

Avoiding Unsubstantiated Claims in the Advertising and Marketing of Cosmetics and OTC Topicals

ACI's Cosmetics, OTC Topical Drugs,
Cosmeceuticals & Nutracosmetics
Warwick New York Hotel
May 21 – 22, 2007

Ivan Wasserman
Partner, Manatt, Phelps & Phillips, LLP
Washington, DC
iwasserman@manatt.com

[Karen A. Weaver](#)
Partner, Epstein Becker & Green, PC
Los Angeles, CA
kweaver@ebglaw.com

Product Claim Enforcement Authority

- FDA

- Label Claims: written, printed or graphic matter upon the immediate container of any article
- Labeling: written, printed or graphic material that accompanies any article
- As part of Homeland Security / US Customs
- Substantiation Review

- FTC

- Advertising
 - Print
 - Broadcast
 - Web
 - Direct Mail



Enforcement Authority, con't

- FDA

- Product Examinations
- Facility Inspections
- Warning Letters
- Import Detentions / Alerts
- Product Seizures
- Direct Court to Issue an Injunction
- Criminal and Civil Actions



Enforcement Authority, con't

- FTC

- Warning Letters

- Cyber Letters

- CID / Civil Investigative Demand

- Civil Complaint

- Consent Decree

- Criminal Action

Product Claim Enforcement Quasi-Authority



- States Attorneys General
 - In-state advertising only
 - Typically, no FTC involvement
- State Health Departments
 - Based in Product Safety
- Sister Agencies – Competitor Focused
 - NAD
- Consumer Groups & Industry Watchdogs
 - Public Citizen

Claim Standards



- FDA

- Truthful and Not Misleading

- FFDCA

- Fall Within Permitted Regulations (OTC)

- Substantial Evidence

- FTC

- Truthful and Not Misleading / Not Deceptive

- Sections 5 and 12 of the FTC Act

- Scientifically Valid and Reproducible

- Competent and Reliable Scientific Evidence

- Reasonable Basis for the Claim

- Pfizer Factors



FDA's "Substantial Evidence"

- "evidence consisting of adequate and well-controlled clinical investigations"
- Adequate
 - No less than two, although only one is required when the data is "sufficient to establish effectiveness"
 - Requires Confirmatory Evidence
- Well-controlled
 - Double blind placebo

FTC's Competent and Reliable Scientific Evidence

- “tests, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area, that has 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”

OTC *Pfizer Factors*



- Level of Proof need for ‘Reasonable Basis’
 - Type of Product – health/safety, higher level
 - Type of Claim – if consumer would have difficulty determining truth or falsity, higher level
 - Benefits of Truthful Claim – claims with substantial benefits required a lower level
 - Ease of Developing Claims – other methods when difficult (less expensive claim sources or qualify the claim)
 - Consequences of False Claim – consumer injury, higher level
 - Amount of Substantiation Experts in the Field Believe is Reasonable – industry std testing should be done when available; most cases turn on this factor



NAD

- Advertising Self-Regulatory Body
- Decides competitive challenges
- Brings Cases on Its Own
- Detailed Opinions Provides Good Guidance on Substantiation Standards
- Electronic Retailing Self-Regulation Program (ERSP)



NAD On Anti-Aging Cosmetics

“NAD acknowledges the growth of anti-aging products in the burgeoning cosmetics industryHowever, NAD has become increasingly concerned about a recent trend by manufacturers to promise that their skin care products can achieve dramatic reductions in wrinkles and vast improvements in the appearance of the skin.”

Freeman Beauty Labs (9/20/06)

NAD On Ingredient Testing

- “In the absence of product testing, an advertiser, as a general rule, may not extrapolate testing results on a particular product *ingredient* contained in its product to substantiate performance claims for its *product* when ... It contains other ingredients that could impact upon product performance.”
- “Results in just 15 days”
 - Testing on ingredient not sufficient to support claim



However

- “Formulated to boost microcirculation.”
 - “NAD evaluated this claim as strictly an ingredient claim given the advertiser’s reference to “formulated” and in the absence of any reference to .. ‘proven’ and ‘clinically proven’ or any other representation , which would definitively implicate product performance.”

- *Avon Products Inc., (12/10/03)*

NAD on Comparisons to Medical Procedures



“Many manufacturers of cosmetics products are increasingly posturing their products not only as alternatives to plastic surgery but as delivering the same or similar results. Such promises are compelling to our aging population many of whom are unhappy with their appearance But cannot afford the costly cosmetic procedures necessary for dramatic improvement”

Skin Doctor's Cosmeceuticals (2/06/07)

NAD on Comparisons to Medical Procedures – con't

“An eyetuck without surgery?”

- Not a “mere question”
- Implies you can receive the same results as surgery with product

- *Skin Doctor's Cosmeceuticals (2/06/07)*

- “Needle? Knife? Lipo? No.” “Put your tummy and butt in their place.” Visual of needle.

- Claims could “reasonably communicate” product provides results similar to plastic surgery.

- *Avon Products, Inc. (10/25/05)*

Challenging Advertising At NAD

- **NAD BENEFITS**

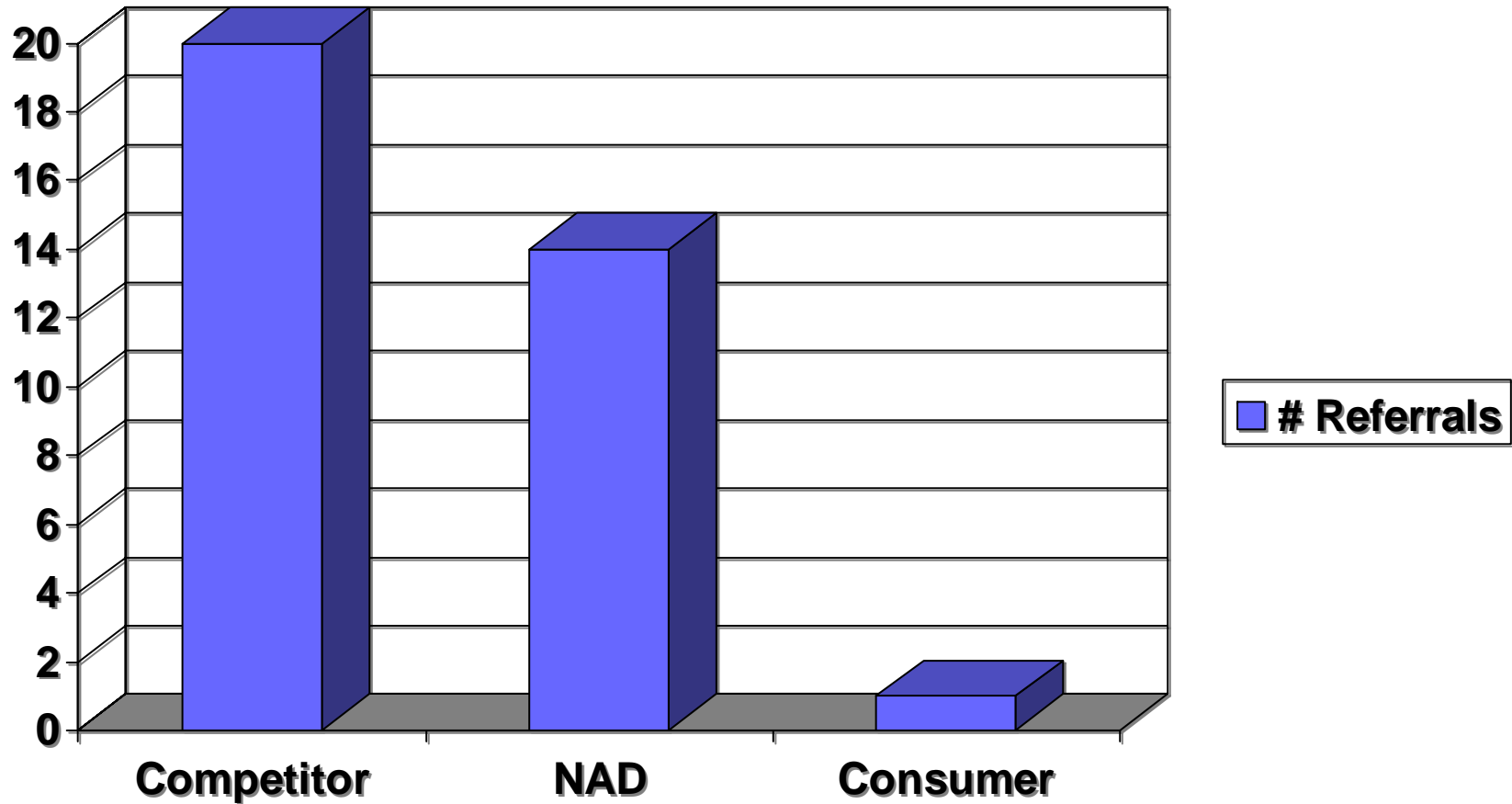
- Lower-cost alternative to litigation
- Process is typically quick and private
- NAD settles disputes fairly and effectively
- NAD attorneys are experts in advertising review
- NAD helps ensure a level playing field
- Advertiser has burden to show reasonable basis

Challenging Advertising At NAD, con't

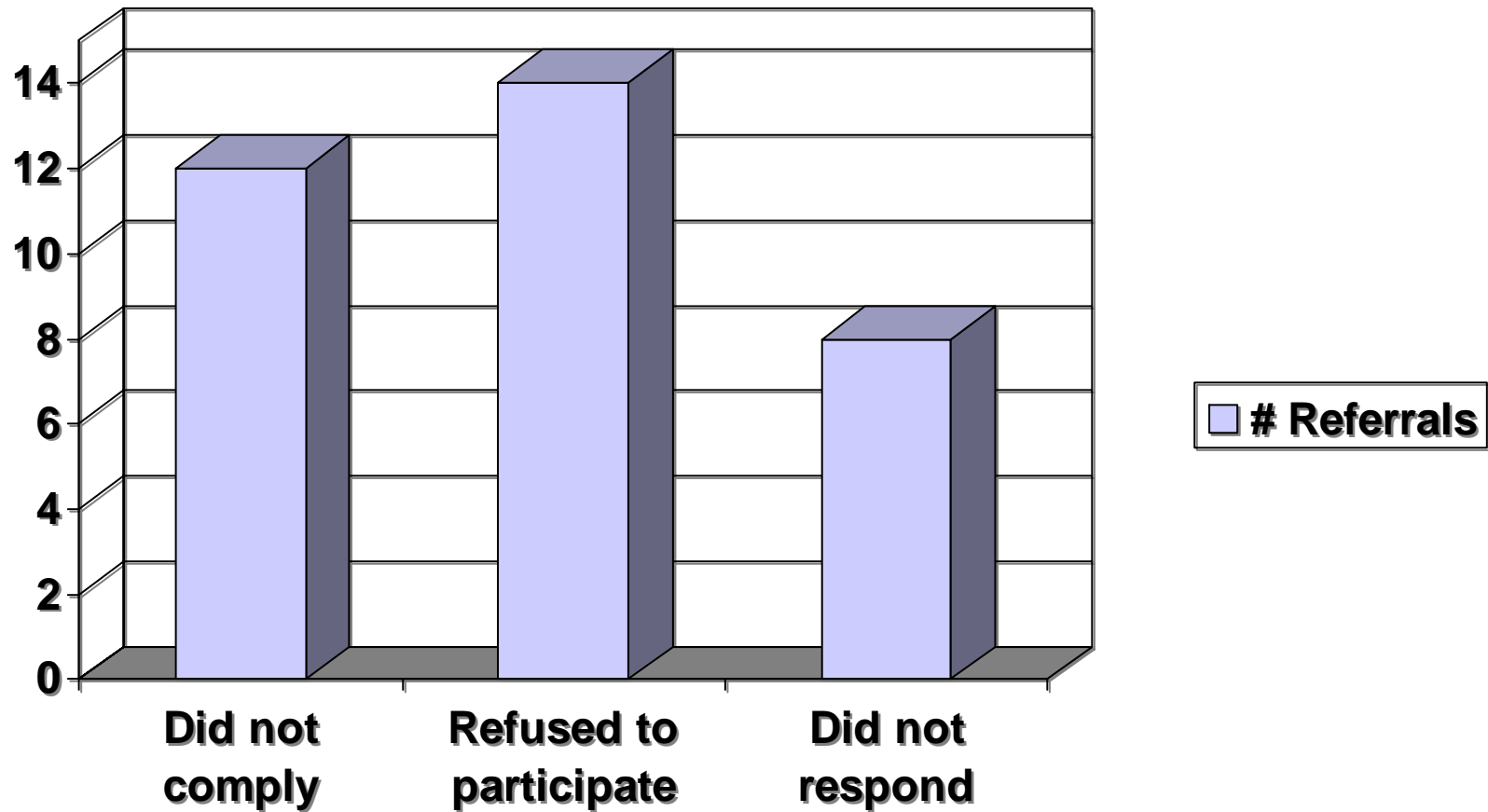
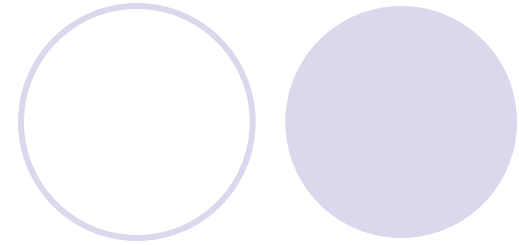
- **NAD DISADVANTAGES**

- Entirely voluntary; cannot compel production of documents
- No damages or attorney's fees
- Cannot force withdrawal of advertising
 - Ultimate sanction is referral to a government agency
- NAD tends to “split the baby.”

NAD/NARB Referrals (2004-2006) By Challenger Type



NAD/NARB Referrals (2004-2006) By Reasons for Referral



Research Methods



- Objective

- Analytical
- Surveys
- Clinical Trials

- Subjective

- Consumer Research
- Competitor Research
- Clinical Trials

A decorative graphic at the top of the slide consists of two groups of circles. The left group has a solid light purple circle on the left and an outlined light purple circle on the right. The right group has a solid light purple circle on the left, an outlined light purple circle in the middle, and a solid light purple circle on the right. The word "Analytical" is written in black text, with the first group of circles partially overlapping it.

Analytical

- Substantiates

- Concentration

- Purity

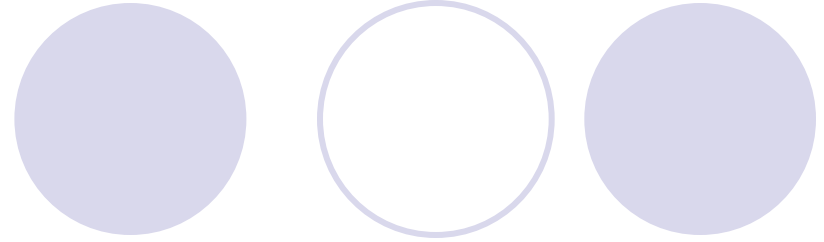
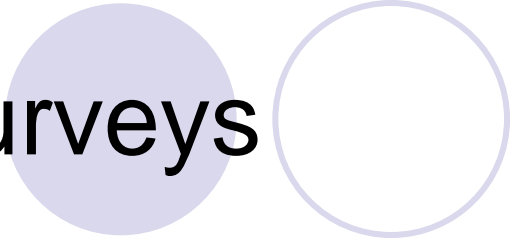
- Effectiveness

- Measure product absorption

- Results

- Measure dryness, wrinkle width / depth

Surveys



● zzz

Clinical Trials

A decorative graphic at the top of the slide consists of two groups of three circles. The first group on the left has a solid light purple circle on the left, a white circle with a light purple outline in the middle, and a solid light purple circle on the right. The second group on the right has a solid light purple circle on the left, a white circle with a light purple outline in the middle, and a solid light purple circle on the right.

- Double-blind

- Neither party (subject or clinician) knows the product / placebo being applied

- Placebo-controlled

- Active + Placebo Used

- Crossover

- Same subjects receive product and placebo
- Washout period



Clinical Trial Agreements

- CRO Agreements

- Trial Expectations
- Ownership and Use of Intellectual Property
- Milestones for Payment
- Sponsor / Principal Investigator Agreements

- Subject Agreements

- Full Disclosure
- Release of Liability
- Rights to Use Likeness

Clinical Trial Design



- Quantity of Active
- Same Form / Salt
- Administration Schedule
- Subject Group
- Length of Study

Raw Material v. Final Product Testing

- Raw Material Testing
 - Analytical
 - Animal or patch testing
 - Clinical Trial
 - May only be for Safety testing
 - Non-exclusive
- Final Product Testing
 - Analytical
 - Product elegance
 - Clinical Trial
 - Performance
 - Exclusive but Pricey



Claim Development / Strategy

- Consumers Purchase Products Based On
 - Brand
 - Reputation
 - Recommendation
 - Price
- Subjective Overwhelms Objective Decision Making



Claim Development / Strategy

- Why?
 - Purpose / Company Endpoint
- What?
 - Is Necessary to Get You To the Endpoint
- By Whom?
 - Reliance on Other Individuals
- Where?
 - In-house? CRO?
- When?
 - Proximity to New Product Launch or Marketing Focus

Types of Claims



- **Cosmetics**

- Features and Benefits
- Product Comparison
- Testimonials / Endorsements

- **OTC Topicals**

- Drug Monograph
- Features and Benefits / Quality
- Product Comparison
- Testimonials / Endorsements

Cosmetic Claims

A decorative graphic consisting of two groups of three circles. The first group on the left has a solid light purple circle on the left, a white circle with a light purple outline in the middle, and a solid light purple circle on the right. The second group on the right has a solid light purple circle on the left, a white circle with a light purple outline in the middle, and a solid light purple circle on the right.

- Features / Benefits

- “Appearance”

- “Look of”

- “Beautify”, “Cleanse”

- Higher Standard for “Quantifying” Claims

- “visibly reduces the look of fine lines and wrinkles by 25%”

- Higher Standard for “Time” Claims

- “Instantly”

- “Within Minutes”

- “Within 7 Minutes”



OTC Claims

- OTC Monograph

- Final Monograph

- Stick to the CFR Text
- Minimal Variability based on Quality

- Tentative Final Monograph

- May Expand Claims, IF
 - Patient Safety is Not Compromised
 - Clearly Substantiated
 - Within General Meaning of the Monograph
 - Maintain “Self-limiting” Parameters



Cosmetic / OTC Claims

- Product Comparison

- Quality

- Ingredient based

- Performance

- Consumer based

- Price

- Value based

- All must be substantiated and kept on file

Cosmetic / OTC Claims, con't

- How to Substantiate Comparison Claims

- Analytical Data

- Document date, sample, method, outcome

- Trial / Survey Data

- Subjective Outcome

- Product, duration, inclusion / exclusion criteria, metrics, consumer perception

- Objective Outcome

- Above plus trial design, methods, apparatus, statistical findings

- Point in Time Data

- Source

- Date

Use of Clinical Trial Data



- Based on Final Product

- Conservative Approach – 0.05 p-value

- “20% reduction in wrinkle depth after 30 days of use”

- More Aggressive Approach – craft claims that reflect the data, whether or not 0.05 significance is reached

- “Users report softer smoother skin in 2 days”

- Based on Ingredient

- Clearly indicate that the claim is based on specific ingredient results

- “Clinically proven ingredients improve skin tone” v.
“Clinically proven to improve skin tone”



Cosmetic / OTC Claims, con't

- Testimonials

- Name

- Data

- Original writing or recording

- Endorsements

- Contract Terms

- Must be User or Prescriber

- Continuity of Specialty or Industry

- i.e., Use Dermatologist or Entertainment Personality

With Claims, Intent is Everything

- The FDA and FTC Determine the Regulatory Status of Cosmetic Products Based on Intended Use
- Intended Use is Determined by Claims on the Product Label, Labeling and Advertising
- Overall “look and feel”

Specific Claims



- “All Natural” v. “With Natural Ingredients”
 - All - No Synthetic Ingredients in the Formulation
 - With – One or More Natural Ingredients
 - Best to Specify Which Ingredient is Associated with the Claim
- Percentage of Natural Ingredients
 - 100% is the Only Usable Percentage from a Marketing Perspective
 - Use ONLY if ALL Ingredients are Natural, including preservatives or any Ingredients with <1% Concentration



Other Label Uses for “Natural”

- Specific Natural Ingredients
 - “Contains Natural Aloe Vera”
- Specific Manufacturing Methods
 - “Contains Naturally Derived Peppermint Oil”
- Specific Functional Claims
 - “Brightens Your Skin’s Natural Radiance”

Anti-Aging Claims



- “Counteract”, “Retard”, “Control” the Aging Process
- “Repair” or “Restructure” the Skin
- “Rejuvenate”
 - Oasis Document
 - Foreign product – FDA
 - US product – Civil litigation
- “Molecules Absorb and Expand, Exerting Upward Pressure to ‘Lift’ Wrinkles Upward”

Cosmetics as Drugs



- Intended to Treat or Prevent Disease
- Intended to Affect the Structure or Function of the Body of Man
 - Determined by Claims
 - Determined by Statement of Identity
 - Determined by Formulation

Cosmetic as Drug – Determined by Claims

- Prevent or Treat Disease
 - Psoriasis, Eczema, Dandruff
 - Dry, Flaky Skin or Scalp
- Affect Structure or Function of the Human Body
 - Wrinkle Removers
 - Virtual Face Lift



Oral Hygiene Products

- Toothpaste v. Teeth Whiteners
 - “Brightens” v. “Whitens” Teeth
- Breath Freshener v. Anti-Gingivitis / Anti-Bacterial
 - “Fights Odor Causing Bacteria” v. “Prevents Gum Disease”

“Hormone” Claim



- Appearance of “Hormone” Anywhere on a Cosmetic Label, Including the Ingredient List, will Automatically Render the Product a Drug

Cosmetic as Drug – Determined by Statement of Identity

- Antiperspirant
- Deodorant
- Antiperspirant / Deodorant

Cosmetic as Drug – Determined by Ingredient / Formulation

- Toothpastes
 - Non-Fluoridated
 - Fluoridated
- Tanning Products
 - Self-tanners
 - Sunscreens

Other Formulated Cosmetic / Drug Products

- Wild Yam Cream
 - Be Careful as to Source
 - Be Careful as to “Hormone” Claims
- Glucosamine / Chondroitin
 - Be Careful as to Permitted Ingredient
 - Be Careful as to “Active” Ingredient Claims
 - Be Careful as to Efficacy Claims



OTC Drug Advertising

- FTC Review on Case by Case Basis
- Factors
 - The amount of consumer injury caused by the advertising
 - The potential risk to the user's health
 - Whether or not the claims involved are the type that consumers can evaluate for themselves
 - Whether or not other legal avenues can be pursued or self-regulating groups can address the issues
 - litigation brought by a competitor under the Lanham Act ([15 U.S.C. §1125\(a\)](#))
 - National Advertising Division of the Council of Better Business Bureaus; and
 - Whether or not the case will help clarify an important legal question.
 - Appropriate Use of FTC Resources

OTC Drug Advertising, con't

- CHPA Code of Advertising Practices, 22 items, i.e.
 - Advertising should urge consumers to read and follow label directions;
 - Claims of safety and efficacy should be supported by clinical and other scientific evidence, responsible medical opinion or experience through long use;
 - Advertising should omit inducements, such as prizes, to encourage unnecessary use of the medicine and should not show ingestion of the medicine;
 - Comparisons with competing products should be based on differences that are perceptible to the user and are scientifically supported;
 - Testimonials must be from actual product users; and
 - Advertising should not use health professionals as spokespeople.

Next Greatest Product – Puffery or Deception?

- Puffery

- Subjective in Nature
- Enticement

- Deception

- May be Proven Inaccurate

- Turning Point:

- Potential Consumer Harm
 - Economic
 - Product Safety



QA/QC Responsibility

- Development
 - Overall Strategy
 - What is the Company's Endpoint?
 - Specific Design
 - Appropriate Results
 - CRO Contracts
 - Subject Disclosures and Release
- Oversight
 - Development of Metrics
 - Is the Strategy Working?
 - Monitor Clinical Results
 - Match Claims to Data
- Ongoing Review
 - Update Substantiation Files on a Going Forward Basis

How Complaints / Litigation Shape Claims

- Agency Actions
- Quasi-Agency Actions
- Civil Actions

FDA / FTC Case Law



Historical Perspective

- U.S. v. Sudden Change (1969)
 - Intended Use Based on Product Claims
 - “Ignorant, Unthinking, Credulous Consumers”
- U.S. v. Line Away (1969)
 - Unnamed Ingredients
 - Advertising Claims
- Estee Lauder v. U.S. (1989)
 - Anti-Aging Claims



FDA / FTC Case Law

More Recent Developments

- In re Revlon, (1993) - unsubstantiated collagen and sunscreen claims
- In re St. Ives Labs (1991) – unsubstantiated comparison of cosmetic's effect to Retin A drug product
- In re Dr. Patricia Wexler (1992) – false and misleading claims of expert endorser associated with a baldness cure
- In re Tru-Vantage International (2001) – snoring treatment claim challenge
- In re Natural Organics, Inc (2000) – drug claim challenge for ADD/ADHD

FTC Warning Letters



- February 15, 2007

- “Reduces Redness”

- “Smoothes Scaly Skin”

- In addition to: “Intended for individuals with chronic skin redness and flaking...associated with dermatologic conditions like seborrheic dermatitis or rosacea.”, “Inflamed oily skin associated with troublesome dermatologic conditions..dramatic relief...for oily and acne prone skin..clinically proven to reduce redness, eliminate scaling, and help soft, smooth skin reappear.”

FTC Warning Letters, con't

- February 15, 2007, con't

- Under a “Clinical Trials” Heading

- 71% of participants demonstrated reduction in redness
- 88% of those with scaly skin had marked reduction in scaling
- 69% of participants demonstrated an improvement in skin tone
- 92% of those reporting itching, stinking or burning prior to the study reported a reduction in one or more symptoms



FTC Warning Letters, con't

- February 15, 2007

- Testimonials

- “You don’t have to put up with red, dry, flaky, itchy, irritated skin and you don’t need to use a prescription medication”
- “I was always flushed. I was always red...I tried [product] and my skin cleared up enormously”
- “I was suffering from eczema, my skin around my eyes was really flaky...I tried [product]...overnight I could feel the roughness go away...I’ve had no breakouts from eczema at all”

FTC Warning Letters, con't

- July 7, 2006

- “A real reduction in wrinkles, particularly the crow’s feet around my eyes”
- “Helps correct the effects of sun damage on the skin”
- “Decreases the length and depth of stretch marks”
- “Stimulates the renewal of skin cells”
- “After twelve weeks, hair thickness increased by 69%, while hair growth rate increased 33%”

FTC Warning Letters, con't

- September 26, 2005

- Combination of “body shape” and “cellulite toning” imply a change to the body’s structure
 - “body shape: cellulite reduction cream”
- “Simply by massaging [product] into your skin twice a day, you can tone and firm those problem areas that diet and exercise can’t shape on their own”
- “I was considering plastic surgery. But now I don’t have to”

FTC Warning Letters, con't

- September 26, 2005

- “This anti-aging skin serum helps reduce wrinkles and fine lines”
- “[Product] works as an instant lifting serum and active anti-aging ingredient”
- “[Product] may reduce wrinkle length and width nearly by a combined 50%”



Consumer Generated Actions

- Lanham Act

- False Representations

- Scheufler v. Estee Lauder – allegations of false advertising and unfair competition against anti-aging claims associated with Crème de la Mer

- Products Liability

- Negligence

- Duty to Warn