

### **FTC Drops Bomb on Pom: Finds Ads Touting Health Benefits of Pomegranates Unsubstantiated and False**

Last week, the Federal Trade Commission issued its much-anticipated ruling in the agency's case against POM Wonderful. In a unanimous 5-0 decision, the Commission found that Pom's advertisements touting the amazing health benefits of its pomegranate juice and supplements were false. Finding that Pom's deceptive advertising was "serious and deliberate," the Commission issued a 20-year injunction that bars Pom from making disease-treatment or prevention claims for any products, unless supported by "two randomized, well-controlled, human clinical trials."

But the Commission stopped short of giving FTC prosecutors all of the relief they had requested. In a decision that should give some comfort to food and supplement makers, the Commission ruled that Pom is not required to obtain FDA's prior approval before making health claims for its products in the future.

#### **Commission Finds 36 Pom Ads Deceptive**

FTC filed suit against Pom in September 2010, alleging that 43 of Pom's ads conveyed false messages that its products are proven to treat, prevent, or reduce the risk of heart disease, prostate cancer, and erectile dysfunction. Following a full evidentiary hearing, an Administrative Law Judge held that 19 of the ads conveyed false disease-treatment or prevention messages. The ALJ further found that Pom's scientific "research" suffered from significant flaws and could not serve as competent and reliable substantiation. But the ALJ rejected the FTC's position that all disease-related claims for foods and supplements require randomized clinical trials like those routinely done by drug manufacturers.

Both Pom and FTC appealed to the full Commission. Based on its own examination of the 43 disputed ads, the Commission found that 36 were false and misleading—17 more ads than the ALJ had found unlawful. All 36 ads, in the Commission's view, combined references to clinical research, heart health, prostate health, and erectile dysfunction in ways that reasonably conveyed that Pom's products treat or prevent disease.

Pom had argued that its ads only conveyed that its products provide general health benefits. The Commission disagreed, ruling that Pom's reliance on parody, humor, and qualifiers such as "may" in its ads did not dispel their false disease-treatment and prevention messages.

#### **Randomized Clinical Trials Required For Disease Claims, Even For Foods**

The Commission disagreed with the ALJ's conclusion that randomized clinical trials are not required to substantiate disease-treatment and prevention claims for foods and supplements. In the Commission's view, only human clinical trials are sufficient to support such impactful health-related claims. Thus, according to the Commission, the fact that such studies are prohibitively expensive for most food and supplement manufacturers to perform is not a reason to hold foods and supplements to lower substantiation requirements.

The Commission did not decide whether food and supplement makers, in general, need one, two, or perhaps even more randomized clinical trials to support disease-treatment or prevention claims. But in light of the serious health conditions referenced in Pom's ads, and Pom's history of intentional deception, the Commission held that Pom must have at least two randomized clinical trials before it makes future claims regarding disease treatment or prevention.

### **FDA Pre-Approval Not Required**

In recent years, the Commission has resolved false advertising cases against other food and supplement makers with consent decrees that, as a "fencing in" remedy, require the companies to obtain FDA approval before making disease treatment or prevention claims in the future. The FTC staff sought to impose the same requirement on Pom, but the Commission balked.

The Commission offered little explanation for its decision not to require FDA pre-approval in this case, but by not ordering this remedy, the Commission was able to sidestep Pom's serious objection that FTC had exceeded its statutory authority by requiring FDA pre-approval in earlier cases.

### **Conclusion**

This fight is far from over. Pom has already stated that it intends to appeal the Commission's decision in federal court. But the decision is yet another reminder that food and supplement makers will be held to a high standard when touting the health benefits of their products or ingredients in advertising to consumers. FTC's crackdown on unsubstantiated disease claims for foods and supplements continues.

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