Client Update

D.C. Circuit's *POM Wonderful* Decision Points To Reduced Substantiation Burden For Advertisers

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On January 30, the D.C. Circuit Court of Appeals held in *POM Wonderful, LLC, et al. v. Federal Trade Commission* that the FTC did not have an adequate basis to require POM Wonderful, LLC to conduct a minimum of two successful "randomized and controlled human clinical trials," or RCTs, before making any future advertising claims about its products' effects on disease prevention and treatment. The Court modified the FTC's order to require only one RCT. This is a blow to the FTC's efforts to promote the two-RCT standard, which has concerned consumer product companies that see the standard as costly and unnecessary.

BACKGROUND

POM touted medical studies as showing that its products have a beneficial effect on the prevention and treatment of heart disease, prostate cancer and erectile dysfunction. An administrative law judge upheld FTC staff charges of false advertising. The Commissioners of the FTC affirmed, finding numerous deficiencies in POM's studies, including small sample sizes, a lack of appropriate control groups, and statistically insignificant results. The FTC faulted POM for failing to acknowledge in advertisements that other studies showed the products had no effect on the studied diseases. The FTC also found that POM's references to the studies it did cite as "promising" or "initial" did not effectively neutralize the claims' falsity.

Going forward, for claims regarding general health benefits, the FTC order required POM to possess "competent and reliable scientific evidence," the FTC's baseline standard for all substantiation. For claims regarding effect on diseases, the order mandated that POM conduct at least two RCTs with statistically significant results.

This was only the latest in a series of somewhat controversial efforts by the FTC to promote two RCTs as a standard. Notably, in a series of high-profile consent orders arising out of national advertisers' claims about their products' health benefits, a two-RCT standard has been imposed going forward. Prominent examples include *In re L'Occitane, Inc.*, a consent order dealing with skin cream that was advertised for weight loss benefits, and *In re The Dannon Co., Inc.*, a consent order dealing with yogurt products that were advertised to promote regularity and reduce illness.

Because these were settlements, no court in recent years has evaluated the two-RCT standard. (In 1986, the D.C. Circuit did uphold a two-RCT standard for claims about the efficacy of over-the-counter painkillers in *Thompson Med. Co., Inc. v. F.T.C.*, 791 F.2d 189.) Even in the consent order context, though, the two-RCT standard was not universally embraced. FTC Commissioners Maureen Ohlhausen and Joshua Wright have questioned the imposition of a two-RCT requirement in certain consent orders, with Commissioner Ohlhausen calling two RCTs "a one-size-fits-all approach to substantiation" that "impos[es] . . . rigorous and possibly costly requirements" that could keep "useful information" from consumers.

D.C. CIRCUIT DECISION

POM petitioned the D.C. Circuit Court of Appeals for review of the Commission's order. The Consumer Healthcare Products Association, Council for Responsible Nutrition, Alliance for Natural Health USA and TechFreedom joined together as *amici curiae* in support of POM and in opposition to the two-RCT standard. In their brief, Alliance for Natural Health USA and TechFreedom argued that requiring RCTs for disease-related claims "ordinarily amounts to an outright prohibition on such claims," given the cost of an RCT, noting that the "FTC's own experts testified that a suitable study must involve 10,000 to 30,000 participants at a staggering cost of about $600 million."

In last week's D.C. Circuit decision, a three-judge panel first sustained the FTC's conclusion that POM's ads contained misleading and deceptive claims. But the Court reversed the two-RCT requirement on First Amendment grounds, applying the test for commercial speech restrictions found in *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980). While the Court agreed that the government has a substantial interest in the accuracy of information used to market products to consumers, it held that at least in this case, the two-RCT standard was not sufficiently tailored to protect that interest. Echoing Commissioner Ohlhausen, the panel said that under a two-RCT standard,

"consumers may be denied useful, truthful information about products with a demonstrated capacity to treat or prevent serious disease."

The Court noted that the FTC has required less than two RCTs in certain other orders involving disease claims — in some cases, requiring only the usual Commission baseline of "competent and reliable scientific evidence," and in others, just one RCT. The D.C. Circuit panel modified the POM order to require that POM possess one RCT before making future disease-related claims.

FTC RESPONSE AND IMPLICATIONS

The FTC responded to the D.C. Circuit decision with a public statement claiming victory, pointedly noting that two RCTs still might be warranted in some future cases. The statement did not suggest that the FTC plans to seek Supreme Court review in *POM*.

A movement towards one RCT could have significant implications for companies in reducing the time and cost needed to place truthful advertising claims about health benefits in front of consumers. It remains to be seen whether the FTC accepts last week's *POM* decision as signaling a fundamental disapproval of the two-RCT standard, or continues to push for two RCTs on the facts of future cases.

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Please do not hesitate to contact us with any questions.