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# FTC Tastes Sweet Victory in POM Wonderful Deceptive Advertising Appeal

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The District of Columbia Circuit Court of Appeals handed the Federal Trade Commission a critical win on January 30, 2015 by affirming the Commission's January 2013 decision holding POM Wonderful LLC in violation of the FTC Act for its deceptive advertisements alleging pomegranate juice and supplements could treat, prevent, or reduce the risk of heart disease, prostate cancer, and erectile dysfunction. The decision shows the continued reach of the FTC into the scientific bases for health-related advertising, the extensive deference courts give to the agency's expertise, and that substantive disclaimers may be the only way to avoid liability.

## Background: A Quick Glance at *POM Wonderful*

Since 1998, POM has invested over $35 million in over 100 studies at 44 institutions to discover and promote the health benefits of pomegranates. In particular, POM claimed that its juices and supplements could treat, prevent, or reduce the risk of heart disease, prostate cancer, and erectile dysfunction.

POM ad campaigns from 2006 to 2009 trumpeted results showing that daily consumption of pomegranate juice increased blood flow by up to 30% in one year. The study underlying that claim assessed 19 participants, showing statistically insignificant, preliminary results that were later disputed by two subsequent, larger POM-funded studies. A $1 million campaign placing 70 ads in publications nationwide claimed a reduction in arterial plaque and better blood flow based on the same study.

Another national ad campaign from 2007 to 2009 stated that drinking POM would slow the growth of prostate cancer, reducing PSA doubling times from 15 to 54 months. The study serving as the basis for these statements, however, was conducted without a control group and with a population of patients who had already either had radical surgery or endured radiation or cryotherapy to slow cancer growth, likely biasing the results.

During the same period, POM issued press releases and ran a series of ads touting the pomegranate's ability to improve erectile function simply by drinking an eight-ounce glass of juice. POM cited a commissioned crossover study analyzing 53 patients in eight weeks that ended with inconclusive results on an international standard of measure for erectile dysfunction.

After a lengthy investigation, the FTC filed an administrative complaint in September 2010 against POM for its heart disease, prostate cancer, and erectile dysfunction claims. The administrative judge found 19 ads in violation of the FTC Act. On appeal, the full Commission found 36 ads in violation and issued a three-part order for injunctive relief, including (1) a prohibition on representations that POM juice or supplements could prevent or treat any disease, including heart disease, prostate cancer, and erectile dysfunction, (2) a requirement that future disease-specific claims are substantiated by two randomized and controlled human clinical trials (RCTs), (3) a prohibition on misrepresentations of disease-specific scientific studies, and (4) a bar on general health statements without "competent and reliable scientific evidence."

## DC Circuit Court Decision: Deferring to the Commission

The Court reaffirmed its prior holdings granting deference to the agency in fact-finding and the Commission's adjudicatory decisions. The Court stated that the factual findings of the Commission were "conclusive," that

whether the ad was an efficacy ad or establishment ad was “a question of fact the evaluation of which is within the FTC’s peculiar expertise,” and that the Commission’s legal conclusions need only be “supported by substantial evidence on the record as a whole.” The Court recognized that the Commission’s findings, so long as they are supported by the evidence, are binding, noting that the agency is often more capable of determining when an ad is “deceptive” within the confines of the FTC Act. This highly deferential standard on both the facts and the law essentially adopts the Commission’s findings without independent review.

In its analysis, the Court employed a three-step inquiry, echoing the agency’s analysis, to determine whether the advertisements were deceptive under the FTC Act: (1) what claims are conveyed in the ad, (2) whether those claims are false, misleading, or unsubstantiated, and (3) whether the claims are material to prospective consumers. Materiality was not in dispute.

The Court’s determination of the claims conveyed in the ads began with a discussion of whether the claims were considered efficacy or establishment claims. Efficacy claims suggest that the product performs as advertised, but without any suggestion of scientific evidence of its effectiveness. To defend its efficacy claims, a company need only possess a reasonable basis to uphold the claim. Establishment claims, on the other hand, are ads suggesting that the product’s effectiveness or superiority has been scientifically proven. For these more specific claims, courts (and the agency) impose heightened scrutiny, including evidence that satisfies the relevant scientific community that the claim is true. Essentially, it is the difference between saying “pomegranates are good for you” and “pomegranates cure cancer.”

Here, the Court found that the ads were subject to more exacting scrutiny as establishment ads due to the specific disease-related claims. As the Commission found and the Court affirmed, 34 ads stated that clinical studies proved POM products could treat, prevent, or reduce the risk of heart disease, prostate cancer, and erectile dysfunction. The ads did not just describe the research to allow the customer to determine the validity of their health claims, but instead suggested that the studies were convincing proof of efficacy — and the Court accordingly required more scientific proof.

The Court’s analysis focused primarily on the second step of the inquiry and upheld the FTC’s determination that the claims were unsubstantiated. The studies could not serve as the basis for the claims in the ads because they suffered from several fatal flaws, including an insufficient sample size, a biased population, and statistically insignificant results. These flawed studies, according to the Court, would not live up to any standard in the medical community to provide a basis for POM’s statements. As a result, the ads were unsubstantiated and in violation of the FTC Act.

Despite the overwhelmingly favorable ruling for the FTC, the Court knocked down the section of the FTC’s order requiring that POM substantiate each of its disease-specific health claims with two RCTs. As part of its First Amendment analysis to determine whether the FTC’s order overly restricted POM’s right to free commercial speech, the Court found that, though the government had a substantial interest in curbing commercial misinformation and requiring an RCT was “perfectly commensurate” with that interest, ordering two RCTs was not a “reasonable fit.” Requiring more than one RCT was not the least restrictive way to justifiably constrain POM’s commercial speech because it imposed an additional burden without any further scientific certainty that would quell concerns that POM’s ads were misleading or unsubstantiated.

## Analysis

This decision yields two critical takeaways: (1) courts are highly deferential to the agency’s adjudicative decisions under its own laws, adopting the Commission’s opinion almost entirely; and (2) substantive disclaimers may allow advertisers to trumpet health-related claims without requiring RCTs.

First, the Court’s repeated deference to the Commission on both the facts and the law demonstrates the influence that the Commission’s internal adjudicative process has on the outcome of a case. Without conducting an independent analysis and instead relying almost entirely on the agency’s determinations, the Court only serves to augment the agency’s expanding reach into health-related advertising cases.

In all aspects of this case, the Court deferred to the agency’s holdings. At one point, the Court confirmed that the

law “does not permit the reviewing court to weigh the evidence” but only to determine whether it supports the legal conclusion. This essentially provides the Commission with carte blanche to enforce the FTC Act against potentially deceptive advertisements with little oversight. It is unlikely the agency would rather seek a federal district court for its initial enforcement efforts when its internal adjudicative process can yield such positive results with less risk of an unfavorable decision. Such a standard makes the FTC’s administrative “home court advantage” even stronger and even more challenging for those facing investigation and administrative proceedings before the Commission.

Second, despite an otherwise overwhelmingly favorable outcome for the Commission, industry was given some significant guidance that substantive disclaimers may allow advertisers to trumpet health-related claims without requiring RCTs. Though the Court made it more difficult for advertisers to soften the language in order to avoid FTC scrutiny, it provided another mechanism for asserting health-related claims. Calling a study “preliminary” or “initial” is no longer sufficient; instead, a “substantive disclaimer” may be required, such as a statement that “evidence in support of this claim is inconclusive.” But the Court allowed a gaping exception that companies “still may assert health-related claim[s] backed by medical evidence falling short of an RCT if it includes an effective disclaimer disclosing the limitations of the supporting research.”

One of the Court’s main complaints with POM’s advertising was that it cherry-picked favorable studies without reference to more scientifically stringent studies with opposite outcomes. By adequately describing the deficiencies of the product, companies can avoid shelling out for expensive clinical trials to substantiate their advertising claims. This will allow companies seeking to compete in a market increasingly focused on fitness to tout the health benefits of their products while successfully avoiding agency second-guessing.

**If you have any questions about this topic, please contact the author(s) or your principal Mintz Levin attorney.**





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