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Give Me a Break, Is That Really a Disease Claim?

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Agenda

- **What is a Claim?**
- **FDA "Claims" Enforcement Trends**
- **Claim Substantiation**
- **FTC Enforcement Trends**
- **Questions**

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

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)

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Health Claims

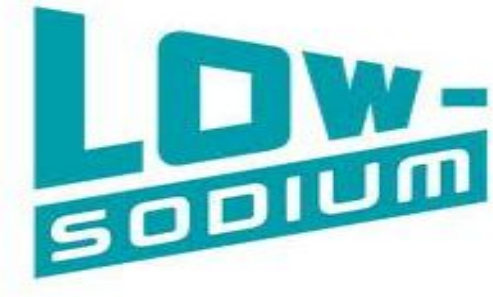
Qualified Health Claims

- 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."

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.



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Structure/Function Claims

FDA

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.

Structure Function Claim Criteria

FDA has developed criteria to assist companies in determining whether a particular claim is a permissible structure/function claim or an impermissible disease claim.

1. **A claim <u>may not</u> suggest that the product has an effect on a specific disease or class of disease.**

   Ex. 1: Reduces the pain and stiffness associated with arthritis.

2. **A claim may not refer to a characteristic sign or symptom of a disease or class of disease.**

   Ex. 2: Lowers (or helps maintain) blood sugar levels.

Structure Function Claim Criteria, continued

3. **References to signs and/or symptoms of natural states are permissible as long they are not uncommon and would not cause significant harm if left untreated.**

   Ex. 3: Helps alleviate [chronic] constipation. FDA considers "chronic" to be implied.

4. **A claim may not be disguised as a product name**.

   Ex. 4: "Arthex" or "Cho-less-terol" are impermissible, but "Mood Health" and "Joint Flex" are okay.

5. **A claim <u>may not</u> refer to a supplement's formulation if the statement suggests that the product is/was an FDA-regulated drug.**

   Ex. 5: *"Contains l-carnitine — Formerly only available as a prescription drug."*

Structure Function Claim Criteria, continued

6. **Citations to an article that refers to a disease in its title are permissible if the labeling taken as a whole does not imply a disease prevention or treatment claim.**

7. **The use of the terms disease, diseases, antiviral, antibacterial, antiseptic, antibiotic, analgesic, diuretic, antidepressant, vaccine, analgesic, or any other word suggesting that the product belonged to a class of products intended to cure, treat, or prevent disease, is not permitted.**

   Ex. 7: Stimulates the bodies antiviral capacity.

8. **The use of pictures, vignettes, symbols, or other means in a manner that would otherwise suggest the presence of a disease condition is not permitted.**

Ex. 8: Picture of a hand with red joints may be considered an implied disease claim because the red could be interpreted as a sign of pain or arthritis.

Structure Function Claim Criteria, continued

9. **A claim <u>may not</u> suggest that the supplement (or its ingredients) belong to a particular class of drugs or is a substitute for a particular therapy.**

   Ex. 9: “Herbal antidepressant” OR “Maintain joint health without NSAID’s”

10. **A claim <u>may not</u> suggest that a product is useful as a companion to regular drug therapy, or that it prevents or treats adverse events associated with a disease if the adverse events are also disease conditions.**

    Ex. 10: “Helps maintain blood sugar levels in insulin dependent people.”

11. **FDA adds a final catch-all criterion that prohibiting the use of a claim that “otherwise” suggests a disease or disease condition.**

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Developing Structure/Function Claims

Key Words to Use:

- Support
- Maintain
- Promote
- E.g. “Promote optimal heart health.”

Key Words to Avoid:

- Treat
- Relieve
- Prevent
- Cure
- Therapy or therapeutic
- Build or strengthen (for immune system claims)
- Correct

Claims related to cholesterol, blood pressure, or blood sugar/glucose, should technically use the wording “Helps maintain healthy [Cholesterol/Blood Pressure/Blood Sugar] levels that are already within the normal range.”

Risk Assessment Exercise:
Structure/Function Claims

"Diabeta Formula"

Immune support formula intend to enhance cellular resistance at the deepest level.

Ossify (AH-suh-fy)

Intransitive verb

1. **To change into bone; to become bony.**
2. **To become hardened.**

Transitive verb.

1. **To change into bone; to convert from a soft tissue to a hard bony tissue.**
2. **To harden.**

Natural Herb Tea Laxative

JointSupport^{Rx}

"I have suffered with skin lesions for about 10 years …with your product I have been able to heal the lesion and the one on my leg went from infected to drying up and almost gone, the rest of my body lesions are also reducing, as a result of your product …"

Current "Claim" Enforcement Trends

Inflammation

2013 Examples:

- "Holm Oak (an ingredient in your product) … [a]nti-inflammatory and antibiotic properties." [[Brower 9/9/2013]]
- "It supports…the body's natural anti-inflammatory response." [[Y.S. Health 8/29/13]]
- "Grape seed extract contains polyphenols which have been shown in clinical studies to exhibit anti-inflammatory activity. … For example in a study conducted by the University of Rovira, in Spain, researchers concluded that Grape Seed Extract demonstrates a potential health benefit in inflammatory conditions…. " [[Nature Cast Products 7/15/13]]
- "[Product] is an all-natural herbal supplement known to reduce pain and inflammation…" [[Entrenet 5/8/2013]]

Current "Claim" Enforcement Trends

Blood Sugar

- FDA issued 9 WLs in June-July 2013 against companies marketing dietary supplements allegedly claiming to mitigate, treat, cure or prevent diabetes and related complications.
- How far is too far? Below are cited "disease" claims:
  - "Naturally control and maintain you blood glucose levels."
  - "Sugar Balancer"
  - "Lower blood sugar & A1c levels . . . ."
  - "[Product] not only helps to bring down the blood sugar level, it also helps repair β cells and restore the function of pancreas."
  - "Lessened total insulin needed."
  - "It has been proven by a research . . . to have similar effects to medicines used in diabetes treatment."
  - "NEW – Advanced Nutraceutical Stops This Silent Killer Before It Destroy[s] You . . . And those You Love!

Claim Substantiation

- FTC and FDA require "competent and reliable scientific evidence" to substantiate all claims used in advertising and structure/function claims 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

- Advertising Claims
  - More often than not, advertising claims will not suggest that a certain level of support exists for a claim. In this situation, the level of scientific support necessary to substantiate a claim ***depends on the amount of research experts in the field would consider adequate*** to establish the claim's truthfulness.
  - Context is KEY.
    - E.g., Not a health claim, but a statement of dietary guidance: "A diet rich in fruits and vegetables may reduce the risk of coronary heart disease."
    - No reference to a specific substance.
    - Do not include graphics depicting medicine or heart health.
    - Must be truthful and not misleading.

Claim Substantiation

- Factors Affecting Required Levels of Substantiation:
  - Type of product
  - Type of claim
  - 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

- **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 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
    - 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
  - 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

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Claim Substantiation

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Your Partner in Clinical Research!

YOUR clinical study is YOUR evidence evaluated by Regulatory authorities
BUT
in the nutrition industry we start off with a handicap!!!

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Surrogate endpoints are risk biomarkers that have been shown to be valid predictors of disease risk. They are biomarkers intended to substitute for a clinical endpoint such as incidence of disease or mortality.

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Claim Substantiation

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Evidence Based Medicine vs. Evidence Based Nutrition

Parameter	Drugs	Nutrients
Essentiality	None	Essential
Inadequacy results in disease	No	Yes
Homeostatically controlled by the body	No	Yes
True placebo group	Yes	No
Baseline “status” affects response to intervention	No	Yes
Systemic function	Isolated	Complex networks
Targets	Single organ/tissue	All cells/tissues
Effect size	Large	Small
Side effects	Large	Small
Nature of effect	Therapeutic	Preventative

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Claim Substantiation

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The intent for Pharmaceutical studies is to treat disease populations and bring them to normal targets

IN CONTRAST

The intent of Dietary Supplement studies is to prevent disease in normal/pre-clinical populations

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CONCEPT for RCT is similar in Pharma and nutrition studies

HOWEVER

NUMBER OF SUBJECTS IN PHARMA STUDIES ARE IN **THOUSANDS** *VS* **HUNDRED OR LESS** IN NUTRA STUDIES

Therefore margin for error in nutra studies is significantly higher than in pharma studies

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Claim Substantiation

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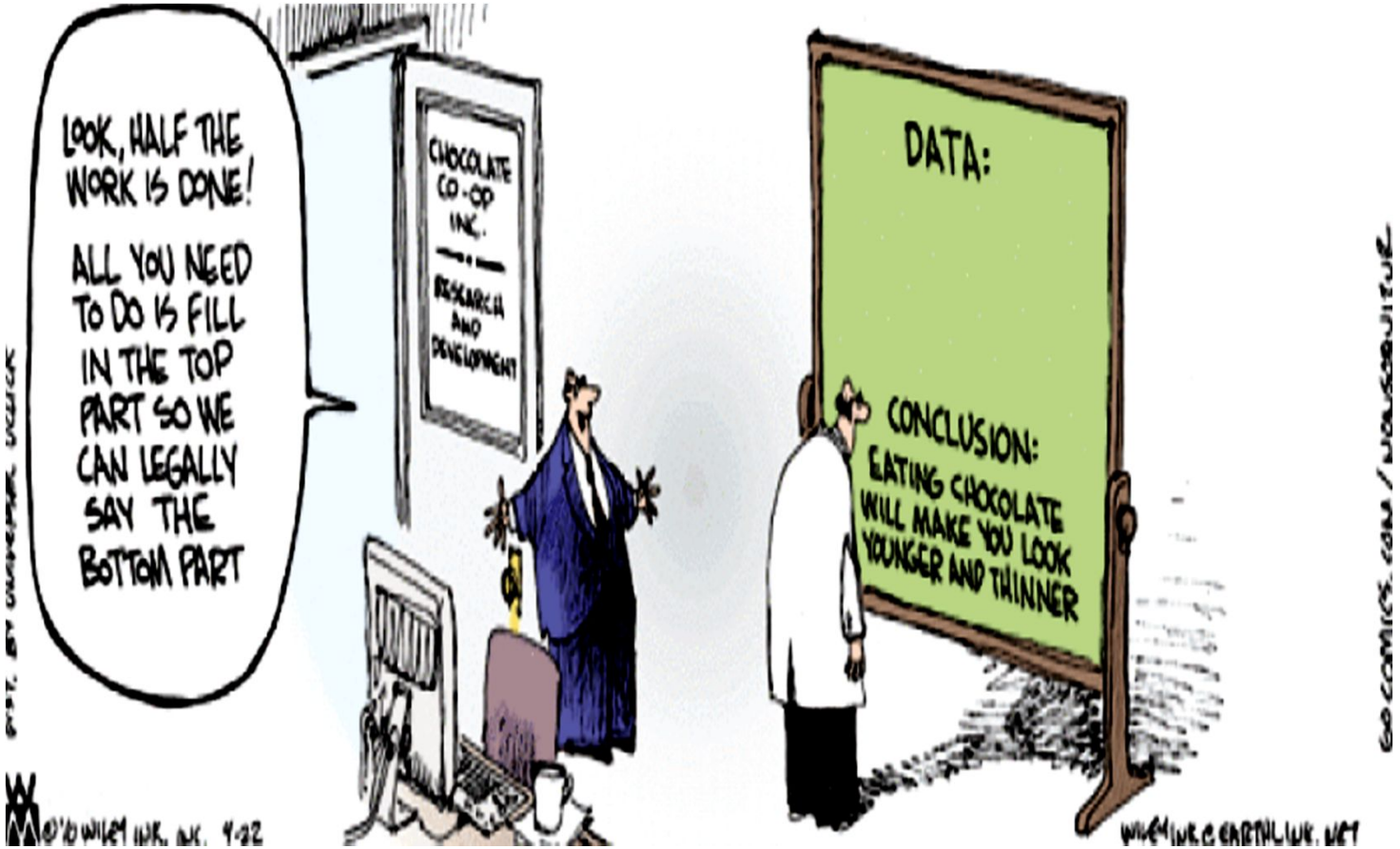
Burden of Proof for your claim is up to you !!!



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Claim Substantiation

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STUDY DESIGN IS KEY!!!

Why is the Randomized Double-Blind, Placebo-Controlled Trial the Gold standard for evaluating claims?

THE RCT CONCEPT offers LESS ROOM FOR ERROR

Because they control for confounding factors RCT's offer the strongest evidence of casual relationship

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Claim Substantiation

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A Well Designed RCT

1. Control for Confounding (age, weight, smokers)
2. Random assignment of subjects to treatment (is it appropriate method?)
3. Double-blind: the subjects and researchers are blinded to assignment, (is it appropriate?)
4. An account of all patients that entered the trial (if no data the reason should be stated)
5. Population subjects should accurately portray the population relevant to the claim and marketing
6. Appropriate control group
7. Duration of study
8. Where were the studies conducted?
9. Adverse event reporting

FTC Enforcement Finds New Prey

- 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."
- 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."

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