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FTC Rules that "Randomized Clinical Trial" Evidence is Necessary to Support Advertising Claims for Juice Beverage and Related Products

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I. Introduction

If you represent food and beverage manufacturers who advertise their products, you will want to be familiar with *In the Matter of POM Wonderful LLC*, a recent decision by the Federal Trade Commission ("FTC"). The FTC's rather weighty decision (over 50 pages) contains a detailed look at the FTC's current stance on the type of evidence that an advertiser must possess in order to make claims about the ability of a food or beverage product to treat serious health conditions. This e-lert provides an overview of the advertising claims involved, a short explanation of the FTC's decision, and some of the key take-aways that you and your clients may want to consider in assessing your food and beverage advertising campaigns.

II. The Challenged Ads

POM Wonderful manufactures and sells a family of pomegranate juice and related products under a variety of "POM"-branded names. From 2002-2012, POM Wonderful spent close to $250 million advertising these products including on TV and radio, in print, and through social media outlets. To help garner its piece of the multi-billion dollar beverage industry, POM Wonderful's advertising campaign touted the health benefits associated with its pomegranate juices and related products. For example, many of the POM Wonderful ads claimed that the POM products would "treat, prevent, or reduce the risk of" serious health ailments such as "heart disease, prostate cancer, and erectile dysfunction." Most of the POM Wonderful ads boasted more specifically that "preliminary" and/or "promising" "clinical studies" proved that using the POM Products "treats heart disease, prostate cancer, and erectile dysfunction or prevents or reduces the risk of each of these diseases." Many of the ads also reinforced these claims by invoking "medical imagery" like white-coated lab technicians, a blood pressure cuff encasing a POM bottle, and EKG sensors, accompanied by taglines such as "[a]maze your cardiologist" and "[l]ucky I have super HEALTH POWERS."

The FTC challenged these ads (and others like them) in 2010, claiming that a total of 43 in all violated Sections 5(a) and 12 of the FTC Act. After a trial that spanned several months, the ALJ determined that 19 of the ads at issue contained implied claims that the products were effective at treating these health conditions and that 14 of those ads touted the existence of "clinical studies" to support those implied claims. While stopping short of requiring that POM Wonderful needed full-blown randomized clinical trial evidence to support these claims, the ALJ nevertheless found the ads deceptive and, accordingly, issued a cease and desist order.

III. The FTC Decision and the Key Take-Aways

In its detailed order reviewing the ALJ's decision, the FTC reviewed each of the ads at issue, the messages conveyed therein, and the underlying substantiation for the advertising claims as introduced at trial. The FTC went further than the ALJ and found that 36 of the 43 ads were deceptive. Although an in-depth review of the FTC order with respect to the individual ads is beyond the scope of this e-lert, there are a couple of key take aways that should be considered.

First, most of the ads produced by POM Wonderful contained "establishment" claims in that they specifically referenced "clinical trials" that allegedly showed that the POM Products were effective at treating, preventing, or reducing the risk of heart disease, prostate cancer, and ED. According to the FTC, when an advertiser claims that its food or beverage products treat, prevent, or reduce "serious diseases" such as the ones at issue, the advertiser must have "Randomized Clinical Trial" ("RCT") evidence to back up those advertising claims. A properly structured RCT will select participants randomly, will be double-blind, and will have both a test group and a control group. While POM Wonderful produced expert testimony regarding certain studies and other medical research regarding the general "health benefits" associated with pomegranates and pomegranate juice, the FTC found this evidence did not meet the RTC gold standard in a number of respects. The FTC also rejected the notion that requiring RCTs for food product health claims rises to the same level as the FDA's standards for proof of drug claims. The Commission made clear it was not holding POM to a pharmaceutical standard, because the FDA regulations for drugs require multiple phases of clinical trials producing different and greater substantiation than what the FTC required of POM. Interestingly, the FTC found that the POM products were food and dietary supplements, but also that they made disease prevention claims, a notable feature of what the FDA considers a drug claim.

Thus, the key holding in the decision makes it clear that when an advertiser claims that a food or beverage product helps treat, reduce or prevent serious diseases, the FTC is going to expect robust substantiation in the form of RCTs.

Second, consistent with prior FTC precedent, the decision makes it clear that when reviewing an ad for compliance with the FTC Act, it is necessary to consider the entire "gestalt" of the ad itself instead of considering individual elements. This principle was particularly important here because although some of the ads did not expressly rely on "scientific" evidence *per se*, the imagery and creative execution of those ads, particularly when combined with the text, would leave the consumer with the impression that using the POM Products at issue would be effective at treating, preventing, or reducing the risk of disease. For example, a POM bottle in the shape of an intravenous bag, the use of the Caduceus (a well-recognized symbol of the medical profession), and white-coated scientists all reinforced the message that these products at issue were effective in treating and preventing the serious health conditions that were mentioned in the ads. The FTC's treatment of the imagery is an important reminder that the visual effects of an ad simply cannot be divorced from the text. The unitary whole should always be considered.

Finally, the FTC decision also discusses the use of "qualifiers." In several of the ads, the scientific evidence relied upon was characterized as "preliminary," "promising," "encouraging," or "hopeful." POM Wonderful argued that because it qualified the nature of the clinical studies in this way, these particular ads were not making "establishment claims." The FTC rejected the argument finding that POM Wonderful's "use of one or two adjectives does not alter the net impression that clinical studies

prove their claims. This is especially true when the chosen adjectives – promising, encouraging, or hopeful – provide a positive spin on the studies rather than a substantive disclaimer."

IV. Conclusion

In the Matter of POM Wonderful LLC is an important decision to keep in mind when considering the type of health and wellness claims that can be made when it comes to food and beverage products. The claim-substantiation standard appears to have been raised to a level that is closer to what is required of drug claims, but that is applied here across product lines to food and beverage products. If the advertising claims impliedly or expressly assert that the product helps treat, prevent or reduce the risk of a serious health condition, then it will be necessary to back that up with well-designed and well-executed RCTs.

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