

Nutritional Outlook Quotes John E. Villafranco On Claim Substantiation in Light of POM Wonderful Decision

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Partner [John E. Villafranco](#) was quoted in the Nutritional Outlook article, "FTC Upholds Judge's Decision that POM Wonderful Made Unsupported Health Claims, Says Two Randomized Controlled Trials Needed to Support Any Claims." The FTC struck down an appeal from pomegranate firm POM Wonderful in a case that found POM guilty of making unsupported, deceptive health claims for its products. In its final order, the Commission stated that health claims should be supported by two randomized, well-controlled human clinical trials.

Mr. Villafranco commented, "No question; the decision marks yet another step toward the two-study requirement, In practice, the longstanding 'competent and reliable scientific evidence standard' has been dynamic and has been understood by industry to mean that advertisers should employ or retain experts to advise on the consensus among scientists for the type of studies needed to support a specific claim, to ensure that claims are based on evidence consistent with the state of science regarding the benefits of product ingredients at the time a claim is made."

" Today's decision represents the FTC's latest departure from the dynamic standard. This will undoubtedly make it harder for supplement manufacturers who seek safe harbor by modeling after requirements in FTC orders. It will also likely reduce the role of scientific experts in dictating the proper way to substantiate a claim, in favor of a rigid two-study requirement,." he said.

To read more, please click [here](#).