



Marketing and Advertising to an Aging Population

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Agenda



- Legal Landscape
- Regulators & Enforcers
- Claims & Standards Overview
- Recent Cases

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All Claims Must Be Truthful, Not Misleading, And Adequately Substantiated

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What is Advertising?



Nearly **everything** is advertising and can be a claim!

What you commonly think of...

- Websites
- Print Ads & Handouts
- Commercials
- Online Ads
- Social Media
- Email Campaigns

...and some that may surprise you:

- Blog Posts
- Google Ad Words
- Presentations
- Affiliate Programs
- Press Releases
- HCP Marketing

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Thinking Critically When Formulating Advertising



1. Identify Claims: What claims are being made?
2. Categorize Claims: What types of claims are these?
3. Identify Support: What type of evidence is needed to support these claims?
4. Analyze Validity Of Evidence: Is this evidence good enough?

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Anatomy of a Claim



- Advertisers are responsible for the truthfulness and accuracy of both **EXPRESS** and **IMPLIED** claims.
 - Express = the claim language on its face
 - Implied = reasonable interpretation/takeaway of the claim
- This responsibility includes unintended implied claims!
 - An advertiser is responsible for all reasonable interpretations of its advertising, including messages that it may not have intended to convey.
 - Consumers can have many interpretations of the same claim. Advertisers are liable for *reasonable* interpretations, and what is "reasonable" is subjective with no definite legal standard.

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Context is KEY!



*A claim that is literally true may, in the **context** in which it is presented, still convey a message that is false or misleading.*

- Claims are reviewed in their context, not a vacuum.
- Surrounding context can influence a claim's reasonable implications.
- Visual breaks in ads can make a significant difference.
 - Think font changes, color changes, visual proximity

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Claim Substantiation



- Advertisers must have a **reasonable basis** for product claims.
- What constitutes a reasonable basis depends on:
 - Type of product advertised
 - Type of claim
 - Benefits of a truthful claim
 - Consequence of a false claim
 - Amount of substantiation experts in the field believe is reasonable
- The FTC requires substantiation be in place prior to disseminating the ad.
 - Failure to have this is an independent violation of law even if the claim is actually true.



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What kind of substantiation is reasonable?



- Product tests conducted under repeatable, reliable conditions.
- OBJECTIVE:
 - Instruments
 - Expert Graders
 - Blinding/Controls
 - Statistically Significant & Clinically Relevant Results
- SUBJECTIVE: Questionnaires
- ENSURE CLAIM MATCHES THE TYPE OF SUPPORTING EVIDENCE!

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What is NEVER a reasonable basis?




- Newspaper or magazine articles
- Blog posts
- Testimonials from customers
- Consumer reviews
- Money back guarantees
- Low return or complaint rate

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Health Claims



Claims affecting consumer health or safety require a relatively high level of substantiation:

COMPETENT AND RELIABLE SCIENTIFIC EVIDENCE


“Tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have 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.”

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Health Claims



In practice, regulators look for certain hallmarks of “reliable” evidence:


- Well-controlled human intervention studies
 - Preferably double-blind, placebo-controlled, randomized trials
- Statistical significance between groups
- Clinically significant results
- Healthy population matching target demographic
- Validated, objective measurements
- Matches directed conditions of use
 - Ingredients & dosage
- Adequately powered sample size

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Health Claims



Some types of information are helpful background, but alone may not adequately substantiate a claim:


- Animal studies
- In vitro studies
- Review articles
- Meta-analyses
- Expert reports

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Disclosures Must be Clear and Conspicuous



- All material information must be disclosed.
- Disclaimers must be clear and conspicuous (The Four Ps):
 - *Prominence*: Big enough for consumers to read and notice.
 - *Presentation*: Wording and format easy for consumers to understand (i.e., free of legal jargon).
 - *Placement*: Information/link easy to find and where consumers will likely look.
 - *Proximity*: Disclosure close to the claim it qualifies.
- Disclaimers cannot be contradictory.

Warning: Enforcement trends seem to signal even stronger requirements.



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There are many potential enforcers.
Each has their own role and risk assessment.




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FTC's Enforcement Priorities



- Protecting older consumers is a top priority and issues annual "Protecting Older Consumers" reports every October.
- The FTC identified "unsubstantiated health claims" as a top priority in its 2021 report, including dietary supplements that target older adults, false claims about COVID-19 treatment and prevention.
 - Ongoing focus in 2022.

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Memory and Cognition Support Claims



- **Procera AVH Dietary Supplement (FTC 2015)**
 - FTC entered into a settlement agreement that banned defendants from making unsubstantiated claims, including that the product would reverse age-related mental decline and memory loss.
 - Marketers paid a total of \$1.4 million to the FTC and CA law enforcement.
- **Senior Moment Advanced Memory Enhancing Dietary Supplement (FTC 2004 and NAD 2002)**
 - FTC entered into a settlement agreement that banned defendants from making unsubstantiated claims, including that the product could prevent memory loss and restore memory function in adults.
 - NAD concluded that there was insufficient evidence to provide a reasonable basis for performance claims such as that the product would alleviate the "tip of the tongue" memory problems" or "enhance" memory function. The studies involved older patients with various cognitive diseases while the products were targeted towards a healthy population.
- **Cebria Supplements (NAD 2017)**
 - Cebria supplement was targeted towards older healthy populations and made several performance claims, including that within 30 days it would improve, protect, and increase speed and ability of memory recall.
 - Cebria also used consumer testimonials, "results not typical" disclaimer.
 - NAD concluded the underlying substantiation was not sufficient to form a reasonable basis for the claims.
 - Advertiser initially appealed, noting that FTC reviewed the substantiation before deciding not to take further action, but ultimately withdrew the appeal.

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Heart Health Claims




Health Research Laboratories, LLC Whole Body Supplements, LLC

- In 2022, the FTC announced settlements with two companies that claimed without basis that The Ultimate Heart Formula (UHF), BG18, and Black Garlic Botanicals *prevent or treat cardiovascular and other diseases*, and that Neupathic cures, mitigates, or treats diabetic neuropathy.
- Companies and their owner permanently banned from selling dietary supplements.

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Healthy Joints, Strong Bones 

- **Gravity Defyer** (FTC – currently pending)
 - Footwear company sued for making allegedly unsubstantiated pain relief claims targeting older adults suffering from arthritis, joint pain, and other medical conditions.
- **Synovia** (FTC 2020)
 - Settled claims that dietary supplement could treat arthritis, alleviate joint pain, including claims that the supplement would pave the “pot holes” in damaged joints, replace injected medications, and reduce arthritis pain by 95%.
 - Defendants paid \$821,000 to settle charges, barred from using deceptive testimonials.
- **Supple** (FTC 2016)
 - Settled claims that Supple, a glucosamine and chondroitin liquid supplement, provided complete relief from chronic and severe joint pain caused by arthritis, fibromyalgia, and was scientifically proven to eliminate joint pain. Compared pain relief to drugs or surgery and claimed that the product would repair cartilage, rebuild joints, and restore mobility and joint function to consumers with severe mobility issues.
 - \$150 million judgment, mostly suspended.

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Reasonable Consumer Standard 

Moore v. Trader Joe’s Co., No. 19-16618 (9th Cir. July 15, 2021).


- “100%” in the “100% New Zealand Manuka Honey” label could be read in multiple ways: “100% could be a claim that the product was 100% Manuka honey, that its contents were 100% derived from the Manuka flower, or even that 100% of the honey was from New Zealand.”
- In order to state a claim, plaintiffs must prove “more than a mere possibility that the seller’s label might conceivably be misunderstood by some few consumers viewing it in an unreasonable manner. Rather, the reasonable consumer standard requires a *probability that a significant portion of the general consuming public or of targeted consumers, acting reasonably in the circumstances, could be misled.*”

The Court reinforced the importance of considering context:

- (1) the impossibility of making a honey that is 100% derived from one floral source;
- (2) the low price of Trader Joe’s Manuka Honey; and
- (3) the presence of the “10+” on the label.

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Reasonable Consumer Standard 

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Key Takeaways:

- Consumers do not interpret labels to mean the impossible;
- Consumers must consider all the information available to them, including context; and
- FDA guidelines can support a “literally true” defense

“[W]here plaintiffs base deceptive advertising claims on unreasonable or fanciful interpretations of labels or other advertising, dismissal on the pleadings may well be justified.”

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TRENDS



- Trans-esterified "fish oil" not actually "fish oil"
"Irrevocably transformed"
- Micro-Adulteration:
Benzene in Sunscreens and Anti-perspirant;
Per- and Poly-fluoroalkyl Substances; and
Heavy Metals.
- CBD supplement/food challenges

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Lauren Aronson
lauren@amintalati.com
202-918-7850

Matthew Orr
matt@amintalati.com
213-985-7219

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