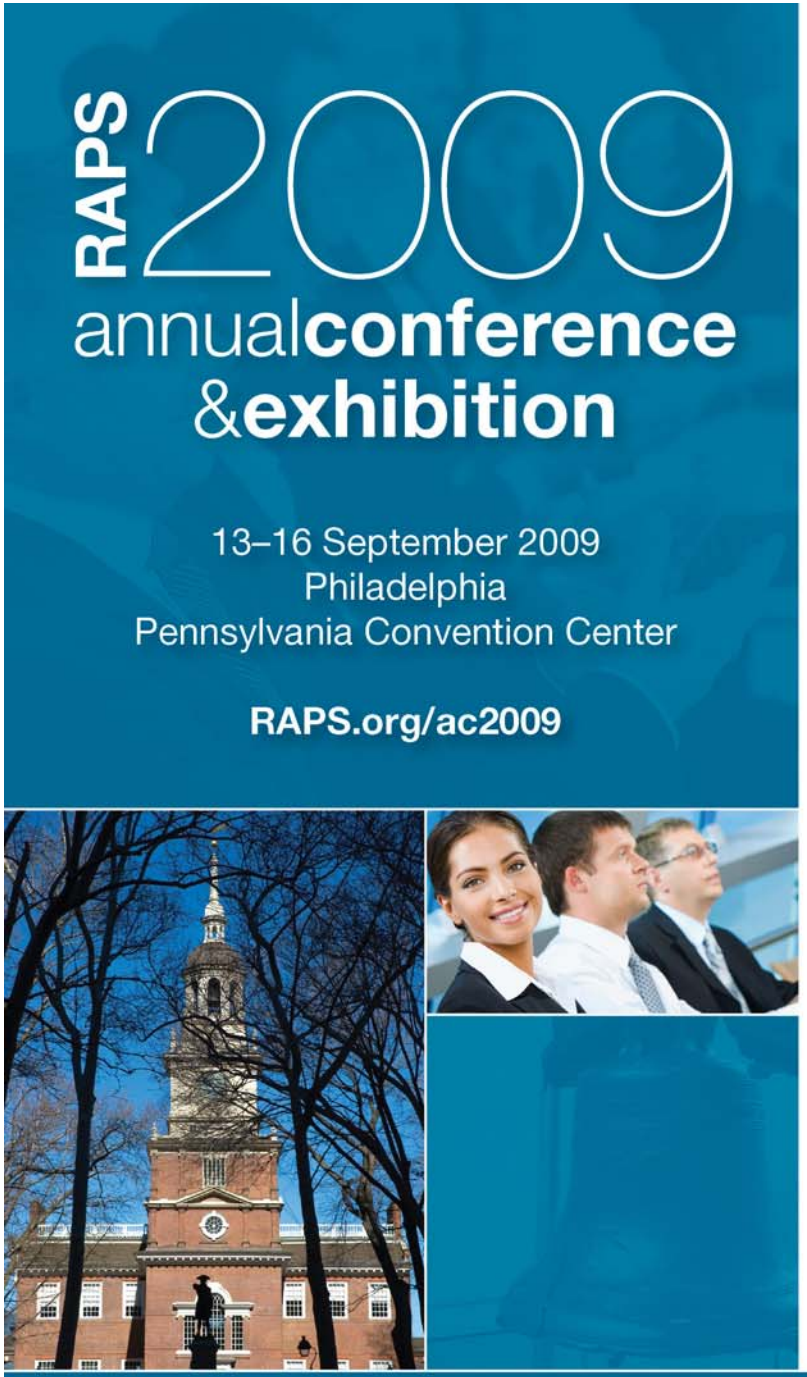


# Practical Pointers On Advertising Healthcare Products

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SUCCEEDING IN THE NEW REGULATORY LANDSCAPE

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# Evaluating Your Substantiation

All health related claims must be substantiated by "competent and reliable scientific evidence." FTC defines this as:

> *"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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# Evaluating Your Substantiation

## Factors Affecting Required Level of Substantiation

- Type of product
- Type of claim
- Benefits of truthful claim
- Consequences of false claim
- What qualified experts in field believe is reasonable

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# Evaluating Your Substantiation

## Establishment Claims

- Expressly state the level of support or suggest a certain level of support
  - "Ten studies show"
  - "Doctors agree"
  - "In a recent clinical study"
- Must be supported by the claimed level of evidence

# Evaluating Your Substantiation

## Non-Establishment Claims

- Do not suggest that a certain level of support exists for a claim
  - "Helps increase metabolism"
  - "Promotes joint comfort"
  - "Lose up to 20 pounds"
  - "Begins to neutralize acid in 10 minutes"

- Level of scientific support necessary depends on amount of research experts in the field would consider adequate to establish the claim's truthfulness.
  - *Note: It would be unusual for one or two small studies to adequately substantiate a claim.*

# Evaluating Your Substantiation

## Scientific Evidence Must "Match" the Claim

- Evidence must be relevant to specific claim
- Study endpoints must match claim
  - You must understand meaning of claim to determine what endpoints are relevant
    - Responsible for all possible interpretations of claim
- Consider:
  - Dose
  - Dosage form
  - Route of administration
  - Formulation
  - Total length of exposure
  - Frequency of exposure
  - Study population

# Evaluating Your Substantiation

## OTC Monograph Drugs

- Most claims for drugs sold pursuant to OTC monographs must mirror claims in monograph
  - Indications for use
  - Dose
  - Directions
- Additional performance claims require independent scientific substantiation
  - “Fast acting”
  - “Absorbs quickly”

# Evaluating Your Substantiation

- Generally not sufficient alone, but provide additional support:
  - 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
  - Meta-analysis
    - May identify relevant reports, which may provide substantiation
  - Product monographs (non-OTC monographs)
    - May provide background information useful to understand relationship between substance and claimed effect

# Evaluating Your Substantiation

## Foreign Studies

- Beware of differences between populations
  - Diet
  - General health
    - *E.g.,* Low incidence of cardiovascular disease vs. U.S. population
  - Patterns of use
- Ensure ingredient is same
  - Language/dialect could cause same name to apply to two different substances
  - For all ingredients, testing and purity must meet U.S. standards

# Evaluating Your Substantiation

## Potential Pitfalls

- Bias or confounders
- Lack of appropriate randomization and blinding
- Use of inappropriate scales
- Statistical procedures
- Presence of other ingredients that may have independent effects
- Differences between protocol and actual study
  - *E.g.*, dropouts affecting number called for in protocol

# Anatomy of A Disclaimer

Are there any material disclosures needed to prevent a potentially misleading interpretation?

- Important to focus on the “net effect” of the advertisement
- Disclaimer must be clear and conspicuous
- Statements like “results not typical,” “not all consumers will get this result” are generally not adequate
- Disclose what the generally-expected performance would be or the limited applicability of the endorser’s experience to what consumers may expect to achieve

# Anatomy of A Disclaimer

Disclaimers can be good advertising:

Disclaimers as Clarifications

- “Based on a clinical trial of 50 people…!”
- “Helps reduce the appearance of wrinkles in women over 40…”
- “Helps reduce the appearance of cellulite!”

Successful disclaimers are an integral part of advertising rather than a distraction.

# Comparative Advertising

- Examples
  - “Works faster, better than product X”
  - “Fastest absorption among category X”
  - “#1 Doctor recommended”
  - “Best selling” or “#1 selling”
- FTC’s View
  - Comparative claims permissible
  - Must compare like products
    - Mechanism of action important
    - Requires clarity to avoid consumer deception
- Must have substantiation for superiority claims
  - Head-to-head studies likely required
  - Market surveys
- Naming comparative products, providing editorial comment on comparative formulations risky

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# Comparative Advertising

## Challenges from Competitors

- Litigation
  - Lanham Act, Section 43(a)
  - State “mini FTC” acts
- Self-regulation
  - NAD
  - ERSP
  - Network challenges
- Potential significant legal expenses

# FTC's Recent Activities

## FTC Cases Since 2000

- Over 20 cases against marketers making disease treatment or prevention claims for their products.
- Over 35 cases involving weight-loss claims.
- At least 7 cases involving libido and performance enhancing claims.
- Several cases on anti-aging and hair loss prevention claims.

Red Flag Claims

Clinically Proven Claims

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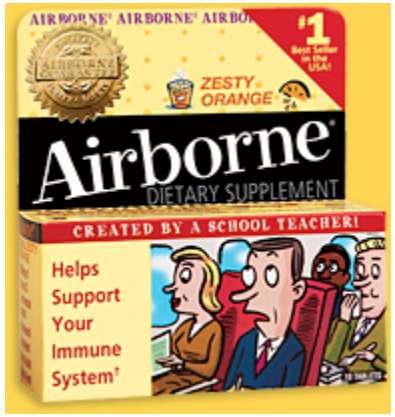
# FTC's Priorities

## FTC Cases Since 2000

- **Weight-Loss**
  - 2004—FTC Consent Agreement with American Dream Enterprises, marketer of Fat Seltzer.
  - 2008—Pure Health Labs, Ultralife Fitness, and True Genix Settlement Agreement regarding internet weight-loss claims for hoodia products.
  - 2009—Settlement with two dietary supplement marketers regarding unsubstantiated weight-loss claims for hoodia products.
- **Disease Claims**
  - 2008—11 FTC Complaints against marketers based on cancer-related claims, 6 resolved by consent ingredients. No treatment is recognized to treat all forms of cancer. In order to support cancer treatment claims, must have well-conducted, placebo-controlled, randomized, double-blind, clinical trials.

# FTC's Priorities




## Airborne

- First action was taken against Airborne, marketer of the name-brand product.
- Subsequent cases against store-brand versions of Airborne products—CVS, RiteAid.
- Claims used were essentially the same.
- Consent orders plus $500,000 in consumer redress.

# FTC's Priorities

## Over-the-Counter Drugs and Cosmetics

2000—FTC contempt motion against Bayer Corporation

- Original consent order prohibited therapeutic performance claims for any nonprescription internal analgesic product without competent and reliable scientific evidence.
- Bayer claimed or implied that Bayer Aspirin could help prevent strokes or cardiovascular disease, without a reasonable basis.
- FDA allowed only specific statements linking aspirin products with a reduced risk of cardiovascular disease or stroke, and only in practitioner labeling.
- FDA could have pursued Bayer, but FTC took action instead.

# FTC's Priorities

## Over-the-Counter Drugs and Cosmetics

2002—A & S Pharmaceuticals, marketer of over-the-counter drugs, directing that company to refrain from misrepresenting the extent to which any product is made in the United States. The claim "made in the U.S.A" can only be applied to products that are:

1. Composed of all, or virtually all ingredients or component parts made in the United States, or

2. The product of all or virtually all manufacturing in the United States.

# FTC's Priorities

## Over-the-Counter Drugs and Cosmetics

2009-Contempt Order against QVC for violation of a 2000 FTC Order

- $1.5 million civil penalty, plus $6 million in consumer redress.
- Lipofactor: eliminate/reduce cellulite and weight-loss claims
- Claims subject to the earlier Order were cold and flu relief and prevention claims for Cold-Eeze Zinc Lozenges.

# FTC's Priorities

## Lane Labs

- Rare example of an FTC loss.
- FTC  contempt motion against Lane Labs for violation of an earlier FTC Order, based on claims made for AdvaCAL calcium supplement and Fertil Male products.
- "Clinically shown" performance claims, comparative claims to other calcium supplements, and quantified performance claims, were found adequately supported.
- FTC's experts were not as reliable, and the agency did not meet its burden to prove contempt.

# FTC's Priorities

## Internet Advertising

- FTC cooperates with other agencies on internet surfs.
- In 2007 FTC cooperated with FDA and Competition Bureau Canada on an internet surf that resulted in e-mailed FTC warning letters to 112 websites.
- In 2002, FTC cooperated with the Australian Competition and Consumer Commission and 19 members of the International Marketing Supervision Network of consumer protection law enforcement agencies on an internet surf. FTC sent over 280 advisory letters to domestic and foreign websites that made questionable health claims.
- FTC has stated its commitment to monitoring failures to disclose in new forms of online advertising, such as flogs (fake blogs), message board seeding, and mobile search marketing.

# FTC's Priorities

## Oprah and Dr. Oz

- Picking up where FTC leaves off.
- Lawsuit against over 50 marketers alleged to have used Dr. Mehmet Oz's name without permission.
- Plaintiffs are Dr. Oz and Harpo, Inc., owner of the "OPRAH" and "O" family of trademarks and copyrights.
- Defendants are marketers of dietary supplements including resveratrol and acai berry products.

# National Advertising Division

- High-priority referral service for FTC
- NAD takes cues from FTC rulings and cases.
- CRN and NAD partnership has resulted in an increased focus on healthcare products.
- FTC may be in direct communication with NAD and exert influence over NAD decisions in some cases.

# Electronic Retailing Self-Regulation Program

- Also a referral service for FTC, specifically for internet advertising.
- Has addressed fake blogs not clearly identified as advertising.
- Can respond quickly to new trends in internet marketing.

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# Broadcast Networks


- Alternative or adjunct to an NAD or ERSP challenge.
- Have internal advertising claims evaluation processes that are similar to NAD or ERSP's.
- Generally not public, regardless of the Network's decision.

# State Enforcement Actions

State Attorneys General are active on consumer protection issues under State "mini-FTC Acts."

- California challenges hoodia content of dietary supplement products.
- Illinois complaint against acai berry companies advertising "free trials."
- Illinois settlement with Coke, Nestle and Beverage Partnership Worldwide over claims that Enviga-brand green tea beverage burns extra calories, resulting in weight loss.
- New Jersey lawsuit against Geon Technologies, marketers of TrimSpa hoodia product, for misleading consumers.

# Miscellaneous FTC Policies

## Green Guides

- Guides for the use of environmental marketing claims.
- Govern:
  - General environmental benefit claims (e.g. “Eco-Safe,” “Environmentally Friendly,” or “Non-Toxic”);
  - Degradable/biodegradable/ photodegradable claims;
  - Compostable claims;
  - Recyclable and recycled content claims; and
  - Ozone safe/friendly claims.

# Miscellaneous FTC Policies

## Mirror Image Policy

- Enforcement policy recently repealed by the FTC.
- Original policy: FTC will not ordinarily challenge claims in advertising that promote the sale of books and other publications when the advertising purports only to express the opinion of the author or to quote (mirror) the contents of the book or publication.
- Applied to advertising promoting the sale of videos, CDs, etc., as well.
- FTC's position is that the policy is no longer needed because the 1st Amendment has been interpreted as protecting commercial speech in the same context.

# Summary: Best Practices

- Tailor your product to the available science. Even if you can produce product studies, it will help to have a background of scientific support.
- Take time to evaluate the costs of producing the studies you need versus the risk of advertising without those studies.
- Tailor your proposed claims to the science.

# Summary: Best Practices

- Have a third party look at your studies
- Focus on:
  - Clinical Relevance
  - Dosage and Formulation
  - Target Demographics
- E.g. FTC vs. Abbott Labs (maker of Ensure)

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