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15-SECOND ADVERTISING LAW ALERT

FTC ISSUES AWAITED POM DECISION; DUCKS KEY SUBSTANTIATION ISSUE

The Federal Trade Commission released yesterday its long-awaited decision on alleged drug claims made for POM Wonderful products and the substantiation needed to make such claims.*

BRIEF BACKGROUND

This was an appeal of an Administrative Law Judge decision by POM to the full Commission and a cross-appeal by FTC's Complaint Counsel who prosecuted the case.

The ALJ found that some challenged advertisements were false or misleading because they implied that POM products treat, prevent, or reduce the risk of heart disease, prostate cancer, or erectile dysfunction. He also found that some of those ads also unlawfully implied that that the claimed effects on disease were clinically proven.

The ALJ found that, for a safe food not advertised as a substitute for medical treatment, such claims needed to be supported by the "competent and reliable scientific evidence" standard, which he defined more narrowly than the FTC staff.

He did not mandate that one or more clinical studies must always be a necessary part of that standard. He also refused to define as a specific part of the evidentiary standard that required clinical studies be "well-designed, well-conducted, double-blind, randomized controlled clinical trials" (so-called "RCTs").

POM appealed virtually every liability-related facet of the ALJ decision. Among other things, FTC's Complaint Counsel appealed the ALJ's refusal to impose the specific RCT terms as part of the standard. It also appealed the ALJ's refusal to require U.S. Food and Drug Administration pre-approval of future disease-related ad claims by POM.

DECISION

The Commission denied POM's appeal and added more claims to the liability list. More important, it declined to "reach the question of the number of RCTs needed to substantiate the claims made" as a general standard; it did require, however, that future POM disease-related claims be supported by at least two RCTs. It also declined to require FDA pre-approval of any such claims.

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* *In the Matter of POM Wonderful LLC, et al.*, Docket No. 9344 (Jan. 10, 2013).