SUBSTANTIATION WORKSHOP

WHAT NEEDS TO BE SUBSTANTIATED AND HOW TO CRAFT CLAIMS THAT WON'T BE CHALLENGED

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A COMPLIANCE OFFICER'S DREAM

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A COMPLIANCE OFFICER'S NIGHTMARE

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STRUCTURE/FUNCTION CLAIMS

This presentation is limited to Structure/Function claims. But there are a whole bunch of other claims you need to worry about!

IMPORTANT THINGS WE WON'T BE DISCUSSING

- The Irresistible Impulse: Drug Claims
- The "Unholy Trinity" of Class Action Food Claims
  - Protein Grams
  - 0 g Added Sugar/No Added Sugar
  - Flavor
- Ingredient Challenges, like fish oil

WHAT NEEDS TO BE SUBSTANTIATED?

WHAT NEEDS TO BE SUBSTANTIATED?

FDCA SECTION 403(r)(6) – 21 U.S.C. 343(r)(6)

"A statement for a dietary supplement may be made if –

(A) the statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient,

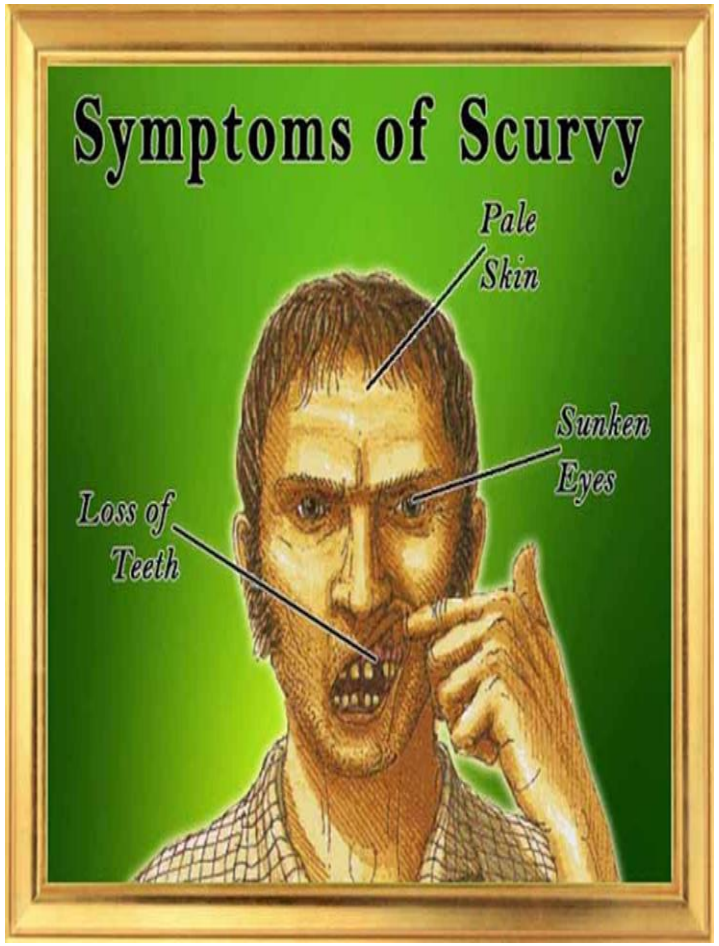
(B) **the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading**, and

(C) the statement contains, prominently displayed and in boldface type, the following: 'This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.'"

WHAT NEEDS TO BE SUBSTANTIATED?

ANSWER — Any of the following claims:

- Nutritional Deficiency Claims—"Vitamin C and Scurvy"
- Structure Function Claims
- General Well Being Claims—"Supports optimal health"



WHAT NEEDS TO BE SUBSTANTIATED?

- What is a Structure/Function Claim?
  - Not a disease claim. 21 C.F.R. § 101.93 (g)(2)
  - General "strengthen," "improve," and "protect" statements.
  - How it Works statements:
    - "Zinc works to supporting the function of natural killer cells and other immune cells."
  - How it Maintains statements:
    - "Chromium helps maintain healthy blood sugar levels already within the normal range."
    - "Fiber helps maintain digestive regularity"

WHAT NEEDS TO BE SUBSTANTIATED?

Top Ten Tips to Avoiding a Disease Claim—See 21 C.F.R. § 101.93(g):

1. Don’t mention a specific disease by name.
2. Don’t mention a common sign or symptom of a disease.
3. Don’t mention abnormal/severe forms of natural state.
4. Don’t mention a drug product class.
5. Don’t mention a specific drug.
6. Don’t say it augments a therapy or drug.
7. Don’t say it mitigates adverse effects of a therapy or drug.
8. Don’t say it helps the bodies response to a disease.
9. Don’t use pictures, symbols that describe a disease or disguise a claim as a product name or by association.
10. Remember: it is not just individual statements in isolation. The whole label must be read together.

STRUCTURE FUNCTION WORKSHOP

1. Treats arthritis
2. Relieves painful joints
3. Prevents cystic acne
4. Powerful Anti-Viral Properties
5. Calcium builds strong bones
6. Nature’s Prozac®
7. Maintain blood sugar levels in insulin dependent people
8. Reduces nausea associated with chemotherapy
9. Helps your natural cold and flu response

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STRUCTURE FUNCTION WORKSHOP

- Treats arthritis
- Relieves painful joints
- Prevents cystic acne
- Powerful Anti-Viral Properties
- Maintain blood sugar levels in insulin dependent people

STRUCTURE FUNCTION WORKSHOP

- Treats arthritis
  - Supports Joint health and flexibility
- Relieves painful joints
  - Helps maintain proper joint function
- Prevents cystic acne
  - Clean skin without common acne
- Powerful Anti-Viral Properties
  - Works to support proper immune function
- Maintain blood sugar levels in insulin dependent people
  - Use as part of a healthy diet to help maintain healthy blood sugar levels

STRUCTURE FUNCTION WORKSHOP

Front

Back

Side

Side

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EXPRESS v. IMPLIED CLAIMS

FTC: "When identifying claims, advertisers should not focus just on individual phrases or statements, but rather should consider the ad as a whole, assessing the net impression conveyed by all elements of the ad, including the text, product name, and depictions.

When an ad lends itself to more than one reasonable interpretation, the advertiser is responsible for substantiating each interpretation."

FTC EXAMPLE: EXPRESS v. IMPLIED CLAIMS

"An ad for a dietary supplement called 'Arthricure' **[BING, BING, BING! RED FLAGS!]** claims that the product maintains joint health and mobility into old age. The 'before' picture shows an elderly women using a walker. The 'after' picture shows her dancing with her husband. The images and product name likely convey implied claims that the product is effective in the treatment of the symptoms of arthritis, and may also imply that the product can cure or mitigate the disease. The advertiser must be able to substantiate these implied claims."

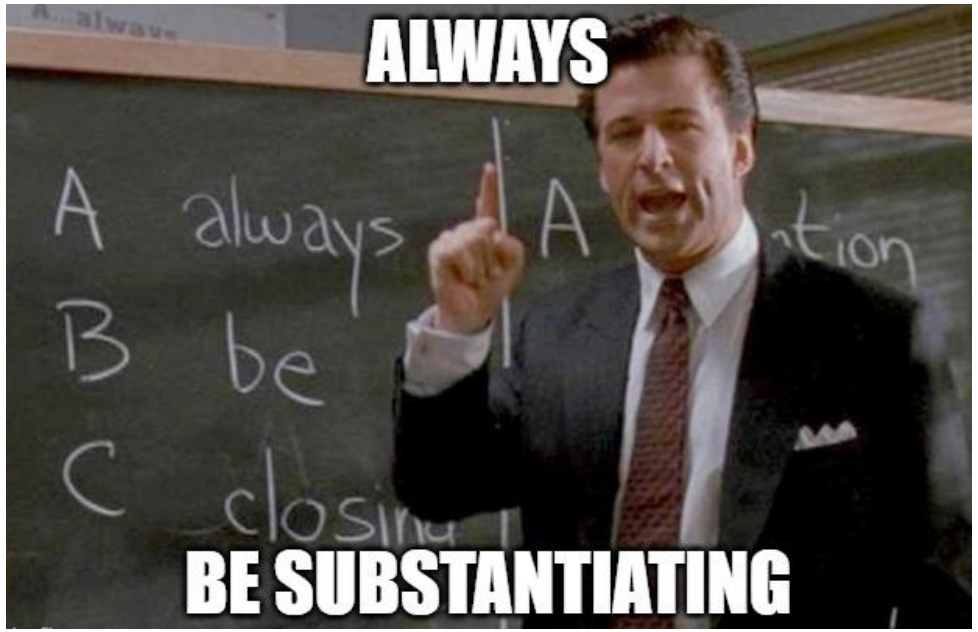
LITIGATING STRUCTURE FUNCTION & SUBSTANTIATION

Remember — in litigation, a Plaintiff's lawyer <u>can</u>:

- Bring a state law claim that the purported structure function claim is in fact a disease claim:
  - In that case, the structure/function pre-emption safe harbor does not apply.
- Bring a state law claim that a product sold as a dietary supplement is an unapproved drug:
  - This has been at issue, for example, in recent wave of CBD class action cases.
- Bring a falsity claim if their own evidence shows the structure/function claim is provably false:
  - Lack of substantiation is not enough.
  - Must have some scientific basis to refute the structure function claim.
  - Anecdotal evidence is not enough.

WHEN SHOULD CLAIMS SUBSTANTIATION BE PART OF THE CONVERSATION?

- Always:
  - Production inception
  - Developing supply chain partners
  - Crafting labeling and advertising
  - Retail & distribution environment
  - Mergers & Acquisitions



FTC/FDA GUIDANCE FOR THE INDUSTRY

- April 2001 **FTC** Dietary Supplements: An Advertising Guide for Industry

- January 2009 **FDA** Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the FDCA
  - "Our guidance document is modeled on, and complements, the FTC guidance document." (Sort of…)

FDA GUIDANCE

"In determining whether the substantiation standard has been met with competent and reliable scientific evidence, we recommend that firms consider the following issues in their assessment:

- The meaning of the claim(s) being made;
- The relationship of the evidence to the claim;
- The quality of the evidence; and
- The totality of the evidence."

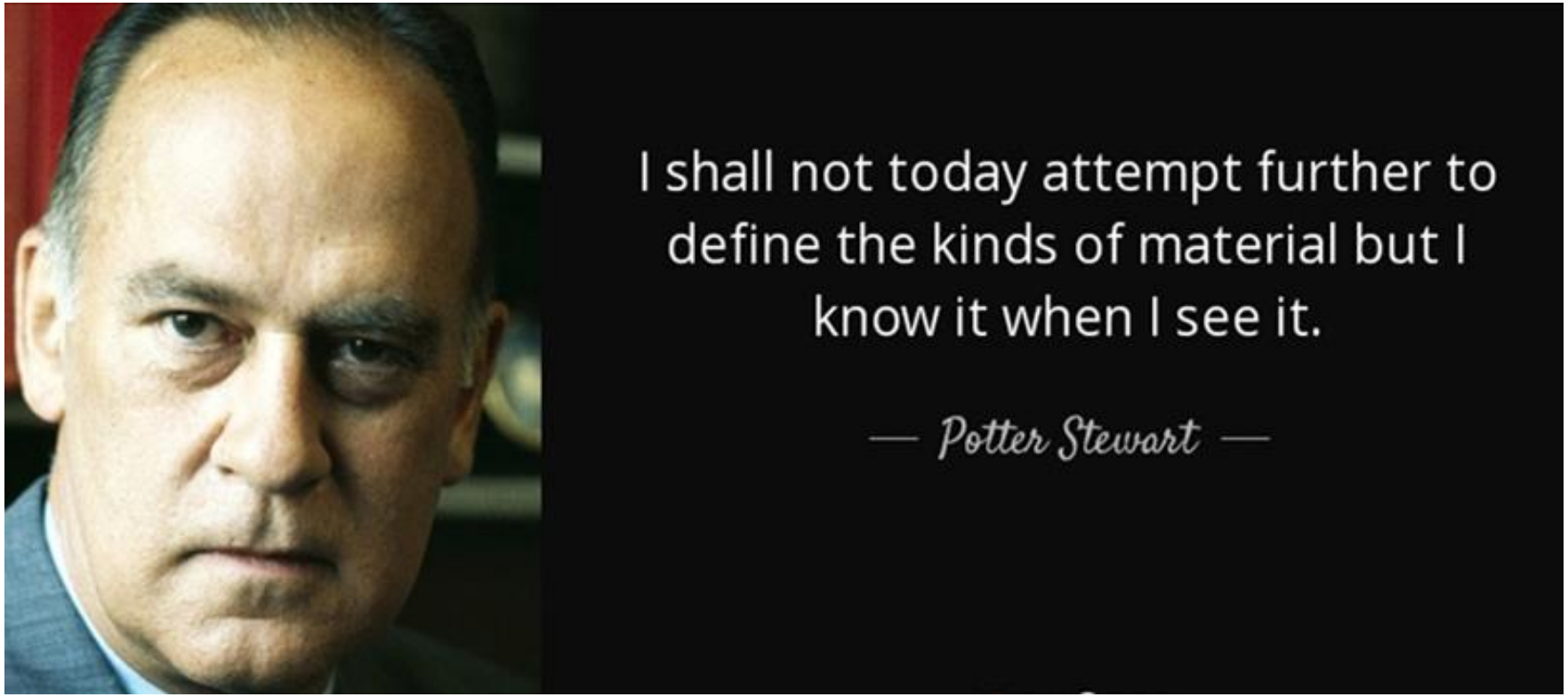
FTC/FDA GUIDANCE FOR INDUSTRY

FTC: "The FTC's standard for evaluating substantiation is sufficiently flexible . . . ."

FDA: "Our approach provides manufacturers flexibility in the precise amount and type of evidence that constitutes adequate substantiation."

Weigh the claim against the substantiation.

FTC/FDA CLAIM SUBSTANTIATION IS LIKE PORNOGRAPHY



WEIGHING CLAIM AGAINST THE SUBSTANTIATION

The Meaning of the Claim

- The Type of Product: Health Claims = Higher Level of Substantiation
  - "_____ is an advanced sexual health formula. _____ features L-Arginine, an amino acid that enhances nitric oxide production. Nitric oxide helps maintain blood vessel tone, which plays a key role in sex."
  - "A single dose of this supplement will open blood vessels for good blood pressure and a stronger heart and that means you will enjoy vibrant health."
- Consumers' Understanding of Claim: If consumers understand the claim (i.e., established claim), then less substantiation is needed.

WARNING

Making claims that refer to a specific level of support can expose you to an FTC investigation, which is known to advertising lawyers to cause FTC enforcement actions and class-action lawsuits.

Examples

- Doctors recommend
- [Insert ingredient here] has been used by the inhabitants of [insert exotic location here] for thousands of years to [insert non-disease claim here]*
- Scientists agree . . . .

These statements seem harmless, but FTC views them as containing **implied claims** beyond the **express statements**.

*FTC: "Advertising claims based solely on traditional use should be presented carefully to avoid the implication that the product has been scientifically evaluated for efficacy."

WEIGHING CLAIM AGAINST THE SUBSTANTIATION

The Relationship of the Evidence to the Claim

- **Avoid logical leaps**! The substantiation must directly meet the claim:
  - *"All men are mortal. Socrates was a man. Therefore, all men are Socrates."* From Love & Death
- Particularly Common Logical Leaps:
  - Studies show Ingredient X has Beneficial Effect Y.
  - Studies show that Beneficial Effect Y has a positive impact on Health Condition Z.
  - Therefore, Ingredient X has a positive impact on Health Condition Z.

WEIGHING CLAIM AGAINST THE SUBSTANTIATION

The Relationship of the Evidence to the Claim

If you are relying on published studies of an ingredient for efficacy, make sure your dietary supplement satisfies all the study parameters:

- Dose
- Dosage Form
- Formula
- Study Population (including foreign studies with populations with different diets/behaviors)
- Study Period

. . . **And consider whether the other ingredients in the supplement impact the science**.

WEIGHING CLAIM AGAINST THE SUBSTANTIATION

The Claim Substantiation Test:

FTC: "The FTC typically requires claims about the efficacy or safety of dietary supplements to be supported with competent and reliable **scientific evidence**, defined in FTC cases 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."

FDA: Ditto.

TYPES OF SUBSTANTIATION

"The FTC will consider all forms of competent and reliable scientific research when evaluating substantiation."

Good: ***Epidemiologic Evidence*** – particularly with a plausible biological mechanism to explain the evidence. FDA: *"generally . . . considered background information, but alone may not be adequate to substantiate a claim."*

Better: ***Animal & In Vitro Studies*** – The latter is useful for conditions that may take years to develop. FDA: Same.

Best: ***Human Clinical Studies***

- Peer-Reviewed, Double-Blind, Placebo-Controlled Clinical Studies (Gold Standard).
- Observational Studies (every other type of human study). FDA: *"Observational studies have a more limited ability than intervention studies to distinguish relationships between a substance and the outcomes being evaluated and cannot provide causal evidence."*

TYPES OF SUBSTANTIATION

Bad: ***The Individual Consumer Experience***

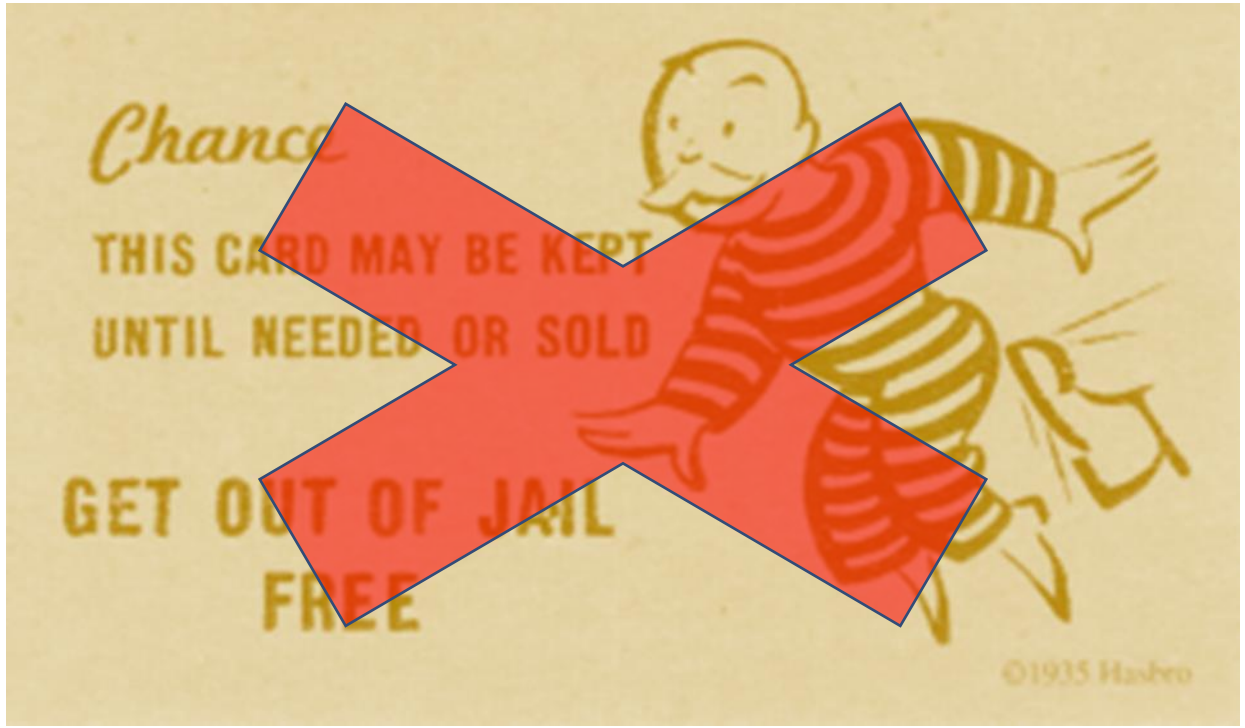
Exception: A claim that is specifically limited to the consumer experience and doesn't carry an implied claim.

Example: Anti-Aging Product

- "Youthful Glowing Skin Without Surgery or Chemicals" **[BING! BING! BING! RED FLAGS!]**
- "These natural fruit acids lift away the top layer of dead skin cells, reducing the appearance of fine lines and wrinkles, particularly around the eyes."

TYPES OF SUBSTANTIATION — POSSIBLE EXCEPTION

"The Benefits of a Truthful Claim and The Cost/Feasibility of Developing Substantiation for the Claim"



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TYPES OF SUBSTANTIATION – THE FDA BLACK HOLE

"The amount of substantiation that experts in the field believe is reasonable."

THE TOTALITY OF THE EVIDENCE

The glass is not half full.

Don’t ignore contrary studies and evidence.

Are the positive results statistically significant?

THE ALLAN AND CAROL JOHNSON TEST

HOW TO CRAFT CLAIMS THAT WILL NOT BE CHALLENGED

- Don't make drug claims. You **must** resist the urge!
- Craft your claims carefully to avoid implied claims.
- Understand your claims. Ask people what they think your claims mean.
- Don't step beyond the claims you intend to make.
- Don't suggest a certain level of substantiation – unless you have it.
- Only make established claims. (But that wouldn't be fun or profitable!)
- Don't use consumer self-reporting unless the claims are clear that they are based on self-reporting and there are no implied claims.
- If making a traditional use claim, make sure the claim is limited to the traditional use and does not make an implied claim.
- Don't engage in leaps of scientific logic, even if they make sense to you.
- Appropriately qualify the science behind the claims when necessary. Don't rely on the DSHEA Disclaimer.

HOW TO CRAFT CLAIMS THAT WILL NOT BE CHALLENGED

- Make sure the studies upon which you rely are statistically significant.
- Make sure you are comparing apples to apples in relying on studies. (Dose, Dosage Form, Formula, Study Population, Study Period, Other Ingredients in Formulations).
- Pay heed to the hierarchy of studies: (1) Human Clinical Studies (double-blind); (2) Human Clinical Studies (Observational); (3) Animal Studies; (4) In Vitro Studies; (5) Epidemiological Studies.
- Review all relevant research. Don't pick and choose.
- Have written SOPs that explain how you substantiate claims.
- Create a Claims Review Committee ("CRC").
- Have employees who possess the legal knowledge to understand the meaning of claims on the CRC or use outside resources.
- Have employees who possess the scientific knowledge to evaluate the substantiation for claims on the CRC or use outside resources.
- Maintain claims substantiation files.

QUESTIONS?

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