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CLIENT ALERT

The D.C. Circuit's *POM Wonderful* Decision: New Precedent for Advertisers Making Disease and Health Claims

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The United States Court of Appeals for the D.C. Circuit recently decided the closely-watched case of *POM Wonderful, LLC, et al. v. Federal Trade Commission*, No. 13-1060 (Jan. 30, 2015), an appeal from the full Commission's decision in an FTC administrative proceeding. According to recent statements by FTC Chairwoman Edith Ramirez, the FTC itself views this precedent as a major affirmation of its advertising enforcement program. Moreover, the FTC characterizes this as the first litigated decision involving the FTC's analysis of health and disease claims for conventional food products.

Many FTC consumer protection enforcement proceedings are either resolved without litigation by entry of an agreed settlement or involve slam-dunk wins by the FTC against parties accused of clear fraud. As a result, courts don't often get exposed to closer FTC cases that provide an opportunity to analyze fundamental issues such as claims interpretation, extrinsic evidence, applicability of the First Amendment to commercial speech, and remedies. By contrast, this case was hard fought by well-represented adversaries and involved advertising claims that were based, directly or indirectly, on what the defendants asserted to be $35 million in supporting scientific research. The ultimate opinion therefore provides a number of important lessons for any advertiser seeking to make claims that are (or should be) backed by scientific research.

The decision largely affirmed current FTC practices for advertising orders, including its longstanding practice of "fencing in" defendants' future conduct by imposing restrictions on a broader range of advertising activities than those challenged in the complaint and by requiring defendants to possess more stringent substantiation for future advertising claims than would necessarily be required under the standards applicable to all advertisers. However, the court also reviewed FTC precedent – including settlement agreements entered "without litigation or explanation of the Commission's reasoning" – for the FTC's controversial practice of requiring defendants to have *two* randomized and controlled human clinical trials (RCTs) to support future advertising claims for products claimed to prevent, treat, or cure diseases and other serious health conditions. After concluding that the two-RCT requirement was "selectively imposed in specific circumstances based on particular concerns," the court held that "the Commission has failed in this case adequately to justify" the requirement. Accordingly, it modified the FTC order against the POM defendants to require "at least one RCT," and left open the possibility that two RCTs might be appropriate relief under the right circumstances in future FTC orders.

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BACKGROUND OF THE CASE

A brief summary, based on the court's description of the facts, will set the table. Two wealthy entrepreneurs acquired and planted thousands of acres of pomegranate orchards in California and started the closely held POM Wonderful LLC and an affiliated company to make, market, and sell pomegranate products, including juices and dietary supplements containing pomegranate extract. To their credit, as part of the anticipated marketing campaign, they also funded extensive scientific research at a wide variety of institutions to explore the potential health benefits of pomegranates. By 2010, POM claimed to have spent over $35 million on such research, having sponsored more than 100 studies at 44 different institutions. Unfortunately for POM, however, it faced a challenge experienced by numerous advertisers: a disconnect between marketing claims and underlying scientific support.

Challenged Claims

As is apparent from the extensive record available from the FTC docket, POM ran creative, funny, aggressive, eye-catching advertising that touted the money it had spent on research and characterized the findings of that research in a manner suggesting that drinking pomegranate juice significantly improved heart health, reduced the risk of prostate cancer, and mitigated erectile dysfunction, among other medical benefits. While the ads in some cases attempted to qualify the claims with adjectives suggesting that the research was "preliminary" or "promising," it is fair to say that its ads did not prominently disclose that some of the benefits it was touting had not been proven – or were even called into doubt – by its own research.

For example, the famous "Cheat Death" ad showed POM's distinctive juice bottle with a frayed hangman's noose around it and touted "the antioxidant power of pomegranate juice." Other ads made specific health benefit claims, such as:

- "New research offers further proof of the heart-healthy benefits of POM Wonderful Juice."
- Drinking POM can result in a "30 percent decrease in arterial plaque" and can improve blood flow to the heart by 17 percent.
- Daily consumption of pomegranate juice can lead to "prolonged post-prostate surgery PSA doubling time."

Uncommon Procedural History

Not surprisingly, the FTC took notice of these and other striking claims of disease prevention and health benefits for POM products. Initially, POM attempted to short-circuit the FTC's investigation by filing suit against the FTC to enjoin further proceedings. When that legal gambit failed, as it consistently does in FTC enforcement actions, the FTC initiated an administrative trial before an FTC Administrative Law Judge (ALJ). Administrative trials have been less common in FTC consumer protection cases in recent years, reportedly because the agency's choice to proceed administratively limits the availability and timing of injunctive conduct relief and also limits the recovery of monetary relief to future violations of the administrative order rather than to the conduct underlying the initial order. Some outside commentators also suggested that the decision to proceed administratively reflected the Commission's wish to establish new legal precedent regarding the appropriate level of substantiation in a more controlled environment. The decision to proceed administratively also means that a trial decision by the FTC ALJ inevitably winds up in front of the full Commission as the first level of appellate review,

giving each Commissioner the opportunity to weigh in on the matter and issue a Commission decision before the federal appellate court weighs in, which is exactly what happened here.

The ALJ's Ruling

After a lengthy administrative trial, the ALJ ruled against POM, finding that 19 specific advertisements lacked sufficient substantiation for various implied claims that POM products treat, prevent, or reduce the risk of heart disease, prostate cancer, and erectile dysfunction. The ALJ found POM liable under the FTC Act and ordered POM to cease and desist from making further claims about the health benefits of any food, drug or dietary supplement unless those claims were non-misleading and supported by competent and reliable scientific evidence.

The Commission's Order

Both sides appealed to the full Commission, which not only affirmed the ALJ's finding, but also found that nearly 20 more of POM's promotional materials also violated the Act. The full Commission imposed an order requiring POM to refrain from representing that any food, drug or supplement "is effective in the diagnosis, cure, mitigation, treatment or prevention of any disease" absent "competent and reliable scientific evidence" that the representation is true.

In key passages, the Commission order effectively defined "competent and reliable scientific evidence" in two ways, depending upon the type of claim:

- With respect to drug and disease claims, the order defined competent and reliable scientific evidence to require "at least two randomized and controlled human clinical trials (RCTs)." In the years leading up to the POM case, the FTC had begun to impose this stringent requirement in settlement agreements and speculation had arisen in the legal community that it would become the FTC's *de facto* rule for all such claims going forward and would not be limited to fencing-in relief to address future conduct by defendants.
- With respect to less-specific health benefit claims, the order also required competent and reliable scientific evidence, but did not mandate a specific number or type of scientific studies to be conducted.[1]

Issues on Appeal to D.C. Circuit

The defendants then appealed the Commission's Order to the D.C. Circuit, arguing that the Commission erred in its interpretations of the claims in POM's ads, imposed too stringent a substantiation requirement, failed to give adequate notice of what substantiation standard was required of them, and unduly restricted their First Amendment rights to tout emerging science regarding the health benefits of pomegranates. As we explain below, the court rejected most of these arguments and reversed only the part of the challenged order in which the Commission required POM to conduct at least two RCTs before making any disease-related claims.

THE COURT'S DECISION

Standard of Review

The court applied a deferential standard of review under which Commission orders must be upheld "if supported by evidence…," FTC Act §5(c), 15 U.S.C. §45(c), a standard essentially equivalent to the "substantial evidence" standard under the Administrative Procedure Act. In other words, the court made clear that it would not second-guess the Commission's

factual determinations as long as an evidentiary basis existed in the record to support the Commission's conclusion that none of POM's research was sufficient to support its claims regarding the effect of pomegranate juice on heart disease, prostate cancer and erectile dysfunction (ED).

D.C. Circuit Adopts the Commission's Analytical Framework

The court also accepted the FTC's traditional advertising analysis, under which the FTC examined POM's advertising for the "net impression" and considered whether "at least a significant minority of reasonable consumers" would "likely" interpret the ad to assert a particular claim. The court did not require the FTC to have extrinsic evidence of how consumers interpreted POM's claims, such as a consumer survey, but instead followed the FTC's analysis by applying its own linguistic and contextual analysis to the challenged POM ads and agreeing broadly with the FTC's assessments of those claims.

The court also accepted the FTC's traditional distinction between ads making general "efficacy" claims and those containing "establishment" claims. An efficacy claim promises a general performance benefit for the advertised product, but does not suggest the existence of a particular level of scientific support for the claim. The FTC requires advertisers to have a "reasonable basis" for efficacy claims. An "establishment claim," in contrast, conveys expressly or by implication that a benefit associated with the product is supported by science, and the FTC requires advertisers to possess at least the level of scientific support conveyed by the ad. For establishment claims that reference a particular study, "the advertiser must possess the specific substantiation claimed." For non-specific establishment claims such as a claim that the product is "medically-proven," without reference to a particular study, the FTC requires the advertiser to "possess evidence sufficient to satisfy the relevant scientific community of the claim's truth."

D.C. Circuit Affirms Nearly All of the Commission's Rulings

The court broadly affirmed the FTC's determinations that POM's advertisements conveyed establishment claims that were not adequately substantiated. The court noted in particular that some of the ads touted the millions of dollars that POM had spent on medical research in addition to making specific statements regarding heart, prostate and ED benefits. Adjectives used by POM in some of the ads that attempted to qualify the certainty of the research, such as "promising," "initial," or "preliminary," were deemed insufficient to "neutralize the claims made when the specific [health] results are otherwise described in unequivocally positive terms."

In passages of the opinion that provide valuable object lessons to advertisers seeking to make health claims, the court agreed with the FTC regarding the key shortcomings of POM's factual evidence in support of its aggressive health claims for pomegranate juice. For example:

- Don't ignore contrary research.
  With respect to the alleged heart benefits of pomegranate juice, POM had first funded a small clinical trial in Israel, consisting of 19 patients with carotid artery stenosis (narrowing of the artery), randomized to either a test group that consumed pomegranate juice or a control group that consumed placebo for a period of one year. This first study purported to show that patients who drank pomegranate juice had a 30 percent reduction of stenosis, while those in the placebo group had a 9 percent increase of stenosis. However, subsequent research failed to corroborate these promising initial results. Two large-scale U.S. university studies later found no statistically significant differences between drinking pomegranate juice or a placebo with respect to most of the heart health endpoints

measured. Despite learning of these conflicting study results, POM's advertising continued to tout the results of the first, small-scale Israeli study, "without any acknowledgment" of the later, contrary findings.

- Don't imply a causal benefit where none has been shown.
  POM also sponsored research to determine whether drinking pomegranate juice could prevent prostate cancer. A UCLA study followed 46 patients who had been diagnosed with prostate cancer and who had already been treated by surgery or other advanced cancer therapy. The study, which required the patients to drink two 8-ounce glasses of pomegranate juice daily, had no control group. The study concluded that the patients' "PSA doubling time," a measure of the rate of growth of tumor cells, increased from 15 to 54 months. The study author noted, however, that patients who have undergone similar cancer treatments commonly experience a lengthening of PSA doubling time regardless of whether they consume pomegranate juice. POM nevertheless touted the cancer study results with "no mention of the limitations" of the underlying study.

- Don't base ad claims on non-validated measures of health benefit.
  POM sponsored a crossover study – a scientifically valid methodology in which each participant serves as both a test subject and a control subject – of 53 patients experiencing mild to moderate ED. The study used two different measures, only one of which had previously been established as a statistically valid assessment of ED. Neither measure showed a statistically significant connection between pomegranate consumption and improvement in ED, but the non-validated measure came closer to showing a statistically significant improvement. POM based its ED ads on the unvalidated measure without mentioning the negative results from the validated measure.

Court Rejects POM's Legal Attacks on FTC's Basis for the Order Requirements
After confirming the factual basis for the injunctive order against POM, the court disposed of all but one of POM's additional procedural and constitutional attacks on the order.

- First, the court rejected POM's argument that the FTC could not require an RCT as fencing-in relief without first proceeding through notice and comment rulemaking. The court reasoned that the fact that an order arising out of an adjudication may include provisions that the FTC then applies prospectively does not convert adjudication into rulemaking. In addition, it found the FTC's decision to require at least one RCT to be consistent with prior Commission precedent, and not the radical departure that POM had argued.

- Second, the court concluded that liability had been properly imposed on Matthew Tupper, POM's former chief operating officer and president, because the facts showed that he had participated directly in the deceptive acts and practices and had authority to control them. The court rejected Tupper's argument that it first had to prove he had knowledge of the false or misleading nature of the ads to be found liable. The court held that such *mens rea* was only necessary when the FTC assesses equitable monetary relief, which was not sought in this case.

- Finally, and in the only portion of the decision that went against the FTC, the court overturned the portion of the order in which the FTC required POM to conduct *two* RCTs before making any future disease-related claims. It held that the First Amendment prohibits a challenged restriction on commercial speech that is "more extensive than is necessary to serve that [governmental] interest" of preventing consumer harm from misleading or false advertising

> **claims. It found that the FTC had failed adequately to justify a categorical floor of two RCTs for any and all disease claims, because there may be circumstances where one RCT is adequate, particularly if corroborated by other kinds of scientific evidence. Imposing a categorical requirement of two RCTs might result in denying consumers useful, truthful information about products that have a demonstrated capacity to treat or prevent serious disease.**
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> **The fact that the FTC had imposed a requirement of two RCTs in prior orders was considered unpersuasive by the court, because most of the examples were non-litigated consent orders. Moreover, the court reasoned that the need for so-called "fencing-in" relief (the deterrence of future violations of law by those with a history of selective misinterpretation of medical studies) did not justify a two-RCT requirement where there was no showing that "the two-RCT requirement is reasonably linked to the particular history of [POM's] wrongdoing" and the order already required POM to base future claims "on competent and reliable scientific evidence that, *when considered in light of the entire body of relevant and reliable scientific evidence*, is sufficient to substantiate that the representation is true. [court's emphasis]"**

Although the history of this matter suggests that the POM defendants will almost certainly petition for *certiorari*, the court's decision is not a likely candidate for Supreme Court review. The court relied on well-settled law that is not particularly controversial among the various circuits. One would expect this decision to be the final stop.

KEY LESSONS FROM THE *POM* DECISION

The decision provides important reminders for advertisers making claims that link a food or dietary supplement to a health benefit.

First, there is no substitute for rigorous, clinical testing. **Randomized, controlled, double-blinded clinical trials (RCTs) with sufficiently large sample sizes are the gold standard for the FTC and the courts. If the advertiser wishes to make a claim that a product treats, prevents, cures, or mitigates a serious health condition, then at least one well-conducted RCT is highly recommended. However, as the court stated, "an advertiser . . . still may assert a health-related claim backed by medical evidence falling short of an RCT if it includes an effective disclaimer disclosing the limitations of the supporting research." (We offer more thoughts on such disclosures below.) In addition, if a particular claim is one that does not lend itself to scientific support via an RCT (for example, because of the nature of the claim or the product or the intended user), the advertiser should make that determination in consultation with appropriate experts and clearly document the basis for that conclusion.**

Second, advertisers must not ignore contrary evidence. **Even if one RCT provides support for a claim, the advertiser must consider the limitations on the research and decide whether such limitations are material in the context of the proposed claims. For example, if an RCT shows promising results at Week 6, but those improvements disappear by Week 12, it is likely misleading to advertise an unqualified claim that consumers saw an improvement "in just 6 weeks." Similarly, advertisers should not recharacterize results of studies or otherwise adjust study methodology, purpose, or endpoints to generate more positive results. This kind of *post hoc* data mining is universally criticized by leading medical and scientific experts.**

Third, the requirement of two RCTs for monadic, non-comparative disease claims is on the ropes but not dead. **The decision immediately generated considerable press for the one aspect where the court disagreed with the FTC: whether the FTC could require POM to conduct two RCTs to support future disease-related claims. It is important, however, to understand that the**

decision was limited to the factual record before the court and that the court ruled that the FTC had not provided adequate support for two RCTs *in this case.* The court did not, however, rule, as many in industry had hoped, that the FTC could never require two RCTs. In fact, the court held out the possibility that the FTC would be justified in requiring two RCTs for other kinds of claims, such as *comparative* claims for analgesic pain relief.

The FTC did not miss the court's message here. At a legal conference sponsored by the ABA in the weeks after the decision, FTC Chairwoman Ramirez signaled that the FTC would make sure to provide adequate support in the record for future cases in which it required two RCTs. So, for high-risk claims, we believe that the FTC's base substantiation standard is one "RCT *plus*" — that is, an RCT and other scientific evidence corroborating the RCT findings. Comparative efficacy claims might require two RCTs. In addition, although the POM case assessed RCTs in the context of health and disease claims, note that all five current Commissioners believe that the RCT standard also applies to weight-loss claims.

***Fourth, claims can and should be qualified to disclose material limitations.* For health claims, the court expressed doubts that words such as "preliminary" or "initial" were strong enough to alert consumers to research that was less than conclusive. As the FTC has stated in other contexts, to be effective, a disclaimer must be "clear," "conspicuous" (or even "unavoidable"), and easily understood. Fine print disclaimers simply do not work, as we have seen time and time again in enforcement proceedings. For this reason alone, advertisers should make sure that their marketing messages do not develop independently of claims substantiation and that changes to marketing messages over time are accompanied by a new review of the substantiation underlying new claims.**

***Fifth, liability for false advertising is sweeping and severe, and can attach to individuals who have the authority to control false claims.* The FTC does not typically seek to hold Chief Marketing Officers or other members of the C-Suite for large corporations liable for conduct that they were not directly involved in, but it commonly does so in cases involving smaller, closely held entities with less formal delineations of responsibilities and in cases where individuals turned a blind eye to violative conduct. The FTC can even follow the trail of allegedly "ill-gotten" gains to so-called "relief defendants" who may have passively profited from the false claims.**

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[1] **In another part of the Commission's majority decision, not discussed further here because it did not feature significantly in the D.C. Circuit opinion, it rejected the requirement that the defendants seek pre-approval from the FDA before making any drug-type claims.**

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