

# **Is POM Wonderful Really Wonderful? How the FTC, the FDA and Private Litigation Address Deceptive Food Advertising**

Dee Pridgen

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**PERCEPTIONS, PRACTICES & POLICIES**

Pom Wonderful –  
achieve immortality?

**Cheat death.**

The antioxidant power of  
pomegranate juice:



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# Minute Maid's Version



POM Wonderful v. Coca-Cola  
US Supreme Court  
June 12, 2014



# Acai Berry – magic berry from the rain forest?

- Weight loss?
- Prevents colon cancer?
- Claims made using fake news sites
- FTC got TRO & seeks permanent injunction in federal court against 10 websites, and against importer



# Activia – Can Yogurt prevent colds?

- “probiotic” yogurt products
- Boosts immune system & relieves temporary digestive irregularity
- FTC settlement in 2010 requires caveat that it takes 3 servings per day
- Company agreed to stop claiming yogurt can help people avoid catching colds or flu



# Cactus Juice for Pain?

- July 2014, FTC settled for \$3.5 million with makers of cactus juice advertised as “anti-inflammatory wellness drink”
- Claims were not backed by competent and reliable scientific evidence

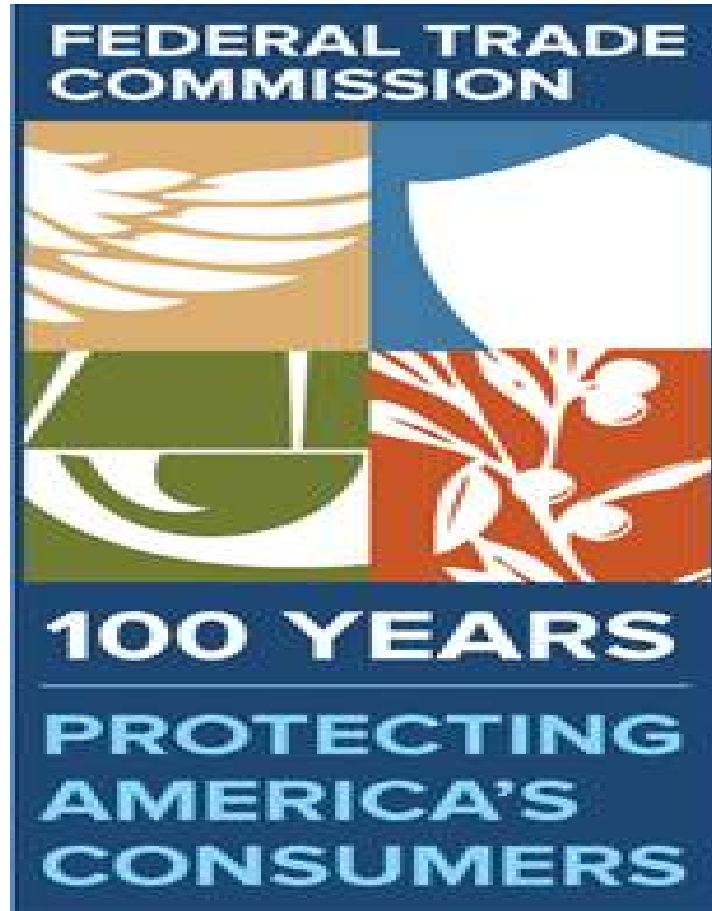


# Green Coffee Bean Extract – Lose Weight w/o diet or exercise? Not so fast, says FTC





# FTC Takes Action



# Federal Regulation of Food & Drugs

- Federal Trade Commission Act (1914, amended in 1938) prohibits unfair or deceptive trade practices and prohibits the dissemination of any false advertisement likely to induce the purchase of food or drugs
- Pure Food & Drug Act (1906) and Federal Food, Drug & Cosmetic Act of 1938 required ingredient labeling and pre-testing of drugs for safety & efficacy

# FDA/FTC Share Jurisdiction Over Food & Drugs

- FTC oversees food and dietary supplement advertising
- FDA oversees food labeling, prescription drug advertising, and over the counter drug testing and labeling
- FTC & FDA coordinate their efforts, FTC accords substantial weight to FDA scientific determinations

# FTC Advertising Substantiation Doctrine

- Ad substantiation doctrine developed in 1970's, in response to Ralph Nader petition
- Based on theory that all ads imply that the advertiser has a reasonable basis for their claims, and if they don't, it's deceptive
- Based on the Pfizer case from 1972, FTC listed six factors of reasonable basis: “the type of claim, the product, the consequences of a false claim, the benefits of a truthful claim, the cost of developing substantiation for the claim, and the amount of substantiation experts in the field believe is reasonable.”

# Sterling Drug v. FTC, 9<sup>th</sup> Cir. 1984

- Claim of superior efficacy for Bayer aspirin made through images in ads
- Claim that efficacy is scientifically established for OTC drug requires two well-controlled clinical studies



# FTC AD SUBSTANTIATION 1984 Policy

<b><u>Type of Claim</u></b>	<b><u>Substantiation Required</u></b>
Most Claims	Reasonable basis
Limited Claims	Substantiation specified in advertisement
“Puffing”	No substantiation
“Establishment” claims for OTC drugs	Two well-controlled clinical studies

# Dietary Supplements and the Effect of DSHEA

- Dietary Supplement Health & Education Act of 1994
- Created separate class of products known as “dietary supplements” which do not need FDA pre-marketing approval
- Dietary supplements often make “drug-like” claims and such claims still need to be substantiated

# Kraft, Inc. v. FTC, 970 F.2d 311 (7<sup>th</sup> Cir. 1992)

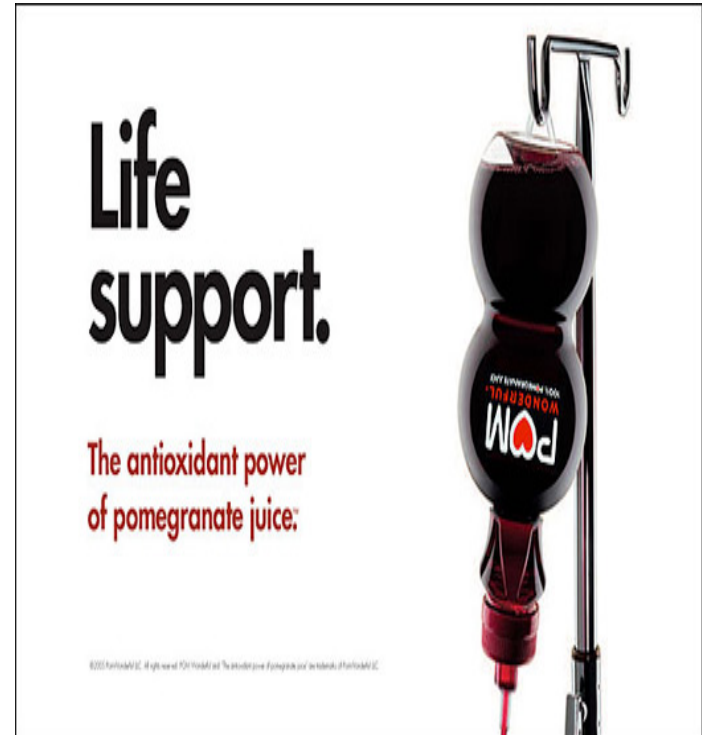
- FTC interprets ads using “Net Impression” test
- Extrinsic Evidence is required only if implied claims are not clear





# Scientific Establishment of POM's Disease Cure/Prevention Claims

- ... \$25 million in medical research ... Not only have this research documented the unique and superior antioxidant power of pomegranates, it has revealed promising results for prostate and cardiovascular health.”



# In re POM Wonderful, FTC Docket 9344, January 10, 2013

- FTC required 2 random clinical trials for claims that a food or beverage product has disease prevention and treatment properties that are scientifically established
- POM appealed saying their First Amendment rights are being violated.
- Decision is currently pending in the District of Columbia Court of Appeals

# Federal Lanham Act

## 15 U.S.C. § 1125(a).

- Lanham Act is federal law that allows one competitor to sue another competitor for disseminating false or misleading advertisements that injure the plaintiff competitor.
- Enacted by Congress in 1946, originally as trademark protection measure, broadened in 1988 to clearly cover false advertising by a competitor.
- Lanham Act is enforced by private suits by competitors. Consumers don't have standing to sue under the Lanham Act.

# The Competing Juice



- “Pomegranate Blueberry Flavored Blend of 5 Juices”
- In fact, the product was 99.4% apple and grape juices, 0.3% pomegranate juice, 0.2% blueberry juice, and 0.1% raspberry juice

# FDA Food Labeling Regulation

- FDA is authorized to regulate labels and packaging of processed foods, and is the agency responsible for the Nutrition Facts label. (Food, Drug and Cosmetic Act or FDCA)
- FDA food labeling laws and enforcement are weak. I.e., FDA has no set meaning for term “natural.” Enforcement is by warning letter, not litigation, they have no power to demand substantiation for labeling claims.

# FDA Regulation

## 21 CFR 102.33(d)

- “if a juice blend does not name all the juices it contains and mentions only juices that are not predominant in the blend, then it must either declare the percentage content of the named juice or ‘indicate that the named juice is present as a flavor or flavoring.’”

# Supreme Court Ruling

## Pre-emption v. Preclusion

- Federal supremacy clause in US Constitution means federal law usually pre-empts duplicative or contradictory state laws
- When one federal law is said to prevail over another federal law, the issue is “preclusion”

# Lanham Act and FDCA Coexist and Complement Each Other

- Nothing in either Lanham Act or FDCA address issue of preclusion of Lanham Act claims if area is covered by FDA regulation
- Lanham Act “protects commercial interests against unfair competition” while FDCA “protects public health and safety”
- Since FDCA has no private right of action, allowing Lanham Act suits “takes advantage of synergies among multiple methods of regulation.”



# What's Next for POM Wonderful?

- The win for POM Wonderful basically means it can pursue its Lanham Act case in federal court. [Note POM had other cases filed against other makers of pomegranate blend juices]
- Supreme Court ruling in Lanham Act case does not directly affect the outcome of the FTC case against POM Wonderful that is now pending in the D.C. Circuit.

# What Does It Mean for Consumers?

- Supreme Court ruling allows competitors like POM to police the marketplace for deceptive food labels through Lanham Act cases despite the presence of federal regulation – this benefits consumers indirectly
- S. Ct. case could be a precedent to enhance Lanham Act suits as an alternative to both FDA and FTC actions to curb deceptive advertising and labeling of food and other products

# What Does It Mean for Regulators?

- FTC's case against POM is unaffected by the S. Ct. decision on the Lanham Act. FTC action was based on its relatively strong power to demand high levels of substantiation from advertisers.
- FDA's relatively weak regulation of food label claims could benefit from obtaining similar authority from Congress.