

# LEGAL CONTEXT OF CONSUMER RESEARCH ON HEALTH CLAIMS AND OTHER FOOD LABELING CLAIMS

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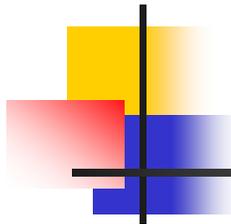
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HHS Office of the General Counsel

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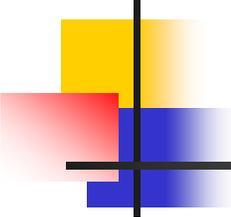


# Purpose

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- Public meeting is for discussion of consumer research.
- Information about legal context is for background only.





# What is a Health Claim?

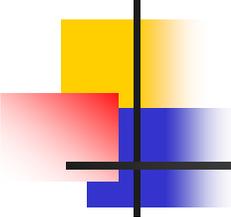
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- For FDA purposes, a “health claim” is an express or implied statement in food labeling about the relationship of a food substance to a disease or health-related condition.

See 21 U.S.C. 343(r)(1)(B); 21 C.F.R. 101.14(a)(1).

- Different from ordinary English meaning of “health claim” as “any claim about health”



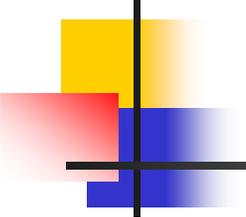


# Health Claims

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- For dietary supplements as well as conventional foods.
- Require FDA review, usually through a petition process.



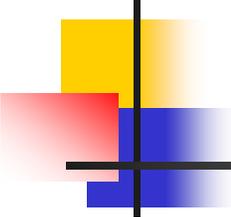


# Elements of a Health Claim

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- “Substance”
  - A specific food or component of food, whether in conventional food or dietary supplement form.  
See 21 C.F.R. 101.14(a)(2).
- “Disease or health-related condition”
  - “Damage to an organ, part, structure, or system of the body such that it does not function properly ... or a state of health leading to such dysfunctioning ... ” 21 CFR 101.14(a)(5).
    - Nutrient deficiency diseases (e.g., scurvy) are not included in this definition.



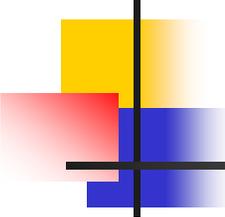


# Examples

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- Substance
  - tuna
  - omega-3 fatty acids
- Disease
  - colon cancer
- Health-related condition
  - adenomatous colon polyps



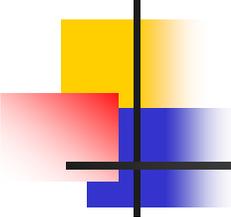


# Purpose of Health Claims

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- To allow foods (including dietary supplements) to bear certain science-backed claims about disease prevention in their labeling without being regulated as drugs
- Risk reduction claims, not “silver bullet” (“Take Ultimate Tablets and you’ll never get cancer”)





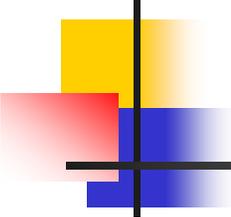
# Definition of “Drug”

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- “Drugs” include (among other things) “articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man.”

21 U.S.C. 321(g)(1)(B).



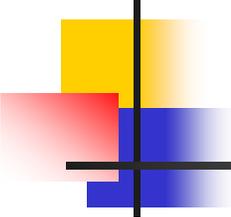


# Examples

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- Claims that would make a product a drug:
  - “prevents colds”
  - “effective arthritis pain relief”
  - “wipes out gout”
  - “shrinks tumors”
- Health claims
  - “may reduce the risk of”





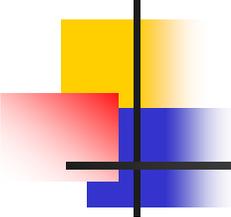
# Scope of health claims

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- Health claims are about reducing the risk of a disease or health-related condition, not treating, mitigating, or curing diseases.

*Whitaker v. Thompson*, 353 F.2d 947  
(D.C. Cir. 2004)



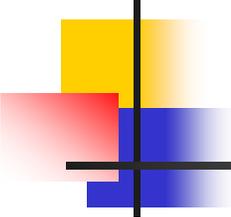


# Types of Health Claims to be Discussed at Today's Meeting

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- “Unqualified” Health Claims
- Qualified Health Claims



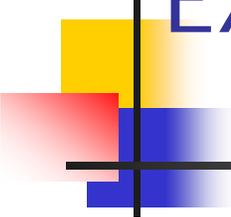


# “Unqualified” Health Claims

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- Also referred to as “SSA health claims” or “NLEA health claims”
- Evidence for claim meets standard set in the Nutrition Labeling and Education Act of 1990 (NLEA): “significant scientific agreement [SSA] among qualified experts”
- Authorized by regulation



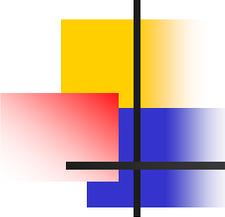


# Examples of Unqualified Health Claims

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- Oat bran: “Soluble fiber from foods such as oat bran, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of food] supplies \_\_ grams of the 3 grams soluble fiber from oat bran necessary per day to have this effect.” 21 C.F.R. 101.81.
- Low sodium foods: “Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors.” 21 C.F.R. 101.74.





# Qualified Health Claims

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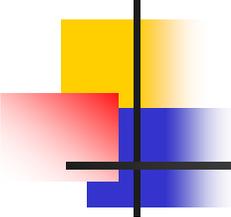
- Qualified health claims are health claims that:
  - are based on scientific evidence that is credible but that does not meet the “significant scientific agreement” standard;
  - include a disclaimer or other qualifying language to prevent consumers from being misled about the level of support for the claim or other important facts (e.g., conditions of use necessary for the risk reduction benefit); and
  - are considered under FDA’s exercise of enforcement discretion (not authorized by regulation).



# Examples of Qualified Health Claims

- "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 [name of the food] provides [ ] gram of EPA and DHA omega-3 fatty acids."
- "Some scientific evidence suggests that calcium supplements may reduce the risk of hypertension. However, FDA has determined that the evidence is inconsistent and not conclusive."



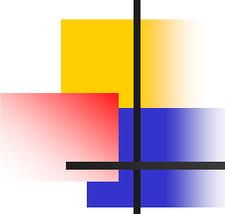


# Why Qualified Health Claims?

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Product of court challenges under the First Amendment to FDA's denial of certain health claims.





# Legal Basis for Qualified Health Claims

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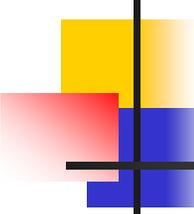
- *Pearson v. Shalala*,  
164 F.3d 650 (D.C. Cir. 1999)
  - The First Amendment does not permit FDA to prohibit health claims that are only potentially misleading, unless the agency reasonably determines that no disclaimer would eliminate the potential deception.



# Other Types of Claims and Label Statements

- Structure/function claim
  - A claim about how a substance or product affects the structure or function of the human body.
  - Example: "Calcium helps build strong bones."
- Dietary guidance
  - Recommendations about dietary patterns and practices that promote health.
  - Example: "Eat plenty of fruits and vegetables every day for good health."





# Why Consumer Research?

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- To understand
  - how claims in food labeling affect consumer perceptions
  - what kinds of claims in food labeling have potential to mislead
- To determine whether potentially misleading health claims can be cured by disclaimers or other qualifying language.
- If answer is yes, what are the characteristics of an effective disclaimer?

