

Client Alert

Latham & Watkins Corporate Department

***POM Wonderful* Opinion Provides Limited Clarification on FTC Substantiation Requirements**

The food and dietary supplement industries have struggled to interpret and implement the Federal Trade Commission's (FTC's) unsettled standard on health claim substantiation. Many in the industry had hoped that the FTC's Office of Administrative Law Judges would clarify its substantiation standard when it issued its decision in the matter of *POM Wonderful LLC* on May 17, 2012.¹ While the decision answered some questions regarding the type of substantiation that is *not* required for certain health-related claims, it remained vague on the type, quantity and quality of support that is required. The decision provided food and dietary supplement manufacturers some relief from some of the more intimidating FTC substantiation requirements, but they must continue to thoroughly and carefully substantiate their claims in light of the uncertainty that remains.

The FTC Regulation of Substantiation for Health-Related Claims

The Food and Drug Administration (FDA) and the FTC share responsibility for the regulation of the advertising and marketing of dietary supplements. Specifically, as described in a Memorandum of Understanding (MOU) governing the division of responsibilities between FDA and the FTC, the FTC is primarily responsible for dietary supplement advertising (under the umbrella of food advertising) and FDA is responsible for its labeling.² Both agencies share an interest in ensuring that advertising or labeling claims have sufficient support, or substantiation, to prevent the distribution of products that are misbranded or marketed with false and misleading claims. FDA relies on the Dietary Supplement Health and Education Act of 1994 (DSHEA) for its jurisdiction over the safety and labeling of dietary supplements, while the FTC derives its authority from the Federal Trade Commission Act (FTC Act). Because DSHEA does not define "substantiation," FDA has relied on its own expertise as well as that of the FTC to ensure that the standard that was consistent.³ The FTC has taken the position that claims that concern health, safety or product efficacy must be supported by "competent and reliable scientific evidence."⁴

"How this opinion will shape regulatory requirements for future health efficacy claims remains to be seen."

The FTC case law defines “competent and reliable scientific evidence” as: “[T]ests, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.”⁵ In deciding whether an “efficacy claim” relating to a product’s attributes, performance or efficacy is adequately substantiated, the FTC will assess: (1) the type of claim — safety, efficacy, health, dietary, etc; (2) the product — food, drug, dietary supplement, etc; (3) the consequences of a false claim; (4) the benefits of a truthful claim; (5) the cost of developing substantiation for the claim; and (6) the amount of substantiation that experts in the field believe is reasonable.⁶ These considerations, known as the *Pfizer* factors,⁷ do not clearly articulate the scope or nature of the information or data required to support the efficacy claim. An “establishment claim” is an “express or clearly implied statement that the advertising claim is supported by scientific or medical studies.” FTC requires that establishment claims must be supported by the level of substantiation represented in the advertisement.⁸ Failing to provide this substantiation constitutes an unfair or deceptive act or practice in violation of the FTC Act. Both types of claims are at issue in the *POM Wonderful* (POM) decision.

The POM decision arose in the context of a conflict between the FTC and food and dietary supplement manufacturers over the type and amount of “competent and reliable scientific evidence” that is needed to support health-related claims. This conflict was highlighted in 2010 by the *Iovate* and *Nestle* consent orders, in which the FTC defined “competent and reliable scientific evidence” in the context of weight loss claims (*Iovate*) and claims to reduce the duration of diarrhea in children and correspondingly reduce absences from daycare and school (*Nestle*). According to the FTC consent orders, competent and reliable scientific evidence to support these claims requires “at least two adequate and well-controlled human clinical trials.”⁹ To the industry’s dismay, the FTC consent orders imposed a substantiation requirement that appeared to be equivalent to that applied by FDA to establish efficacy in the drug approval process.¹⁰ The FTC consent order also required *Iovate* to obtain FDA approval for any claims that its products treat, prevent or mitigate a disease.¹¹ The consent order suggested that a less stringent level of substantiation may suffice for the companies’ other health-related claims, but did not provide examples of the types of claims that did not require the support of two well-controlled human trials.

The FTC’s conclusion in *Iovate* and *Nestle* that certain health-related claims must be supported by two adequate and well controlled human trials appeared to reflect a shift in the FTC’s historical interpretation of the “competent and reliable scientific evidence” standard.¹² However, because the FTC consent orders were issued in the context of specific enforcement actions and continued to suggest that not all claims were subject to this heightened standard, they did not provide needed clarity or predictability regarding the level of substantiation required for health-related claims more generally. In mid-May of 2012, the FTC again took up the issue of the level of substantiation required for health-related claims in the POM decision.

History of the *POM Wonderful* Matter

In September 2010, POM was among the first companies to proactively oppose the FTC’s emerging preference for randomized controlled trials (RCTs) and FDA approval to support disease prevention or treatment claims. In response to the *Iovate* and *Nestle* consent decrees, POM filed a complaint in the United States

District Court for the District of Columbia alleging that the FTC's interpretation of the "competent and reliable scientific evidence" standard was outside of the agency's authority. POM also alleged specific injury claiming that the FTC had informed POM that RTCs would be required to support its disease claims in the future.¹³ POM also alleged that the FTC had exceeded its authority by requiring FDA approval of certain health-related claims, regardless of the substantiation available. POM argued that the FTC Act did not authorize the FTC to require FDA approval to render such claims non-deceptive.¹⁴

Two weeks after POM filed its complaint, the FTC filed an administrative complaint against POM and its parent company, Roll Global, alleging that claims that the POM products prevented or reduced the risk of heart disease, prostate cancer and erectile dysfunction were inadequately substantiated and therefore false and misleading in violation of sections 5(a) and 12 of the FTC Act.¹⁵ POM argued in response that its advertising and promotional materials were substantiated by substantial scientific research and that the FTC erred by applying an overly stringent substantiation standard. The case went before the Office of the Administrative Law Judge (ALJ) on May 24, 2011 and concluded on November 4, 2011. Both parties filed their post-trial and reply briefs in January and February 2012 respectively, and closing arguments were held on March 6, 2012.¹⁶

POM Wonderful Decision

On May 17, 2012, the ALJ, Chief Administrative Law Judge J. Michael Chappell, issued a 335 page initial decision, in which he agreed with the FTC that POM's claims that its products could treat heart disease, prostate cancer and erectile dysfunction, or were clinically proven to do so, were inadequately substantiated and thus false and misleading.¹⁷ In reaching this decision, the ALJ stated that he had evaluated the claims, the substantiation proffered to support them and the testimony of experts in the fields of cardiology and male reproductive health. Based upon this review, the ALJ concluded that POM's claims were not adequately substantiated. Significantly, however, the ALJ did not adopt the substantiation standard advocated by the FTC.

Specifically, the ALJ concluded that the FTC's position that health-related claims must be supported by randomized controlled clinical trials was not authorized by the FTC Act.¹⁸ The ALJ said that claims that a food or food derived product treats, prevents or reduces a disease had to be supported by adequate clinical data, but double-blind, randomized, placebo controlled trials were not necessarily required. Finally, the opinion concluded that more generalized claims that POM's products support prostate health and promote heart health were vague and general enough that they did not necessarily represent disease claims requiring clinical data.¹⁹ The opinion's main conclusions were as follows:

FTC's substantiation standard does not require food and dietary supplement advertisers to obtain FDA approval to make health-related claims for their products

In its lawsuit against POM, the FTC argued that FDA approval was required for any claims that POM's products were effective in the "diagnosis, cure, mitigation, treatment or prevention of [a] disease."²⁰ The ALJ concluded that this requirement was "unsupported by governing precedent" since no previous Commission decision or court ruling (including cease and desist orders) had required FDA approval for such claims²¹ and the FTC Act did not provide any basis for this requirement.²²

Instead, the opinion concluded that the quantum of evidence required to satisfy the FTC's substantial evidence standard depended on the level of substantiation that experts in the field would reasonably require to support the particular claim.²³ This inquiry required solicitation of expert testimony and consideration of various factors including the nature of the product and claims and the risks and benefits of the truth or falsity of the claims.²⁴ In other words, the application of the substantiation standard was variable because it was both claim and product-specific.

Although the POM opinion concluded that the FTC could not require that a company obtain FDA approval before making disease claims, it did not address FDA's authority to do so. Although FDA approval is not required under the FTC Act, the FDA, pursuant to its own authority under the Food, Drug and Cosmetic Act, may impose approval requirements if claims exceed those permitted for foods or dietary supplements. According to FDA's regulations, if a dietary supplement label bears a claim that the product can "diagnose, mitigate, treat, cure or prevent disease," it is subject to FDA's regulation as a drug.²⁵ FDA is likely to treat conventional foods similarly to dietary supplements when assessing whether a disease claim has been made.²⁶ Moreover, FDA must pre-approve all disease claims and such claims can be applied only to those food products and drugs that have already been approved by FDA.²⁷ Regardless of the FTC's authority to impose substantiation requirements for the product's claims, food and dietary supplement manufacturers must also remain mindful that their product claims can subject them to additional FDA requirements if their claims exceed those permissible for food and dietary supplement products.

Disease claims may require clinical studies, but do not necessarily require double-blind, randomized, placebo controlled studies (RCTs) under the FTC's substantiation standard

In the POM matter, the FTC argued that POM's disease related claims were required to be supported by RCTs, defined as well-designed, well conducted, randomized, double-blind, placebo-controlled human clinical trials, in order to demonstrate the claims were substantiated by "competent and reliable scientific evidence." This requirement proffered by the FTC mirrors FDA's standard for evaluating an application for a new drug approval. The opinion concluded that neither the FTC Act nor applicable law supported this requirement. Instead, the ALJ concluded that the determination of appropriate substantiation was a question of fact to be determined by the testimony of experts at trial.²⁸

In determining the level of substantiation required for POM's health-related claims, the opinion focused on the sixth and final *Pfizer* factor, the "amount of substantiation that experts in the field would agree is reasonable."²⁹ Although the FTC had identified several cases³⁰ in support of its position that RCTs were required to support health-related efficacy claims, the decision noted that all or most of those cases acknowledged that the determination of what constitutes "competent and reliable evidence" was a question of fact based on what experts in the field consider to be reasonable. Thus, the ALJ confirmed that depending on what experts in the profession would reasonably require to support a particular claim, scientific evidence other than RCTs may be sufficient.³¹

In the POM matter, the parties presented the testimony of as many as 14 experts in the areas of heart disease, prostate cancer and erectile dysfunction. The opinion concluded that the experts' testimony supported the conclusion that, although experts in the field would not necessarily require RCTs to support claims relating to the treatment or prevention of those diseases, clinical studies would be required.³² The opinion also concluded that the FTC failed to establish that claims that the

product promotes health are “disease claims,”³³ suggesting that a lower level of substantiation is required to support such claims. Whether human or animal studies would be required for health-promotion claims remains to be seen.

In the POM decision, the ALJ concluded that the expert testimony supported the need for RCTs to substantiate claims for nutrient supplements where the product marketing (a) includes a claim that the product treats, prevents or reduces the risk of a disease *and* (b) offers the supplement as a replacement to medical products for such a purpose.³⁴ Although POM claimed that its products prevented, reduced or treated heart, prostate and other diseases, the company did not market these products as an alternative to medical treatment.³⁵ The ALJ highlighted the safety of the product as an important factor for experts to consider in deciding whether RCTs should be required. He found in the POM matter that the, “[g]reater weight of the persuasive expert testimony in this case leads to the conclusion that where the product *is absolutely safe*, like POM Products, and where the claim or advertisement *does not suggest that the product be used as a substitute for conventional medical care or treatment* (emphasis added), then it is appropriate to favor disclosure.”³⁶ Both the ALJ and experts agreed that for such disease claims, “competent and reliable evidence” must include human, clinical studies to show that the product did, in fact, treat, prevent or reduce the risk of disease as claimed, but that these studies did not have to be RCTs.³⁷

A disease claim is more likely to exist if the disease is referred to by name, or the advertisement uses specific language or images tied to the disease

The ALJ also considered whether POM utilized disease claims in its advertising and marketing materials. For example, POM utilized an image of a POM juice bottle saying, “I’m off to save Prostates!” and an image of a POM juice bottle inside a blood pressure cuff with the headline “decompress,” in its advertising. The ALJ concluded that these marketing pictures did not constitute disease claims or more specifically, did not constitute claims to treat prostate cancer and heart disease respectively. In deciding that these advertisements did not contain disease claims, the ALJ found persuasive that the advertisements:

- Did not refer to a disease by name
- Used vague, non-specific, substantially qualified and/or otherwise non-definitive language
- Used language/images inconsistent with the alleged claim
- Did not draw a connection between health benefits or study results and effectiveness for the disease³⁸

Although food and dietary supplement advertisers will not necessarily avoid FTC scrutiny by incorporating these factors into their marketing materials, adopting them may reduce the risk that the FTC will identify a disease claim within an advertisement.

Additional guidance for food and dietary supplement advertisers

The decision offered several other notable insights for food and dietary supplement advertisers:

- Status as a food or food-derived supplement decreases the likelihood that a reasonable consumer will interpret certain claims as drug treatment claims³⁹
- Using qualified language (“may,” “can”) does not necessarily eliminate or prohibit the possibility of making a concrete claim. Common sense and academic

literature reject the notion that a stronger claim cannot be inferred when these words are present. A consumer's interpretation of the claim depends on the "context and totality of advertisement."⁴⁰

- In order to adequately substantiate claims that a product effectively prevents or treats a disease, experts agree that in vitro and animal study results alone are generally insufficient. Successful results from human studies are generally required as well.⁴¹

Conclusion

The ALJ opinion in the POM matter concludes that the FTC cannot require FDA approval or RCTs to substantiate disease claims made by dietary supplement and conventional food companies. However, whether some human clinical study is required is still an open question. The ALJ acknowledged that the determination was very fact specific and made it clear that substantiation requirements depended on what experts stated was reasonable based on the nature of the product, the nature of the claims and the weight of the evidence. How this opinion will shape regulatory requirements for future health efficacy claims remains to be seen. Both the FTC and POM Wonderful have appealed the decision, so the substantiation debate will continue for some time to come. Both sides just made oral arguments at the end of August. Nonetheless, advertisers should attempt to avoid the implication that a product could be an alternative to medical treatment, and because disease claims continue to be subject to FDA review and approval, industry should continue using its best efforts to avoid unapproved drug claims and ensure that its health-related claims have defensible substantiation under its best understanding of "competent and reliable scientific evidence."

Endnotes

- ¹ *In re Pom Wonderful LLC*, No. 9344, Initial Decision at 328 (FTC May 17, 2012), available at <http://www.ftc.gov/os/adjpro/d9344/120521pomdecision.pdf>.
- ² Memorandum of Understanding Between Federal Trade Commission and the Food and Drug Administration, 36 Fed. Reg. 18,539 (FTC Sept. 15, 1971) (notice).
- ³ Lesley Fair, *Substantiation: The Science of Compliance*, <http://business.ftc.gov/documents/substantiation-science-compliance> (last visited Sept. 27, 2012).
- ⁴ *Id.*
- ⁵ *In re Novartis Corp.*, 127 F.T.C. 580, 725 (1999).
- ⁶ *In re Pfizer Inc.*, 81 F.T.C. 23, 91 (1972); see also *In re Thompson Med. Co., Inc.*, 104 F.T.C. 648, 821 (1984), *aff'd*, *Thompson Med. Co., Inc. v. FTC*, 791 F.2d 189 (D.C. Cir. 1986).
- ⁷ Letter from Donald S. Clark, Secretary, FTC, to Jonathan W. Emord, Attorney, Emord & Assocs., P.C., (Nov. 30, 2000) (on file with the Federal Trade Commission), available at <http://www.ftc.gov/os/2000/12/dietletter.htm>.
- ⁸ *In re Pom Wonderful LLC*, Initial Decision at 237.
- ⁹ *In re Nestle Healthcare Nutrition, Inc.*, No. 092 3087, Decision and Order at 3 (FTC Jan. 12, 2011), available at <http://www.ftc.gov/os/caselist/0923087/110118nestledo.pdf>; Stipulated Final Judgment and Order for Permanent Injunction and Other Equitable Relief at 7, *FTC v. Iovate Health Scis. USA, Inc.*, No. 10-CV-587 (W.D.N.Y. July 29, 2010)..
- ¹⁰ CTR. FOR DRUG EVALUATION AND RESEARCH & CTR. FOR BIOLOGICS EVALUATION AND RESEARCH, U.S. DEP'T OF HEALTH AND HUMAN SERVS., GUIDANCE FOR INDUSTRY: CLINICAL TRIAL ENDPOINTS FOR THE APPROVAL OF CANCER DRUGS AND BIOLOGICS at 2, 11 (2007), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm071590.pdf>

- ¹¹ *Iovate Health Scis.*, Stipulated Final Judgment at 5-6.
- ¹² See *In re Dannon Co., Inc.*, No. 0823158, Decision and Order (FTC Jan. 31, 2011), available at <http://www.ftc.gov/os/caselist/0823158/110204dannondo.pdf> (requiring two clinical studies for claims that the product relieved temporary irregularity); *Beiersdorf, Inc.*, No. 092-3194, Decision and Order (FTC Aug. 17, 2011), available at <http://www.ftc.gov/os/caselist/0923194/110823beiersdorfd.pdf> (requiring two clinical studies for claims related to weight or fat loss); *In re Brown*, No. 102-3205, Decision and Order (FTC Oct. 13, 2011), available at <http://www.ftc.gov/os/caselist/1023205/111021dermapsdo.pdf> (requiring two studies for claims regarding the effective treatment of acne).
- ¹³ Compl. for Declaratory Relief at 2, *POM Wonderful LLC v. FTC*, No. 1:10-cv-01539 (D.D.C. Sept. 13, 2010).
- ¹⁴ *Id.* at 8, 10; see also Carolyn B. Phenicie, *FTC's Consent Orders Chill Speech in Industry*, *Emord Petition Says*, TAN SHEET (Elsevier Bus. Intelligence, Bridgewater, N.J.), May 16, 2011.
- ¹⁵ Ben Rooney, *POM Wonderful Charged With Selling Snake Oil*, CNN MONEY (Sept. 27, 2010), http://money.cnn.com/2010/09/27/news/companies/POM_Wonderful/index.htm
- ¹⁶ Docket Sheet of No. 9344 for *In re POM Wonderful, FTC*, <http://www.ftc.gov/os/adjpro/d9344/index.shtml> (last visited Sept. 27, 2012).
- ¹⁷ *In re Pom Wonderful LLC*, Initial Decision at 6.
- ¹⁸ *Id.* at 328.
- ¹⁹ *Id.* at 223-224, 246.
- ²⁰ *Id.* at 315.
- ²¹ *Id.* at 316, 330.
- ²² *Id.* at 321.
- ²³ *Id.* at 244, 289 and 319.
- ²⁴ *Id.* at 318.
- ²⁵ *Structure/Function Claims*, FDA, <http://www.fda.gov/Food/LabelingNutrition/LabelClaims/StructureFunctionClaims/default.htm> (last updated July 28, 2010).
- ²⁶ *Guidance for Industry: Structure/Function Claims, Small Entity Compliance Guide*, FDA (Jan. 9, 2002), <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm103340>.
- ²⁷ *Small Entity Compliance Guide: "Structure/Function Claims;" Availability*, 67 Fed. Reg. 1225 (FTC Jan. 9, 2002), available at <http://www.gpo.gov/fdsys/pkg/FR-2002-01-09/pdf/02-451.pdf> (notice).
- ²⁸ *In re Pom Wonderful LLC*, Initial Decision at 238.
- ²⁹ *In re Thompson Med.*, 104 F.T.C. at 821.
- ³⁰ See *FTC v. Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d 285, 303 (D. Mass. 2008); *FTC v. Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d 1167, 1202 (N.D. Ga. 2008); *In re Thompson Med.*, 104 F.T.C. at 821.
- ³¹ *In re Pom Wonderful LLC*, Initial Decision at 239.
- ³² *Id.* at 328.
- ³³ *Id.* at 222-223.
- ³⁴ *Id.* at 242-243.
- ³⁵ *Id.* at 246.
- ³⁶ *Id.* at 5, 248.
- ³⁷ *Id.* at 5, 253.
- ³⁸ *Id.* at 222.
- ³⁹ *Id.* at 222.
- ⁴⁰ *Id.* at 233.
- ⁴¹ *Id.* at 256, 275.

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