

Industry Communication to Consumers

Martin J. Hahn, Partner

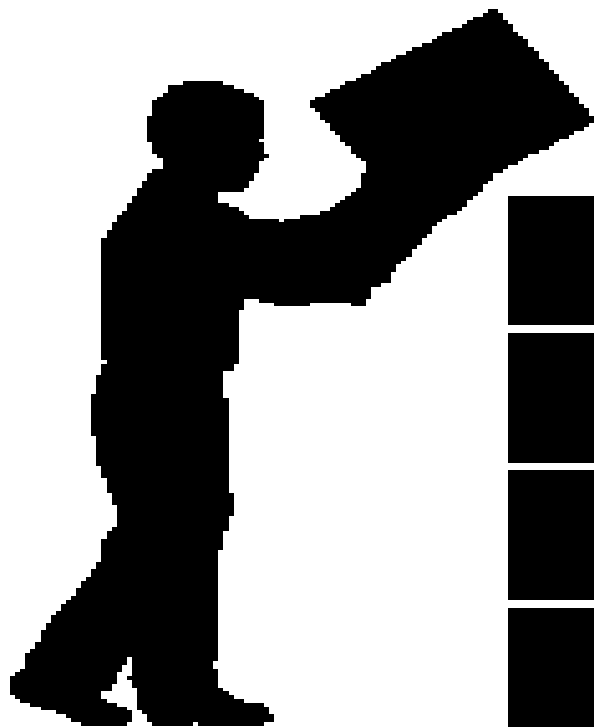
Hogan Lovells US, LLP

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Disclosures/Conflict of Interest

I represent food and dietary supplement companies and trade associations

Claims: “Food” Regulatory Boxes



		Nutrient Content	Cosmetic
		Health	Qualified Health
		Structure Function	Dietary Supplement
		Drug	Dietary Guidance

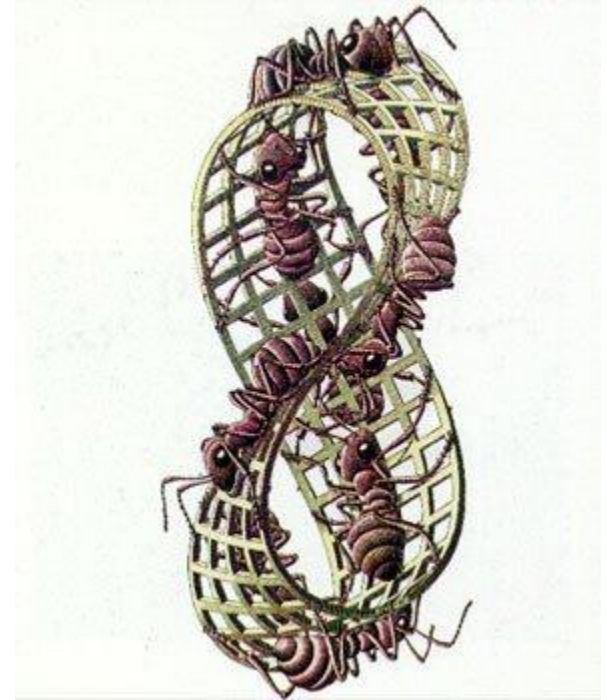
Claims Summary

- **Disease Claims:** use in the diagnosis, cure, mitigation, treatment, or prevention of disease (trigger filing of new drug application)
- **Health/Qualified Health Claims:** reduce the risk of disease—require FDA authorization
- **Structure/Function Claim:** identify the effect of the substance on the structure or function of the body—does not require FDA authorization



Structure/Function Claim Paradox

- Many structure/function claims imply disease prevention
 - Calcium builds strong bones implies reduced risk of osteoporosis
 - Whole oats support heart health implies reduced risk of coronary heart disease
 - Vitamin C supports immune function implies cold/flu prevention



Effective Communication?

Omega-3 Fatty Acid Claim Health claim

“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.”

[See nutrition information for total fat, saturated fat, and cholesterol content.]



Effective Communication?

DHA and EPA support heart health



FTC Regulation of Advertising

- Unlike FDA which focuses on the type of claim, the FTC focuses on substantiation
- Health related claims must be supported by competent and reliable scientific evidence



When is an Implied Claim Misleading?

- A company is responsible for substantiating “all reasonable interpretations” of a claim
- A cosmetic is promoted as “age defying” and studies show it increases elasticity of skin by does not reduce wrinkles
- What percentage of consumers would need to view the claim as implying reduction of wrinkles for it to be considered misleading by the FTC (or a court in a Lanham Act)?



How to Communicate Precision/Personalized Nutrition?

- First Foundational Element
 - The statement must be truthful and not misleading
 - It must be supported by competent and reliable scientific evidence
 - Substantiation is required for both express and reasonably conveyed implied claims



Tell the
Truth!!!!

How to Communicate Precision/Personalized Nutrition?

- Current framework creates complexity depending on the underlying science
- Innovation and research is taking place at lightening speed while our regulatory systems do not



Communicating Precision/Personalized Nutrition

- Use of DNA analysis to identify foods that will help you lose weight (respond to high protein diets)
 - s/f claim
- Modification of diet to impact microbiome
 - s/f claim
- Use of genetic analysis to determine the type of foods an individual should consume (is spinach a priority food or one to avoid?)
 - s/f claim

Communicating Precision/Personalized Nutrition

- Use of genetic analysis to identify diets that will prevent someone at risk of developing type II diabetes
 - Seek FDA approval of a health claim if there is a specific substance that will reduce the risk of disease
- Use of genetic analysis to identify diets for individuals with type II diabetes to reduce insulin dependence
 - Treating type II diabetes is a drug claim
 - s/f claim: supports blood glucose levels within the normal range
- Alterations in microbiome to fight infections (length and severity of flu/common cold)
 - Reducing severity and length of flu is a disease claim
 - s/f claim: supports immune function

Does the current system work?

- Do we want to impose the new drug/medical device system on nutritional interventions for diseases?
- Can we explore other alternative approaches?
 - New legislation?
 - Foods for Special Dietary Use (FFDCA 403(j)): (if it purports to be for special dietary uses it must conform to properties determined by the Secretary through regulations “to fully inform purchasers as to its value for such uses)
 - Medical Foods?
- Do nothing and embrace the “Uber model”?



Martin J. Hahn
Partner

Martin.Hahn@hoganlovells.com

555 13th Street NW
Washington DC 20004
(202) 637-5926
(202) 302-1289 (m)

Hogan
Lovells

www.hoganlovells.com

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