D.C. Circuit Upholds FTC on POM's Advertising, Strikes Two-Study Standard

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The U.S. Court of Appeals for the D.C. Circuit issued an opinion on Friday, January 30, upholding the Federal Trade Commission's findings that POM Wonderful's advertising, in which it claimed that consuming POM Wonderful pomegranate juice could prevent or reduce the risk of heart disease, prostate cancer, and erectile dysfunction, was deceptive. Although the D.C. Circuit acknowledged the importance of clinical trial evidence in supporting disease risk reduction claims, the Court disagreed with the Commission's application of the two randomized clinical trial (RCT) standard, finding it unjustified under the First Amendment.

The D.C. Circuit Held that POM's Advertising was Deceptive

The Court's opinion discusses the research that POM Wonderful conducted regarding heart disease, prostate cancer, and erectile dysfunction and how the studies were used to support the advertising. In this analysis, the Court was critical of POM's selective use of favorable small-scale studies in advertising while disregarding other, larger, unfavorable or inconclusive studies. The Court also noted certain inconsistencies in POM's arguments regarding the inability to conduct RCTs on certain food products, such as the hurdles of blinding and expense, both of which POM overcame to perform its own research. The Court gave appropriate deference to the agency as an expert in determining whether an advertisement is deceptive and substantively upheld the Commission's conclusion that POM's advertising was deceptive.

The D.C. Circuit Held that the Commission Could Not Justify the Two-Study Standard

The Court's broad deference to the Commission makes its dissent regarding the two-study standard particularly striking. The Court accepted that a robust RCT is necessary to support a disease reduction claim. However, using a *Central Hudson* First Amendment analysis, the Court found that the Commission failed to justify the requirement of two studies for all disease claims that POM might make in the future.

First, the Court rejected the Commission's reliance on precedent involving the two-study standard, noting that the key case cited - *Thompson Medical* Co., 104 F.T.C. 648 (1984) - involved comparative claims on OTC analgesics and that the nature of the product and the claims necessitated two studies. The Court also rejected the FTC's reference to recent consent orders involving two studies on the basis that those were not litigated matters and that the provisions in those orders are limited to specific disease claims, not all disease claims, as in the case with the POM Order.

The Court further rejected the FTC's argument that expert testimony supported the FTC's position that two studies are necessary to see if the result can be replicated. It pointed out that it seems

possible that, for some diseases, a single trial could be sufficiently robust as to meet the competent and reliable scientific evidence standard.

Finally, the court rejected the FTC's argument that the two-study standard is necessary because of the petitioners' propensity toward misrepresenting their evidence. The Court noted that the definition of "competent and reliable scientific evidence" requires the petitioners to rely on the "entire body of evidence." Therefore, there is no justification for an additional RCT.

Potential Implications for Industry

This decision has several potential implications for advertisers, as noted below:

- The discussion relative to the science and POM's selective use of it in advertising along with the company's decision to ignore unfavorable or inconclusive scientific results underscores the importance of considering the total body of evidence when determining whether claims are substantiated. Importantly, the Court found no compelling reason to reject the Commission's position that qualifiers such as “promising,” “initial,” and “preliminary” were not sufficient to convey the limited nature of the evidence, particularly when the specific results are characterized in unequivocally positive terms.

- This decision reaffirms the importance of non-RCT evidence in the analysis of the “total body of evidence.” In rejecting the two-study standard, the Commission surmises that a single clinical trial combined with observational research may be sufficient to support certain disease claims. The Court cites to FTC guidance, including the FTC’s *Dietary Supplements: An Advertising Guide for Industry,* as support for this position. This validation of the importance of non-RCT evidence and the Supplement Guide is welcome news, particularly for the dietary supplement industry.

- Recent consent orders suggest that the FTC had pivoted away from blanket application of the two RCT standard as early as last June. Commissioner Ohlhausen’s concurrance in the POM case suggested that the two-study standard was potentially up for debate. Later orders appeared to continue the discussion (GeneLink, L’Occitane Inc.) In June 2014, the i-Health, Inc./Martek Biosciences order involving memory improvement claims did not include the two-study standard but did include a data retention provision relative to the clinical study supporting the product claims.

- Prior to the D.C. Circuit’s opinion, Jessica Rich, Director of the FTC’s Bureau of Consumer Protection, stated that the FTC intended to seek the two-study standard for matters in which the respondent misrepresented their substantiation. This decision does not change the types of claims that are attractive enforcement targets. It may cause the agency to reconsider certain enforcement positions, however. In light of the Court’s opinion, the FTC may have to limit its use of the two-study standard to only those instances where the claim or the product would necessitate two studies to comply with the “competent and reliable scientific evidence” standard.

- Weight loss claims might be the exception. Even Commissioner Ohlhausen seems to have less of a problem when it comes to weight loss, primarily because relatively short trials are possible. She's also noted that, in some cases, there has been evidence of fraud while conducting weight loss trials, which weighs in favor of requiring replication (i.e., two trials).

- This decision may also cause the FTC to reconsider its blanket application of the data retention requirement, particularly where it is not tightly tethered to the underlying facts of the case.