

## FTC Prevails In Case Against Pom Wonderful: Court Issues 20-Year Injunction Barring Unsubstantiated Health Claims

Earlier this week an administrative law judge ruled in favor of the FTC in its closely watched trial against Pom Wonderful, finding that years of advertising by Pom Wonderful falsely exaggerated the health benefits of pomegranate juice and dietary supplements.

The ruling, however, was not a complete victory for the FTC. The judge also rejected the FTC's arguments that aggressive health claims for foods and dietary supplements should be held to the same standard as drug advertising. And the judge declined to order the FTC's requested remedy, which would have required Pom Wonderful to obtain FDA pre-approval before making disease treatment and prevention claims for its products ever again.

### Pom Wonderful Ads Found Deceptive

For nearly a decade, Pom Wonderful was known for attention-grabbing advertisements touting millions of dollars of scientific research purportedly "proving" that pomegranate juice and pomegranate-derived supplements contain powerful antioxidants with unique health benefits. At trial, Pom Wonderful argued that these ads were both literally true, and so funny and light-hearted that no reasonable consumers would infer that its products actually treat or prevent diseases.

The judge was not amused. After carefully reviewing Pom Wonderful's ads, the judge held that many of the ads contested by the FTC strongly implied that Pom Wonderful's products actually treat or prevent heart disease, prostate cancer and erectile dysfunction. The fact that Pom Wonderful's ads were humorous was no defense.

The judge then conducted a painstaking review of Pom Wonderful's scientific research and found significant flaws in the studies. Given the studies' inherent limitations, Pom Wonderful lacked competent and reliable substantiation that pomegranate juice or supplements are capable of treating or preventing any diseases. Pom Wonderful's ads, therefore, were false or misleading in violation of the FTC Act.

The judge entered a sweeping injunction, barring the company from making false and unsubstantiated health claims for its products. Moreover, the injunction covers Pom Wonderful, its founders Stewart and Lynda Resnick, the company's president, and Pom Wonderful's parent company, which sells a variety of other food and beverage products such as Fiji water, Cuties tangerines, and Everybody's Nuts! pistachios. The injunction is to last for 20 years.

### Court Reaffirms The Competent And Reliable Evidence Standard

Although FTC emerged victorious, the judge disagreed with the FTC's position that food and dietary supplement manufacturers must conduct the same types of randomized clinical trials that the FDA requires of drug companies if their advertising suggests that their products are useful in treating or preventing diseases. The judge found that the standards that govern drug advertising are – and should remain – different from those that govern foods and supplements.

Unlike drugs, the judge noted that foods and supplements are generally safe and their side-effects are negligible. Moreover, whereas the efficacy of drugs can readily be tested through clinical trials, clinical trials on foods and supplements are

often very difficult, if not impossible, because foods are more difficult to "blind," differences in study participants' diets and nutritional status may confound the results, and the costs of conducting clinical studies on foods and supplements are often prohibitively expensive and cannot be recouped if the food or supplement is not patentable.

As such, the judge held that it would be unreasonable to expect food and supplement makers to always substantiate disease treatment and prevention claims with randomized clinical trials. Instead food and supplement makers should have "competent and reliable scientific evidence" to support such claims. What constitutes "competent and reliable" evidence will depend on what experts in the relevant field consider adequate for the type of health claims at issue. But especially in the case of foods, substantiation short of randomized clinical trials may be sufficient.

## Court Declines To Order FDA Pre-Approval

The court also declined to order the FTC's requested "fencing in" remedy, which would have required Pom Wonderful to obtain FDA pre-approval before making disease treatment or prevention claims for its products in the future.

In recent years, FTC has entered into consent decrees with a number of food and supplement makers that included this FDA "pre-approval" requirement. FDA approval is generally not required for food and beverage advertising, but FTC argued that requiring companies that have "done wrong" to obtain FDA pre-approval is necessary to ensure these companies' future ads remain "fenced in" the confines of the law.

The judge found that imposing a remedial order against a food and beverage company that requires FDA pre-approval was "unprecedented" and constituted "unnecessary overreaching" by the FTC. In the judge's view, a 20-year injunction barring Pom Wonderful from making unsubstantiated health claims, by itself, should be sufficient incentive for the company to reform its deceptive practices.

## Conclusion

Pom Wonderful and FTC both have publicly claimed victory in the days since the decision became public. It remains to be seen whether either side, if not both, will appeal. ♦

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