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Claiming to be the Best: Understanding How to Substantiate Your Claims

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Agenda

- Brief Overview of Regulatory Agencies and Self-Regulatory Bodies
- What Is a Claim?
- Claim Substantiation Requirements
- Enforcement Trends

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CLAIM SUBSTANTIATION: THE PLAYERS

National Advertising Division

ERSP

State Attorneys General

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Federal Regulatory Agencies

- **U.S. Food & Drug Administration (FDA):** primary responsibility for ensuring the safety of foods, cosmetics, dietary supplements, drugs, biologics, and medical devices in the U.S. under the Food, Drug, and Cosmetics Act (FDCA).

- **Federal Trade Commission (FTC):** authority over advertising for food, dietary supplements, cosmetics, over-the-counter (OTC) drugs, and many medical devices – under the Federal Trade Commission Act (FTCA).

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Primary Jurisdiction?

- Pursuant to a liaison agreement, FDA has primary responsibility for the labeling of FDA-regulated products (including foods, dietary supplements, cosmetics) while FTC has primary responsibility for advertising for *most* FDA-regulated products.
- Not so black-and-white in application:
  - FDA will look to advertising as evidence of "intended use"
  - FTC has taken to evaluating whether claims are appropriate for product classification

Overview of FTC

- The FTC regulates advertising claims and expects that advertisers have "competent and reliable scientific evidence" in support of claims made.
- Advertisers must be able to substantiate all reasonable interpretations of their claims, including messages they may not have intended to convey
- The FTC may challenge an advertisement based on the fact that it is:
  - False or deceptive
  - Likely to mislead reasonable consumers
  - Likely to influence consumer purchasing decisions or otherwise affect important consumer decisions

Overview of FDA

- FDCA also requires that a company possess substantiation that a claim is truthful and not misleading.
- FDA applies a standard consistent with the FTC approach

NAD and ERSP

- The National Advertising Division (NAD) of the Council of Better Business Bureaus and the Electronic Retailing Self-Regulation Program (ERSP) are self-regulatory bodies that review factual claims for truthfulness and accuracy.
- Both offer alternative dispute resolution and provide written decision, typically within 60 business days.
- Accept cases involving:
  - Product performance claims
  - Superiority claims against competitive products
  - Scientific and technical claims
- Compliance with findings is voluntary, but…

National Advertising Division®

State-Level Actions

- State Attorneys General (AGs) enforce state mini-FTC Acts
  - Prohibit deceptive advertising and trade practices
- Private litigation
  - Especially in California under the Consumers Legal Remedies Act (CLRA)

What is a Claim?

- A claim is an explicit or implicit statement that a product has a certain benefit.
  - Express and implied claims are held to the same standard.
  - Claims are identified by assessing the "net impression" conveyed by all elements of an advertisement or label, including text, product name and depictions.
  - Includes statements made in testimonials.

- Types of claims include:
  - Overall Health and Wellbeing
  - Structure/Function Claims
  - Health Claims
  - Nutrient Content Claims
  - Comparative Claims

Structure/Function Claims

Structure/Function claims can:

(1) describe the role of a nutrient or dietary ingredient intended to affect normal structure or function in humans ("calcium builds strong bones");

(2) characterize the action by which a nutrient or dietary ingredient maintains such structure or function, ("fiber helps maintain digestive regularity")

OR

(3) describe a benefit related to a nutrient deficiency disease (like vitamin C and scurvy), as long as the statement also tells how widespread the disease is in the United States.

- Advertiser's responsibility to be able to substantiate.

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Health Claims

Claims discussing the relationship between a nutrient and a disease or disease condition.

- Language is specifically approved by FDA—based on:
  - Significant scientific agreement based on the totality of publicly available scientific evidence.
  - Authoritative statement by a federal scientific body or the National Academy of Sciences.
- Claim cannot deviate from approved language.

Ex: "Adequate calcium and vitamin D throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis." (21 C.F.R. § 101.72)

- Advertiser must be able to show that product meets all requirements to make the claim

Health Claims

Qualified Health Claims

- Characterize the relationship between a nutrient and a disease condition, but they can be based on less than significant scientific agreement.
- Claim language discloses the limitations of evidence in support of the claimed relationship.
- Cannot deviate from FDA-approved language.

Ex: "Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of X provides Y gram(s) of EPA and DHA omega-3 fatty acids."

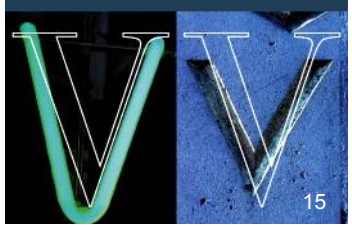
- Advertiser must be able to show that product meets all requirements to make the claim
- FDA can withdraw enforcement discretion

Nutrient Content Claims

Nutrient Content Claims characterize the level of nutrients in a product. E.g., “low fat,” “low sodium,” “excellent source of vitamin C”.

- Examples of nutrient content claims that are not approved by FDA:
  - “Low carb,” or any similar claim. Even a product name such as “Carb-Low” *may* trigger enforcement as an impermissible implied claim.
  - Synonyms for approved claims that have not been specifically approved by the agency.

- Advertiser must be able to show that product meets all requirements to make the claim



Comparative Claims

- FTC View:
  - Comparative claims are permissible.
  - Must be comparing like products– requires clarity to avoid deception of the consumer.
  - Advertiser's responsibility to be able to substantiate.
- Competitors:
  - Litigation: The Lanham Act, Section 43(a)
  - Self-Regulation: National Advertising Division of the Council of Better Business Bureau (NAD)
  - Potential for significant legal expenses.

Claim Substantiation

- What you don't know (or what you *think* you know) can hurt you

Claim Substantiation

- FTC and FDA require "competent and reliable scientific evidence" to substantiate all claims used in advertising and structure/function claims (for dietary supplements and foods)used on labels.
- "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.

Claim Substantiation

- Factors Affecting Required Levels of Substantiation:
  - Type of product
  - Type of claim
  - Context in which claim is used
  - Benefits of truthful claim
  - Consequences of false claim
  - What qualified experts in field believe is reasonable
  - Is specific level of support stated or suggested in the claim?

Claim Substantiation

- Advertising Claims
  - If you make an establishment claim that characterizes the amount of science you possess, you must actually have that amount
    - E.g., Clinical studies show that ingredient X has Y effect
  - For claims that do not suggest that a certain level of support exists for a claim, the level of scientific support necessary depends on the amount of research experts in the field would consider adequate to establish the claim's truthfulness.

Claim Substantiation

- In considering the number and type of studies required to substantiate a claim, advertisers should consider:
  1. The meaning(s) of the claims being made, express and implied;
  2. The relationship of the evidence to the claim;
  3. The quality of the evidence; and
  4. The totality of the evidence.
  5. Accepted norms in the relevant research field.

Claim Substantiation

- **Acceptable Scientific Evidence:**
  - Well-controlled, double-blind studies are likely to be given more weight than non-blind studies;
  - Longer-term studies are better than short-term studies;
  - Study's result should be statistically *and clinically* significant;
  - Nature and quality of the written report is important;
  - Studies published in reputable peer-reviewed scientific journals are looked upon with favor;
  - Studies not published in peer-reviewed journals may be used to substantiate claims if they would be considered properly designed and controlled by experts in the field.

Claim Substantiation

- **Scientific Evidence Must Be Relevant**
  - Evidence must be relevant to specific claim
  - Study endpoints must match claim
    - Ensure that you understand meaning of claim to determine what endpoints are relevant.
  - Consider: dose, dosage form, route of administration, formulation, total length of exposure, frequency of exposure, study population
  - Foreign Research
    - As a general matter OK, but…
    - Note that differences between populations, such as differences in diet, general health, or patterns of use, could confound results.

Claim Substantiation

Issues with Other Types of Scientific Evidence

- FDA View: Alone, items listed below generally will not substantiate claims:
  - Animal Studies– best is based on data from studies in appropriate animal models, on data that have been reproduced in different laboratories, and on data that give a statistically significant dose-response relationship.
  - *In vitro* Studies– best is based on data that have been reproduced in different laboratories.
  - Testimonial/Anecdotal Evidence– "honest opinion" not enough (discussed later)
  - Meta-analysis– may identify relevant reports, which may provide substantiation
  - Product monographs– may provide background information useful to understand relationship between substance and claimed effect

Claim Substantiation

Anecdotal, Traditional and Historical Use

- Anecdotal evidence, *alone*, cannot be used to substantiate a claim even if an individual's experience is true.
- Anecdotal evidence, however, *in connection with* a few well-controlled studies may be sufficient to substantiate a claim.
- A claim based solely on traditional and historical use must so state.
- Traditional and historical claims for serious diseases are not permitted.

Claim Substantiation

Claims Based on Traditional and Historical Use

- Present in way that consumers understand that sole basis for claim is a history of use of product for a particular purpose.
- Dosage form, route of administration, and the like, must match the traditional use.
- Some claims may not be used, even if qualified:
  - Claims that present substantial risk of injury to consumer health or safety if unfounded
    - Could lead consumer to forego proven treatments and self-medicate for serious condition
    - Permissible: "Ancient folklore remedy used for centuries by Native Americans to aid digestion."
    - Impermissible: "American folk remedy for shrinking tumors."

Special Considerations for Comparative Claims

- Take caution in providing editorial comment on the comparative formulations. Preference is to not name the comparative products.
- Must have hard data to substantiate market-based claims, and citation to source is best practice
  - E.g., "#1 calcium brand--more than twice as many customers as #2 brand"
- Performance claims typically require head-to-head studies to substantiate
  - E.g., "Absorbs 2 times faster than X form of ingredient"

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Context Is Key

- The context in which the claim appears is extremely important
- In a vacuum, the claim may not be problematic. But in context, a claim can become an implied claim
  - *E.g.,* "We use superior ingredients in our products"
  - Same claim, used next to a photo of a competitor's product

Testimonials and Expert Endorsements

- Testimonials and expert endorsements for supplements that pertain to the health benefits of a product **must be substantiated as though they were made by the marketer itself, or properly disclaimed**.
- A testimonial or endorsement must represent the experience that a typical consumer can expect with the product, or be properly disclaimed
  - There is no personal opinion exception.
  - Must reflect the honest opinions, findings, beliefs, or experience of the endorser.
  - Any material connection between the endorser and the seller must be disclosed.

Testimonials and Expert Endorsements

- **Disclaimers: FTC's View**
  - If a marketer's substantiation does not demonstrate that the results attested to in a testimonial are representative, then a clear and conspicuous disclaimer is necessary.
  - Marketer should either state what the generally expected results would be or indicate that the consumer should not expect to experience attested results.
    - *E.g.,* On average, subjects reported positive effect on joint health after 12 weeks of use.
    - Vague disclaimers like "results may vary" are likely to be insufficient.

Testimonials and Expert Endorsements

- **3 Ways a Testimonial Can Be Deceptive:** (an example: weight-loss)
  1. Endorser may not have experienced the reported result.
  2. Weight loss may be attributable to other factors, such as diet, exercise, or lifestyle changes.
  3. If testimonial claiming extreme and atypical weight loss is presented as typical and ordinary, it is likely to be deceptive without an indication of the more modest weight loss results that the typical user would experience.

Testimonials and Expert Endorsements

- **Expert Endorsements**
  - Experts qualifications must give the expertise he is represented as possessing.
  - An expert must have a reasonable basis for his/her opinion.
  - Expert's endorsement must be supported by an actual exercise of his expertise in evaluating the product features or characteristics with respect to which he is an expert and which are both relevant to an ordinary consumer's use of or experience with the product and are also available to the ordinary consumer.

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What Does Your Study *Really* Show?

- Taking leaps in logic or "connecting the dots" is one of the most frequent mistakes companies make
  - Your study shows that the product does A
  - You know that A is associated with B
  - Therefore you claim that the product does B
- Using studies that do not match your product exactly in terms of dosage, route of administration, directions for use is another big mistake

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What Does Your Study *Really* Show?

- Was your study conducted on the final product formulation, or just one or more ingredients?
  - Claims based on study that tested only one ingredient should state so:
    - Ingredient X may help support liver health
  - You should be able to demonstrate that the presence of additional ingredients in your product does not change the effectiveness of individual ingredients

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Beware of These Hazards:

- Website reviews posted by customers
- Social Media (*e.g.,* Facebook pages)
- Guarantees
- Doctor-recommended claims
- Study results statistically, but not clinically, significant

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Customer Reviews and Social Media

- By allowing a customer review on its website or social media site (*e.g.,* Facebook page), a company implicitly adopts the statement and is considered to make the claim itself
- Must be able to substantiate underlying claim
- Claim must be appropriate for product category (*e.g.,* No disease claims for dietary supplement products)

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Guarantees

- Regulated by FTC
- Context of Claim:

A. "14-Day Money-Back Guarantee"

B. "Try it for 14 days. If you are not fully satisfied, we will give you your money back."

C. "Guaranteed to see results in 14 days or your money back"

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Doctor-Recommended Claims

- "Doctor recommended," "Dentist recommended," "#1 Doctor-Recommended Brand"
- The fact that the product is recommended by one or even a handful of doctors is not enough
- Regulators expect a national survey of doctors concerning their experience in their ordinary practice
- Survey should be random, statistically representative
- Highly recommend using company that specializes in surveys to design and conduct the survey, as the language of the survey and the way that the survey is conducted will be very important to regulators

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Clinically Significant Results?

- Beware of study results that are statistically significant but not clinically significant
  - *E.g.,* Active group lost 1.5 cm in waist circumference over 8-week study
  - *E.g.,* Using a visual analog scale (VAS) of 1 to 10, subjects' rating of sexual desire went from a 2 to a 3

Enforcement Trends

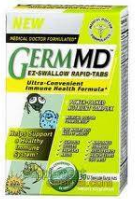
- FTC Enforcement against False Advertising
- Immunity Claims
- State Attorney General Actions
- State Actions in California

Enforcement Trends: FTC Enforcement against False Advertising

- **Nestlé Consent Decree (2010)**
  - FTC complaint charged that Nestlé made deceptive claims in ads that BOOST Kid Essentials (a probiotic) prevented upper respiratory tract infections in children, protected against colds and flu by strengthening the immune system, and reduced absences from daycare or school due to illness.
  - Nestlé entered into a Consent Agreement whereby it had to cease making such claims absent competent and reliable scientific evidence.

Enforcement Trends: FTC Enforcement against False Advertising

- **Iovate Settlement (2010)**
  - FTC charged Iovate Health Sciences U.S.A. with deceptively claiming in ads that dietary supplements Cold MD and Germ MD treated or prevented colds and flu, and that Allergy MD treated or prevented allergies and hay fever.
  - FTC also charged Iovate with deceptively claiming that weight-loss supplements Accelis and nanoSLIM caused weight loss and were clinically proven to do so.
  - Iovate settled with FTC for $5.5 million
    - Settlement also barred Iovate from making any disease claims unless the claim is approved by FDA and making any health related claims without competent and reliable scientific evidence.



Has the FTC Changed the Rules for Substantiation?

- Emerging FTC Standard in Consent Orders:
  1. Bars claims that a dietary supplement treats, cures, prevents, or mitigates disease **until approved by FDA** under its Nutrition Labeling and Education Act "significant scientific agreement" health claim review standard, 21 U.S.C. § 343(r)(5)(d).
  2. Requires **two well-designed clinical trials** substantiating the claim at the time of first advertising to avoid a charge of deceptive advertising.
     - Double-blind, placebo controlled
     - Test final product formulation, not just ingredients
  3. Nonspecific Competent Reliable Evidence Requirement (the “Catch-all”)

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Immunity Claims

- Widely-publicized FTC actions against immune support products: Airborne and store brand equivalents
- FTC has indicated that general "supports the immune system“ claim *may be* substantiated by studies showing improvement in immune system biomarkers
- Slight deviations can significantly change level of substantiation required:
  - “Enhances", "boost" or "strengthens" the immune system: Consumers interpret such claims to mean that the product actually improves the immune system, thereby making it more able to ward off illnesses.
  - Higher level of substantiation required
  - Problematic from an FDA standpoint (disease claim)

FTC Enforcement Finds New Prey I

- Old Trend
  - Target blatantly false and deceptive claims (or those impossible to substantiate) with no or very weak substantiation.
    - "Lose 30 pounds in 30 days!"
    - "[Supplement] will make you look 10 years younger!"
    - "[Product] enables smokers to quit smoking quickly, effortlessly, and permanently."

FTC Enforcement Finds New Prey II

- New Trend
  - Target claims that are commonly accepted as true or having scientific merit.
    - Ingredients Targeted:
      - Calcium
      - Omega-3
      - Vitamin C
    - Types of Claims:
      - "Omega-3 promotes healthy brain development."
      - "Selenium may reduce the risk of certain cancers."

Enforcement Trends: State Attorney General Actions

- "Free Trials"
  - Do customers have to call to cancel within X days or their credit cards will be charged full amount?

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Enforcement Trends: State Actions in California

- Multiple class action cases for purported false advertising
- Settlement announced yesterday concerning major player in homeopathic market
  - Agreed to spend up to $12M to settle several putative consumer class actions claiming it falsely advertised the benefits of its homeopathic remedies. Also agreed to make changes to its product labeling, including adding disclaimers and an explanation of how their active ingredients have been diluted

NAD & CRN Aggressive Initiative

- Initiative begin in 2006 --- goal to **expand the review** of advertising claims for dietary supplements.
- Forward More Cases to FTC

NAD Challenge Trend: Consumer Testimonials

- Heavy reliance on (and citation of) FTC's Revised Guides Governing Endorsements, Testimonials ("Revised Guides").
  - Use as basis for review.
  - NAD decisions often delineate permissible and FTC-compliant forms of advertising.

Post-Production Enhancement: NAD's Newest Attack

- Post-Production Enhancement
  - Just as NAD is targeting consumer testimonials, it is now also challenging post-production enhancement on beauty ads.
    - Launch inquiry into CoverGirl NatureLuxe Mousse Mascara
    - Discontinue post-production-enhanced photos of Taylor Swift.

Questions & Answers

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