manufacturers now need to be very cautious when making any disease treatment/prevention claims with respect to food and dietary supplements. The FTC wants to establish the two-RCT requirement as the standard for making health benefit or disease treatment claims in any food, drink or supplement advertisement, label or promotional material without undertaking a formal rulemaking procedure or issuing any industry guide or policy statement. For health claims alone, the FTC "competent and reliable scientific evidence" standards remain in force, but the POM opinion suggested that one or two RCTs may now be required for general health claims. What the FTC does provide is a simple formula for display of the "healthy" claim for food products or menu items. For example, with all of the research studies on the "Mediterranean diet" published recently, can restaurants with Mediterranean diet menus claim their menus feature healthy dishes? Does the POM decision plant a seed of doubt about what were thought to be settled principles of advertising regulation?