POM Wonderful LLC Raises the Stakes at the D.C. Circuit

May 8, 2014

On May 2, 2014, POM Wonderful LLC ("POM") argued before the U.S. Court of Appeals for the D.C. Circuit, urging it to overturn a Federal Trade Commission ("FTC") decision prohibiting POM from making disease-related claims without first having at least two randomized and controlled human clinical trials ("RCTs") to back them up. POM argued that it will be impossible to perform two RCTs in accordance with the Commission's standard, noting that this standard has never been applied to food products in an FTC order. POM accused the FTC of holding POM, a beverage company, to the same standard as pharmaceutical companies.

In certain advertisements, POM touted a number of studies and questionnaires to support its claim that pomegranate juice and dietary supplements provide health benefits. According to the FTC, however, POM systematically distorted the results of these studies to imply greater health benefits than the results supported. Because of POM's history and alleged demonstrated propensity to suppress and distort scientific results, the FTC imposed the two-RCT requirement to curb misleading advertising and prevent recidivism. However, POM argued that "suppressing and distorting scientific evidence" did not form the basis of liability in the FTC's decision. According to POM, the FTC found the company liable for making unqualified disease claims *i.e.*, not having a particular level of substantiation. POM argued that the two-RCT requirement does not address POM's alleged lack of substantiation. Rather, that remedy addresses POM's alleged suppression and distortion of evidence, which was not a part of the FTC's liability finding.

Beyond being an ill-suited remedy, the D.C. Circuit panel raised concerns that the two-RCT requirement could suppress the release of beneficial data. Under the FTC's order, POM is prohibited from promoting the results of one double blind, randomized, placebo controlled study without having a second "gold standard" study. Judge Douglas B. Ginsburg queried whether the requirement to have two RCTs stifles research and restricts the flow of useful information to consumers. In response, the FTC argued that POM is free to test its draft advertisements with the advertising staff at the Commission. The FTC noted that certain restrictions could be bypassed with well-designed and adequately qualified studies.

Still, POM maintained that its claims were adequately qualified with disclaimers. POM argued that the FTC ignored its disclaimers and erroneously accused the company of making unqualified disease claims. Citing the D.C. Circuit's decision in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), POM argued that it should be allowed to share preliminary studies that are qualified by prominent disclosures. But, Judge Merrick B. Garland pushed back, stating that phrases like "emerging science" and "hopeful [or promising] results" used in marketing materials, such as those presented here, do not adequately qualify preliminary studies under *Pearson*.

The FTC issued its decision *In the Mater of POM Wonderful LLC* in January 2013. That ruling shed some light on the Commission's position as to the level of substantiation required to support a claim that a food or beverage product mitigates or treats a disease. While the FTC's ruling only applied to

POM, a decision from the D.C. Circuit may set the standards for all food and beverage advertisers. Kelley Drye continues to monitor this case and will provide updates. Please check back often.