Substantiation in the Wake of POM Wonderful

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On January 10, 2013, the Federal Trade Commission issued an Opinion *In the matter of POM Wonderful LLC*[2] upholding in part and overruling in part Chief Administrative Law Judge D. Michael Chappell's May 2012 Initial Decision[3] regarding advertising claims for POM Wonderful products. The decision is the most important announcement on advertising law from the FTC in years, with a wealth of warnings and rules for advertisers remember. A summary of the policies addressed:

Substantiating claims – the FTC announced the levels of substantiation required to back claims that a food provides nutritional benefits, claims of general health benefits, and claims that a food treats, mitigates or prevents a "serious disease." Reaffirming the Substantiation doctrine, in effect at the Commission for over thirty years, the FTC explained when it would demand clinical trials and whether it would demand FDA preapproval of claims.

Interpreting claims – the FTC explained whether, when and how it will rely on extrinsic evidence to identify qualified claims. As the agency has held in the past, the Commissioners ruled that they themselves could determine the meaning of many advertisements.

Remedies – to "fence in" POM, the order imposed tougher substantiation standards than the company's competitors will face for future advertising – a twenty-year disadvantage.

Individual liability – the decision imposed individual liability on company officers who participated in the marketing campaigns. Coming on the heels of multi-million-dollar recoveries in substantiation cases, this aspect of the decision raises the stakes in FTC advertising cases.

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[2] Opinion of the Commission *In the Matter of POM Wonderful LLC,* Docket No. 9344, available at http://www.ftc.gov/opa/2013/01/pom.shtm.

[3] Initial Decision by Chief Administrative Law Judge D. Michael Chappell available at http://www.ftc.gov/os/adjpro/d9344/index.shtm.

Background Regarding *In the Matter of POM Wonderful LLC*

The Commission's January 16th ruling addressed an appeal of the Initial Decision issued in May 2012. In the Initial Decision, the administrative law judge (ALJ) weighed charges that the makers of POM Wonderful 100% Pomegranate Juice and POMx supplements had made false and unsubstantiated claims in advertisements, promotions and media appearances that their products would prevent or treat heart disease, prostate cancer, and erectile dysfunction. He found:

> (1) Nineteen of the 43 challenged advertisements and promotional materials of concern to the FTC Staff implied that the challenged POM Products treat, prevent or reduce the risk of heart disease, prostate cancer, or erectile dysfunction ("ED");
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> (2) those 19 claims were false or misleading;
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> (3) and they were material to consumers' purchasing decisions;
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> (4) in the case of a safe food that is not advertised as a substitute for medical treatment, competent and reliable scientific evidence includes clinical studies though not necessarily double-blind, randomized, placebo-controlled clinical trials.

POM Wonderful appealed the Initial Decision arguing that the judge erred in (1) finding that any of the challenged advertising and promotional materials contain implied efficacy or establishment claims[4] that the challenged POM Products treat, prevent or reduce the risk of serious disease; (2) holding that substantiation for such claims required clinical studies; and (3) finding the foregoing claims to be material. POM also argued that the relief ordered by the ALJ was impermissibly broad and ran afoul of the First and Fifth Amendments and that individuals should not be held liable without more participation or control over the advertising.

FTC Staff cross-appealed arguing that (1) the ALJ should have found that all of the 43 challenged advertisements and promotional materials (including four media interviews) made efficacy claims; (2) all but four of these materials also included establishment claims; (3) the ALJ incorrectly applied a substantiation standard requiring only clinical studies, rather than the higher standard of well-designed, well-conducted, double-blind, randomized controlled clinical trials (referred to in the Opinion as "RCTs"). As for the level of substantiation necessary to support future disease claims, Staff argued for pre-approval by the Food and Drug Administration ("FDA").

Upon appeal, the Commission was able to review the case *de novo.* Unlike a federal or state court of appeals, the Commission may consider and decide any factual issue it deems worthy of its attention.

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[4] "Establishment claims" are claims that the products' efficacy has been established scientifically.

Summary of Commission Decision *In the Matter of POM Wonderful LLC*

In pertinent part the Commission Opinion, issued by Commissioner Maureen Ohlhausen, ruled the following:

- Thirty-six (not just nineteen) of POM's 43 ads made efficacy claims and were false and misleading;
    - The Commissioners did not need extrinsic evidence to determine what the ads implied;
    - And they found qualifications such as "may" or "can" in the ads insufficient to moderate the meaning of claims that the FTC found more forceful;
- The Commission's traditional substantiation test would apply;
    - That standard meant that two well-designed, well-conducted, double-blind, randomized controlled clinical trials (RCTs) would be required to substantiate claims that a food can treat, prevent or reduce the risk of the "serious diseases" that POM was discussing in its advertising;
- These conditions do not violate POM's 1st or 5th amendment rights; and
- FDA-preapproval is *not* warranted as part of the remedy in the POM action;
    - But the Commission did not close the door to the requirement in another case.

The Commission also agreed with the ALJ's conclusion that the Respondent's actions were serious and deliberate. Sidestepping one of the more controversial aspects of the case, the Commission declined to base liability on media interviews.

Two Commissioners issued concurring statements: one by Commissioner Ohlhausen (rejecting the two RCT standard and concluding that extrinsic evidence should have been used to determine whether some of POM's ads made implied disease claims)[5] and another by Commissioner J. Thomas Rosch (agreeing with the majority Opinion but noting that "having served as a Commissioner for seven years and having been a trial lawyer for nearly 40 years before… [he is] somewhat skeptical of relying so heavily on the opinions of experts who are paid by both Complaint Counsel and Respondents").[6]

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[5] Concurring Statement of Commissioner Ohlhausen available at http://www.ftc.gov/opa/2013/01/pom.shtm.

[6] Concurring Statement of Commissioner Rosch available at http://www.ftc.gov/opa/2013/01/pom.shtm.

Among the notable Commission rulings and announcements were the following:

- **Qualifiers may not limit the level of substantiation required for a health-benefit claim.** According to the Commission, "[u]se of qualified language such as 'may' or 'can' with respect to the effects of the Challenged POM Products on disease does not modify the messages being conveyed," and "qualifying language with respect to cited studies (such as 'preliminary,' 'promising,' 'encouraging,' or 'hopeful') fails to materially alter the overall net impression that such advertisements were claiming clinical proof."[7] Here the Commission referred to its "Guides Concerning Use of Endorsements and Testimonials in Advertising," 16 C.F.R. § 255.2, and cases and studies involving "up to" claims, which purported to show that consumers do not perceive qualifications.[8]

- **The Commission could determine the net impression of the challenged claims without relying upon extrinsic evidence.** After noting that the Commission considered the extrinsic evidence provided by both parties, the Commission decision clarifies that "only a facial analysis is necessary to determine whether Respondents had indeed made the claims alleged by Complaint Counsel."[9] Commissioner Ohlhausen (who also submitted a concurring opinion), believes that the qualifying language used in some of the exhibits required extrinsic evidence to find an implied claim, but the majority disagreed.

- **The two-clinical-trial standard imposed by the Commission is limited to "serious disease claims."** The Commission attempts to limit the two-RCT standard imposed by the decision to claims regarding the efficacy of particular foods to treat, prevent or reduce the risk of "serious diseases."[10]

- **The Commission considers claims that a product can treat, prevent, or reduce the risk of heart disease, prostate cancer, or erectile dysfunction to be "serious disease claims."** Thus, these claims would require two RCTs.

- **The Commission distinguishes "serious disease claims" from general nutritional and health-benefit claims.** The Commission decision notes that the ALJ and POM experts concluded that RCTs were not necessary to support POM's claims. The Commission justifies departing from the ALJ and POM expert findings, by concluding that both the ALJ and experts based their findings regarding the appropriate substantiation for POM's claims on an unsupported conclusion that POM's claims were general health benefits

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7 *Id.* at 15.

8 *Id.* at 13-14, n 12.

9 *Id.* at 14.

10 *Id*. at 37. Commissioner Rosch submitted a concurring statement, ruling that ED should not be considered a "serious disease," but agreed that 2 RCTs are required *In the Matter of POM Wonderful LLC* because POM made establishment claims regarding the products' efficacy.

claims and not disease prevention claims.[11] The Commission also rejected the ALJ's determination that the level of substantiation needed to support representations that a product treats, prevents, or reduces risk of disease varies according to whether the advertiser offers the product as a replacement for traditional medical care.[12]

- **According to the Commission, expense is insufficient to overcome the RCT standard for serious disease claims**. The Commission rejected the argument that, because of its expense, two RCTs are inconsistent with the Pfizer factors, stating "[a]s we have previously explained, '[w]here the demands of the purse require such compromises [in methodology], the advertiser must generally limit the claims it makes for its data or make appropriate disclosures to insure proper consumer understanding of the survey's results."[13]

- **The Commission upheld individual liability for POM's past president and chief operating officer (COO).** The Commission upheld the ALJ's ruling that Mr. Tupper, a past COO and President of POM Wonderful who, at the time of his employment, was responsible for the operations of the marketing team, "both participated directly in and had the authority to control the acts or practices at issue," and thus should be held individually liable, along with owners Stewart and Lynda Resnick. Pending appeal, all will be subject to a Final Order.

In sum, although the POM case reaffirmed the framework that has governed the law of advertising, the decision gives important lessons on the application of the rules and raises the stakes for failing to follow them.

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[11] *Id.* 19- 22 ("As discussed previously, our conclusions differ from that of the ALJ in that the ALJ relied on expert testimony describing the level of substantiation that would support general claims of "health benefits" associated with consumption of the Challenged POM Products, rather than focusing on the expert testimony about the level of substantiation needed to support the specific disease treatment and prevention claims that are conveyed by Respondents' ads.").

[12] *Id.* at 21.

[13] *Id.* at 37.