The FTC's Recent Food and Supplement Advertising Orders

The opinions expressed are the speaker's and don't reflect the official position of the FTC.

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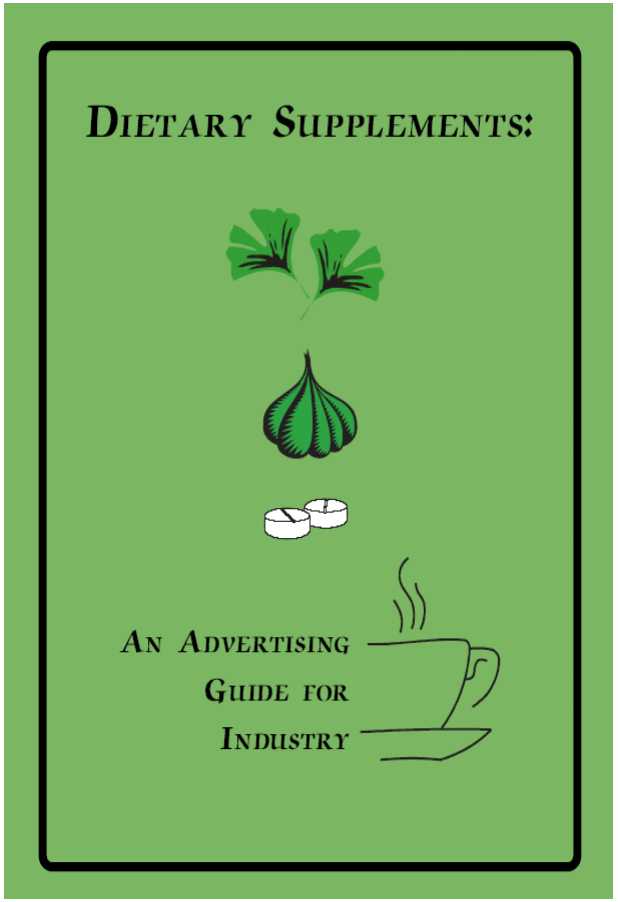
FTC/FDA Coordination

- Overlapping authority
- Liaison agreement:
  - FDA: labeling
  - FTC: advertising
- Agencies coordinate closely on food & dietary supplement policy issues

FTC Advertising Law 101

- FTC Act, Sections 5 & 12
- Advertising must be truthful and not misleading
- Advertisers must possess a reasonable basis for claims they make, and must have at least the level of evidence claimed in the ad
- Health-related claims generally require competent and reliable scientific evidence

FTC Substantiation Standard, as applied



- Rigorous but flexible
- Generally, well-controlled human clinical studies
- High quality (double blind)
- Consistent with larger body of evidence
- Matches product and claim (dose, form, route of administration, degree of effect)

Traditional Order Provisions

- Standard FTC injunctive provision prohibits particular kinds of health-related claims unless the defendant:
  - "possesses and relies upon competent and reliable scientific evidence that substantiates the representation"
- Problem: Doesn't give much guidance to defendant as to what's adequate in particular situations, hard to enforce, courts have misinterpreted

New Order Provisions

- Orders will be tailored to the facts of each case (one size does not fit all)
- FTC is making transparent in orders the analysis it already does to determine whether a claim is substantiated – Pfizer factors, evaluation of entire body of relevant evidence
- For some claims, FTC is using proxy to determining substantiation by referencing FDA determinations

New Order Provisions

- Three tiers (but not every order will have all three):
  - Specified Disease Claims
  - Other Specified Health-Related Claims
  - Residual Fencing-in Provision for any Other Health-Related Claims

Recent Cases

- ***Nestlé Healthcare Nutrition*** (Nestle BOOST Essentials Drink)
- ***Iovate Health Sciences*** (various weight-loss, allergy supplements)
- ***POM Wonderful*** (POM Wonderful pomegranate juice & POMx pills)

Iovate

- Claims included cold/flu prevention; “lose 32 lbs FAST”
- Mischaracterized AllergyMD product as homeopathic
- $5.5 million settlement for consumer refunds

Iovate Health Sciences (Stipulated Final Order 2010)

Nestlé Heathcare Nutrition

- Probiotic straw and drink for children
- Claims: prevention of upper respiratory tract infections; protects against cold and flu; reduces absence from school; reduces duration of acute diarrhea in children up to 13
- Some good evidence, but claims went beyond what the studies showed

Nestlé Healthcare Nutrition (proposed consent 2010)

POM Wonderful

- "Clinically proven" claims about benefits for heart disease, prostate cancer, erectile dysfunction
- No blinding or control in prostate cancer study; no benefit beyond placebo in erectile dysfunction study; many studies for heart disease showed no benefit
- FTC suing company and 3 principals; settlement with science/regulatory officer

POM Wonderful (Complaint 9/27/2010)

New Order Provisions – First Tier

- Specified Disease Claims: Where defendant made claims that product could treat, cure, prevent, or reduce the risk of disease, order will require such claims to be approved by FDA:
  - Through OTC drug monograph or approved new drug application (in the case of diet supplements, and food, if company made treatment/cure claims for food), or
  - By regulations under Nutrition Labeling and Education Act (in case of foods)
- **So:** If claim would not be permitted in labeling, the order won't permit it in advertising

How "new" is this?

- "The absence of an FDA determination that a health claim is scientifically valid will be a significant factor in the Commission's assessment of the adequacy of substantiation for the claims."

Back to the Future

- "The Commission regards the 'significant scientific agreement' standard, as set forth in the NLEA and FDA's regulations, to be the principal guide to what experts in the field of diet-disease relationships would consider reasonable substantiation for an unqualified health claim.

- Thus, it is likely that the Commission will reach the same conclusion as FDA as to whether an unqualified claim about the relationship between a nutrient or substance in a food and a disease or health-related condition is adequately supported by the scientific evidence."

SOURCE: 1994 FTC Food Advertising Enforcement Policy Statement

Reasonable Fencing-in

- Well-established that FTC has wide discretion in determining type of order necessary to remedy challenged practices
- Order may go beyond the illegal practices challenged
- Orders need only bear a reasonable relationship to unlawful practices found

New Order Provisions – Second Tier

- Other Specified Health-Related Claims
  - Based on the record of the investigation, where the level of scientific support required by experts in the field has been established, “competent and reliable scientific evidence” will be tailored, depending on the product/claim
  - One or more clinical trials may be required for particular claims/particular products

New Order Provisions – Second Tier

- ***Iovate***: For weight-loss claims –
- ***Nestlé HCN***: For claims of reduced absences from school/daycare due to sickness –
- Order defines "competent and reliable scientific evidence" as consisting of at least two adequate and well-controlled human clinical studies of the Covered Product, or of an Essentially Equivalent Product

How "new" is this?

- ***Novartis Corp.,*** 127 F.T.C. 580 (1999) (final order requiring two adequate and well-controlled, double-blinded clinical studies to substantiate claims that Doan's is more effective than any other OTC analgesic drug)
- ***Thompson Medical Co. Inc.,*** 104 F.T.C. 648 (1984) (final order requiring two adequate and well-controlled, double-blinded studies to substantiate efficacy and comparative claims for OTC analgesic drugs)
- ***Schering Corp.,*** 118 F.T.C. 1030 at 1120-21 (I.D.) (1994) (discussing appropriateness of order requirement for two clinical studies for weight loss claims, regardless of whether the product at issue is a food or drug, based upon the standard used in Thompson Medical)
- ***Jerome Milton, Inc.,*** 110 F.T.C. 104 (1987) (consent order requiring one or two clinical studies, depending on the claim, for toothpaste)
- ***Viral Response Systems Inc.,*** 115 F.T.C. 676 (1982) (consent order requiring two adequate and well-controlled clinical studies)

New Order Provision – Third Tier

- This provision generally covers broad categories of products and claims beyond those specifically challenged in the complaint
- Claims about the health benefits, performance, or efficacy of foods, drugs, or diet supplements:
  - Standard "competent and reliable scientific evidence" language with two clarifications:
  - Both quality and quantity of evidence must meet accepted scientific norms
  - Evaluate studies in context of entire body of relevant evidence

New Order Provisions: Third Tier

- This provision would also cover “qualified” health claims, i.e., health claims based on strong emerging science not yet authorized by FDA
- Caveat: how do consumers interpret the claim, i.e., is it really qualified?

For More Information

- ***www.ftc.gov***
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- Thank you!