

# STAKING CLAIMS

## **Making Permissible Claims in the Labeling and Advertising of Dietary Supplements**

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# AGENDA

- FDA Regulation
  - Intent
  - Claims
    - Structure – Function Claims
    - Disease Claims
- FTC Regulation
  - Substantiation
  - Endorsements and Testimonials
  - Material Connections
  - Affiliate Monitoring
- Final Thoughts



# REGULATING CLAIMS



- FDA regulates labeling; focuses on the content of claims and whether the claims are legally permissible, although it may also ask for substantiation
- FTC regulates advertising; focuses on format, truthfulness and not misleading, and substantiation of claims
- Both FDA and FTC require material claims to be substantiated by “competent and reliable scientific evidence”
- Creates a balancing act between science to support claims while not making disease claims for non-drug products





# FOOD AND DRUG ADMINISTRATION



# FDA ENFORCEMENT

- FDA regulates labeling
- Labeling is defined in the FDCA as labels and other written, printed or graphic material accompanying a product
- Labeling includes:
  - Brochures
  - Infomercials
  - Web sites
  - Social media
- Even if item doesn't meet definition of labeling, FDA may review for evidence of intent



twitter



# FDA ENFORCEMENT

- Intent
  - FDA may establish intent through numerous sources including:
    - Product labels and labeling
    - Catalogs
    - Brochures
    - Books
    - Audio and videotapes
    - Websites
    - Social Media
    - Oral presentations
  - Thus, any information disseminated about a product by a company or representatives may form “intent”
  - The connection to the company is key – a non-profit organization that is made up of employees or distributors will still be tied back to company as evidence of intent



# FDA ENFORCEMENT

- Examples of information that may establish “Intent” to sell dietary supplement products as drugs
  - Social Media pages, forums, and groups created and run by distributors that offer products for disease purposes
  - Testimonials and personal experiences regarding disease treatment given at meetings run by a company or its distributors, affiliates, associates
  - Books written by members of the company or distributors that promote products for disease purposes
- **To be clear, commercial speech promoting products is not afforded the same protections under the First Amendment right to Freedom of Speech**



# REGULATING CLAIMS



- Claims may be express or implied
- Express Claims:
  - YL Peppermint oil is great for arthritic pain
  - Take YL Thieves at the first indication you are getting a cold or infection
- Implied Claims:
  - Discussion about the benefits of particular ingredients in a product without mention of the product
  - Articles indicating that natural therapies like essential oils work best in the early stages of cancer
  - Personal experiences with recovering from a disease or condition and use of YL products





# CLAIMS

- Three types of claims permitted for Foods, Beverages and Supplements



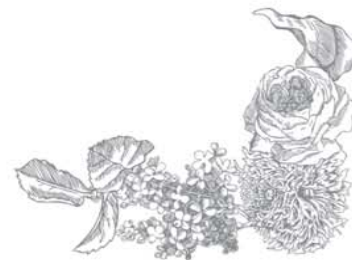
**Structure-Function Claims**  
**Nutrient Claims**  
**Health Claims**



# STRUCTURE-FUNCTION CLAIMS



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# STRUCTURE-FUNCTION CLAIMS

- Structure-Function claims or statements are the most common or “building block” claims that describe an ingredient’s effect on the structure and/or function of the body
  - “Helps support a healthy immune system”
  - Words like support, maintain, and promotes
  - Don’t use words like treats, prevents, cures
  - No pre-approval necessary from FDA, but manufacturer, packer or distributor must submit claims within 30 days of marketing a supplement bearing s/f claims
  - Section 6 of DSHEA and 21 CFR 101.93
    - “These statements have not been evaluated by the Food & Drug Administration. This product is not intended to diagnose, treat, cure or prevent a disease.”



# STRUCTURE-FUNCTION CLAIMS

- **THE #1 RULE TO LIVE BY -- A FOOD, BEVERAGE OR SUPPLEMENT PRODUCT MAY NOT BE INTENDED TO DIAGNOSE, TREAT, CURE, OR PREVENT A DISEASE**
- If it does, it will be considered a drug by the FDA
- It doesn't matter if a company can provide substantiation that a supplement or food product does help with disease; this is because Congress decided only drugs may be offered to diagnose, treat, cure or prevent a disease
- Mentions of specific diseases, such as diabetes, HIV, or cancer, are clear red flags to the FDA



# STRUCTURE-FUNCTION CLAIMS

- What is a disease?
  - Definition of disease at 21CFR 101.93(g)
- “Damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., prediabetes or hypertension)
- 21 CFR 101.93(g)(2) identifies 10 categories of products that are likely to be considered disease claims



# STRUCTURE-FUNCTION CLAIMS

- **21 CFR 101.93(g)(2)(i) Claims an effect on a disease or class of diseases**
  - Claims that mention a disease by name
    - “\_\_\_\_\_ will help reduce the risk of cardiovascular disease”
    - “\_\_\_\_\_ will prevent colds and flu”
  - Claims that otherwise describe a disease
    - “Relieves crushing heart pain” (heart attacks)
    - “Prevents bone fragility” (osteoporosis)
    - “Controls blood sugar in people with insufficient insulin”
  - Remember claims about ingredients that are contained in products are claims about the product



# STRUCTURE-FUNCTION CLAIMS

- 21 CFR 101.93(g)(2)(ii) Claims an effect on a characteristic sign or symptom of a disease
  - Is it a condition that suggests the product is intended to affect a particular disease?
    - "Reduces cholesterol" (heart disease)
    - "Reduces joint pain" (arthritis)
  - You may make a claim that either specifies it is more a non-disease purpose or qualifies it as maintaining already healthy conditions
    - "Reduces inflammation associated with muscle fatigue from exercise"
    - "Maintains cholesterol levels already within in the normal range"



# STRUCTURE-FUNCTION CLAIMS

- **21 CFR 101.93(g)(2)(iii) Claims an effect on abnormal condition associated with a natural state or process**
  - **Claims associated with normal conditions of a natural state or process are permitted**
    - "Mild mood changes, cramps associated to menstrual cycle"
    - "Noncystic acne"
    - "Mild memory or hair loss associated with aging"
  - **Claims associated with abnormal conditions of a natural state or process are disease claims**
    - "Alzheimer's or senile dementias"
    - "Cystic Acne"
    - "Toxemia"





# STRUCTURE-FUNCTION CLAIMS



- 21 CFR 101.93(g)(2)(iv) Implied disease claims because of a product name, formulation, pictures or citations to disease conditions
  - Incorporating the name of a disease in a product name is a disease claim
    - "Arthrit-A-Cure"
    - It doesn't matter if it is only a partial or misspelled
  - If citations are made to publications with disease treatment, they are treated as disease claims
    - Bibliography is permissible; use in text is not
  - Picture or symbols may be disease claims



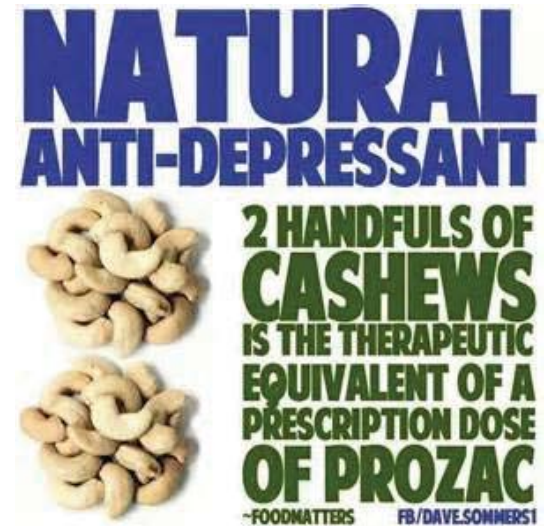
# STRUCTURE-FUNCTION CLAIMS

- 21 CFR 101.93(g)(2)(v) Claims that a product belongs to a class of products that are intended to diagnose, treat, cure or prevent a disease
  - Analgesics
  - Antibiotics
  - Antidepressants
  - Antimicrobials
  - Antiseptics
  - Antivirals
  - Anti-inflammatories
  - Vaccines



# STRUCTURE-FUNCTION CLAIMS

- 21 CFR 101.93(g)(2)(vi) Claims to be a substitute for a product that is a therapy for a disease
  - Claims that suggest a product is a substitute for a drug or therapy for a disease are disease claims
    - “Take \_\_\_\_\_ instead of chemotherapy”
    - The “Natural” alternative, such as “Herbal Prozac”
  - Claims that a product will have fewer side effects than a therapy for a disease
    - “Take \_\_\_\_\_. All of the benefits without the side effects of [drug]”



# STRUCTURE-FUNCTION CLAIMS

- 21 CFR 101.93(g)(2)(vii)  
Claims to augment a therapy or drug intended to diagnose, mitigate, treat, cure or prevent a disease
  - **Claims that a product will assist a drug therapy**
    - “Use as part of your diet when taking insulin to help maintain a healthy blood sugar level”
    - Could say “use as part of your diet to help maintain a healthy blood sugar level”



# STRUCTURE-FUNCTION CLAIMS

- **21 CFR 101.93(g)(2)(viii)**  
**Claims to have a role in the body's response to a disease or to a vector of disease**
  - **"Supports the body's antiviral capabilities"**
  - **"Supports the body's ability to resist infection"**
  - **Can say "supports the immune system"**



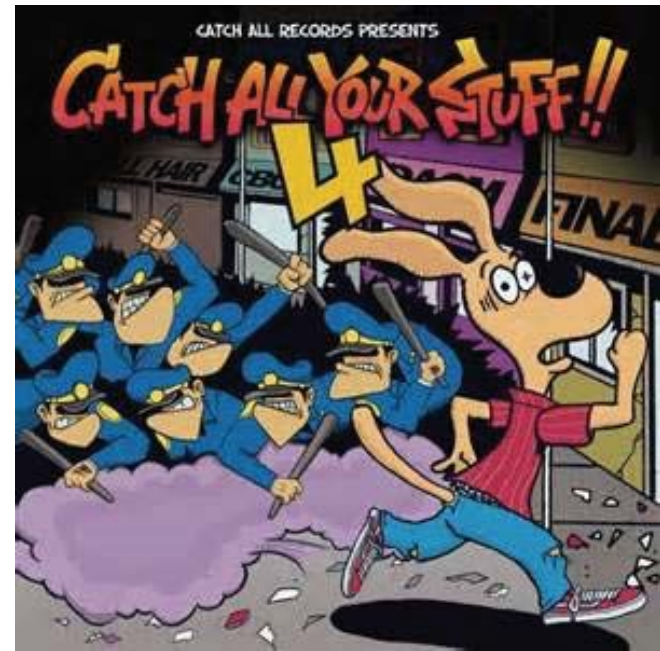
# STRUCTURE-FUNCTION CLAIMS

- 21 CFR 101.93(g)(2)(ix) Claims to treat, prevent or mitigate adverse events associated with a therapy for a disease
  - **Disease claims if the adverse events constitute diseases**
    - "Reduces nausea associated with chemotherapy"
    - "Helps avoid diarrhea associated with antibiotic use"
  - **Claims indicating a product is helpful with a nutrient deficiency caused by a therapy are permissible**
    - "Helps restore Vitamin B depletion associated with \_\_\_\_\_"



# STRUCTURE-FUNCTION CLAIMS

- 21 CFR 101.93(g)(2)(x) Claims to otherwise suggest an effect on a disease (catch-all)



# NUTRIENT CONTENT CLAIMS

**FREE** *excellent source of*  
**LOW** **LIGHT**  
**LOWER** **SOURCE OF**  
**MORE** **REDUCED**  
**lite** **HIGH SOURCE OF**  
**VERY HIGH** **LESS**  
**GOOD SOURCE OF**





# NUTRIENT CONTENT CLAIMS

- **GENERAL CHARACTERISTICS**
  - **Nutrient content claims expressly or implicitly describe the level of a nutrient in a product, using terms such as "high", "low", and "free" or compare the level to another food, such as "more", "less" or "lite"**
  - **21 CFR § 101.13 sets forth general requirements for nutrient content claims**
  - **Nutrient must have RDI or DRV to make nutrient content claim**
  - **No claims may be made for products for infants and children under 2 unless specifically provided for**
  - **Specific nutrient content claims are set forth in 21 CFR § 101.54 to 101.67 and no claims may be made outside of those provided for in the regulations**



# HEALTH CLAIMS



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# HEALTH CLAIMS

- **Two main characteristics of health claims**
  - **Health claims describe the relationship between a food, food component or dietary ingredient and the reduction in risk of a disease or health related condition**
- **Three types of health claims**
  - **Health claims authorized by FDA in regulations**
  - **Health claims based on an authoritative statement of a scientific body of the U.S. government**
  - **Qualified health claims**
- **Currently, there are no health claims approved for essential oils**



# FTC REGULATION



## FEDERAL TRADE COMMISSION



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# FTC REGULATION

- **FTC is primary federal agency that monitors endorsements and testimonials in advertising**
- **FTC is charged with enforcing Section 5 of the FTC Act which prohibits deceptive and unfair acts or practices**
- **Truth-in-Advertising Principles**
  - **Truthful**
  - **Not misleading**
  - **Adequate substantiation**



# FTC REGULATION

- **SUBSTANTIATION**

- **This is the area that carries the biggest risks and possible repercussions from both a regulatory and civil litigation standpoint**
  - **you cannot make claims that are unsupported**
- **All objective claims must be supported by "competent and reliable scientific evidence"**
- **There is no statutory definition but it is defined in FTC cases as "tests, analyses, research, studies, or other evidence that have been conducted and evaluated in an objective manner by qualified persons, that are generally accepted in the profession to yield accurate and reliable results"**
- **Personal experience and opinion is not sufficient substantiation**
- **FTC has required two double-blinded, placebo controlled clinical trials for certain claims in recent Consent Decrees, but still maintains that this is not the new standard for all claims**
- **Reviewed on a case-by-case basis**



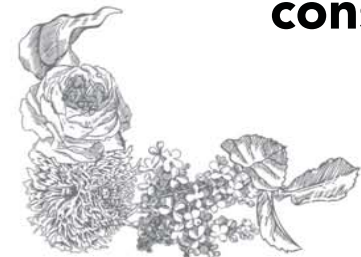
# FTC ENDORSEMENT GUIDES

- **Endorsements**
  - **“Any advertising message that consumers are likely to believe reflects the opinions, beliefs, findings, or experiences of a party other than the sponsoring advertiser, even if the views expressed by that party are identical to those of the sponsoring advertiser.”**
- **Endorsements may be:**
  - **Verbal statements**
  - **“Liking” or retweeting claims**
  - **Demonstrations**
  - **Depictions of the name, signature, likeness or other identifying personal characteristics of an individual**
  - **Name and seal of an organization**



# FTC ENDORSEMENT GUIDES

- **Examples**
  - **A television advertisement for a particular type of golf balls shows a well-known golfer hitting drives off of a tee. This is an endorsement even if the golfer does not make any verbal statements**
  - **A professional racecar driver delivers the advertising message for a tire company in a television commercial. Even if the message isn't depicted as the personal opinion of the driver, consumers are likely to think it is the personal opinion and therefore, it is considered an endorsement**





# FTC ENDORSEMENT GUIDES



- **Examples**

- **Consumer not affiliated with the company purchases essential oils and writes in her personal blog that she doesn't get colds and flu anymore. Not an endorsement attributable to the company**
- **If the consumer got the essential oils for free because a store or online site generated a coupon for a free trial, still not an endorsement**
- **If the consumer is affiliated with the company, either as an employee, a distributor or a blogger paid to write about the product, the personal experience is now an endorsement attributable to the company**



# FTC ENDORSEMENT GUIDES

- *General Considerations*
  - **Endorsements must reflect the honest opinions, findings, beliefs or experiences of the endorser**
  - **Endorser must be a bona fide user of the product when he or she represents as a user of the product**
  - **Both advertisers and endorsers may be liable for improper endorsements**
  - **An advertiser may use an endorsement only so long as it has good reason to believe that the endorser continues to subscribe to the view presented**
  - **An advertiser should secure the endorsers views under reasonable intervals, such as alterations to the products, changes in main competitors products, etc.**



# FTC ENDORSEMENT GUIDES

- *Example*
  - **Consumer states that he has been using a certain essential oil for several years with great results**
  - **Manufacturer/marketer reformulates the product**
  - **Prior to continued use of the endorsement, advertiser should contact consumer to ensure consumer would continue to subscribe to the views presented previously**



# CONSUMER TESTIMONIALS



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# CONSUMER TESTIMONIALS

- **Consumer testimonials used in labeling or advertising become the adopted statements of the company – thus, a company or representatives cannot use testimonials to promote products that make claims the company is not allowed to expressly make**
- **Must be substantiated in the same manner as representations made directly by the advertiser**
- **Testimonials themselves are not “competent and reliable scientific evidence”**
- **The fact that the consumer really believes the testimonial to be true is not sufficient to substantiate the claim**



# CONSUMER TESTIMONIALS

- **Example**

- **Brochure for peppermint oil contains numerous testimonials who claim that they maintained healthy digestive systems (not cured IBS) after using the product**
- **Advertiser must have competent and reliable scientific evidence to support claims that the product supports and maintains healthy digestive systems**
- **Advertiser must also have substantiation that new users will typically experience similar results – this is especially true with weight-loss products**
- **If not typical, you must disclose what typical results are**



# CONSUMER TESTIMONIALS

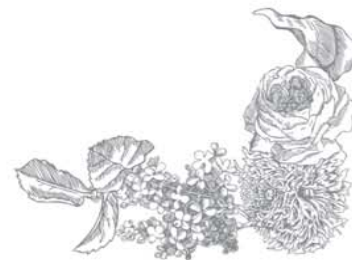
- **Example**
  - **“I lost 50 pounds in 6 months with WeightAway”**
  - **Ad conveys that typical person will lose 50 lbs in 6 months. If consumers cannot expect such results, the ad should disclose the expected results such as “in a 90 day clinical study, the average person lost a total of 5 lbs per month.”**
  - **If the advertiser does not have substantiation of expected results, it should not make specific claims of weight loss**
  - **If an advertiser clearly describes the specific conditions under which results were achieved, it is unlikely to convey that all consumers will have similar results.**



# MATERIAL CONNECTIONS



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# MATERIAL CONNECTIONS

- **Material connections between the endorser and the seller that are not reasonably expected by the audience must be disclosed**
- **Material connections are those connections that might materially affect the weight or credibility of the endorsement**
- **Material connections may be connections of a personal, financial, or business nature, among others**



# MATERIAL CONNECTIONS

- **Example**
  - **An advertisement, a blog entry, or a Social Media entry features the testimonial of a man touting the great night's sleep he had after using Valerian Essential Oil.**
  - **The man is actually a principal, an employee, or a distributor of the company.**
  - **While the testimonial is permissible, the relationship of the man to the company must be disclosed as a material connection.**

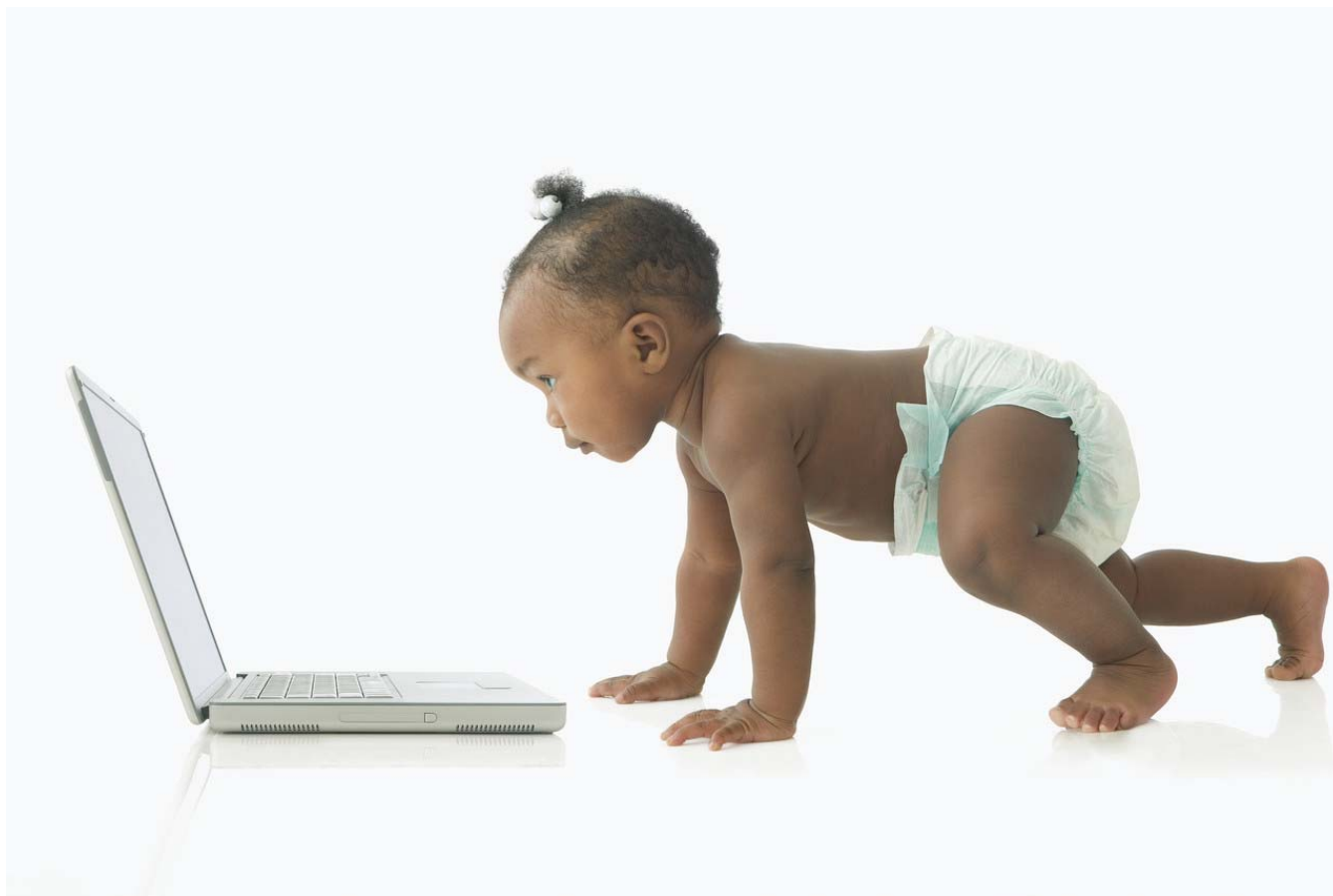


# MATERIAL CONNECTIONS-EXPERTS

- **Example**
  - **Doctor gives an endorsement in an advertisement for a product, stating it is the best she has ever seen**
  - **It is likely that consumers would expect the doctor to be compensated**
  - **However, if the doctor has an ownership interest in the company selling the product, that is a connection that consumers are unlikely to expect and should be disclosed**



# SOCIAL MEDIA



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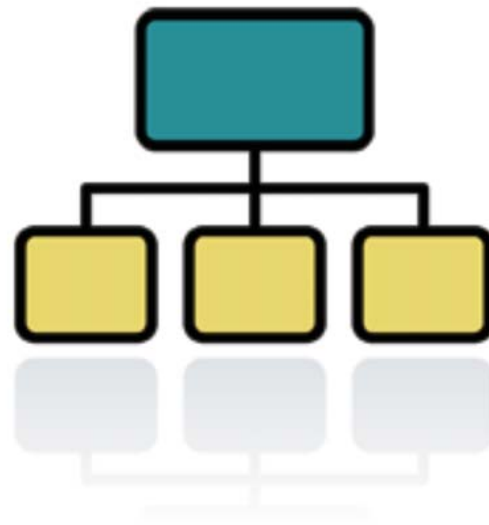


# SOCIAL MEDIA

- **Laws pertaining to advertisements and endorsements apply to Social Media pages on Facebook, Twitter, and Pinterest**
- **Most blogging issues involve material connections; however, remember that intent may be attributed to the company if there is a connection.**
- **Remember the earlier example. If there is a relationship between the blogger and an advertiser that could affect the credibility of the review, relationship should be disclosed.**
- **Disclosure can be as simple as “Company X gave me this product to try...”**



# AFFILIATE MARKETING AND MONITORING



# AFFILIATE MARKETING

- **Affiliates must disclose material connections**
- **If web site contains links to retailers and affiliates get paid a commission, it must be disclosed**
- **Disclosures must be clear and conspicuous, not buried in terms and conditions or on a separate “About Us” page**
- **Must not use deceptive advertising**
- **Must have substantiation for claims**



# AFFILIATE MARKETING-FTC ACTION

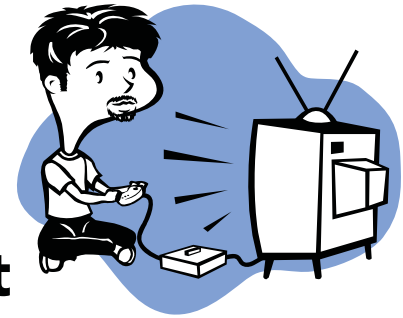
- April 2011, FTC filed actions against IO affiliate marketing operations for using fake websites to promote weight-loss products containing acai berries
- Websites purported to be legitimate news sites investigating weight-loss claims
- Fake reporters, pictures, and testimonials
- FTC alleged:
  - Deceptive and misleading advertising
  - Failure to disclose material connections
  - Lack of substantiation for weight-loss claims





# AFFILIATE MARKETING-FTC ACTION

- *FTC v. Reverb Communications, Inc.*
  - **August 2010 consent decree between FTC and Reverb**
  - **Reverb provided public relations, promotion and marketing services for video game companies**
  - **Reverb employees, posing as ordinary consumers, posted positive product reviews for client video games without disclosing the relationship between the parties**
  - **FTC alleged misrepresentations and failure to disclose material connections**



# AFFILIATE MONITORING

- *Advertisers are expected to have program in place to train and monitor affiliate marketers*
- *Scope of program depends on risk of harm*
- *Program should include:*
  - **Explanation to members of network what can and can't be said about the product**
  - **Set up a reasonable monitoring program to check out what affiliates are saying about your product**
  - **Follow up on questionable practices; there should be repercussions for non-compliance**
- *Unlikely that advertiser will be held responsible for every statement made by an affiliate marketer if company has a reasonable training and monitoring program in place*



# AFFILIATE MONITORING-FTC ACTION

- *FTC v. Legacy Learning Systems*
  - **March 2011 consent decree between FTC and Legacy**
  - **Legacy sold “How to play the guitar” instructional DVDs**
  - **Endorsements posted online appeared to be from ordinary consumers and reviewers**
  - **Endorsements were actually posted by affiliate marketers who received commissions for sales**
  - **Consent order outlines monitoring program:**
    - *Set up system to monitor affiliate representations and disclosures*
    - *Monitor top 50 affiliates each month and 50 others randomly*
    - *Non-compliance results in termination*



# FINAL THOUGHTS



# FINAL THOUGHTS

- *ALL MARKETING OR ADVERTISING BY COMPANY OR AFFILIATES MAY BE VIEWED AS EVIDENCE OF INTENT*
- *CLAIMS MADE BY AFFILIATES, DISTRIBUTORS, ASSOCIATES ARE ATTRIBUTED TO THE COMPANY*
- *STRUCTURE-FUNCTION CLAIMS MAY NOT SHOW THAT A PRODUCT CAN HELP DIAGNOSE, TREAT, CURE OR PREVENT ANY DISEASE*
  - *This is not just express disease names but signs and symptoms, replacements for drugs, etc.*



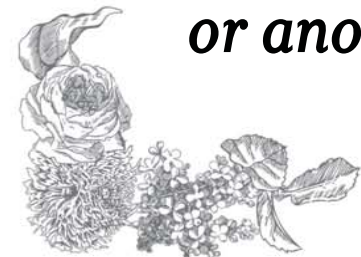
# FINAL THOUGHTS (CONT.)

- ***ALL LABELING AND ADVERTISING CLAIMS MUST BE SUBSTANTIATED BY COMPETENT AND RELIABLE SCIENTIFIC EVIDENCE***
- ***TESTIMONIALS IMPLY EXPECTED RESULTS***
  - ***Non-typical results must be accompanied by a disclosure of typical results***
- ***MATERIAL CONNECTIONS MUST BE DISCLOSED***
- ***SOCIAL MEDIA CLAIMS MUST COMPLY WITH THE SAME LAWS AS ALL ADVERTISING – TRUTHFUL, NOT MISLEADING, AND SUBSTANTIATED***



# LEGAL DISCLAIMER

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# QUESTIONS



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