FTC's Health Products Compliance Guidance

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Federal Trade Commission

Federal Trade Commission Foundational Principles

Overview of 1998 Guidance and Key Changes in 2022 Guidance

Overview of Other Regulatory Activities

Questions

Federal Trade Commission

Foundational Principles of Advertising in 2022 Guidance

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Federal Trade Commission Basics

- FTC enforces Sections 5 and 12 of the FTC Act, along with the FTC's policy statements on deception (1983) and advertising substantiation (1984).

- FTC also issues Policy Statements and "Guides" for specific industries and advertising practices.
  - Not official regulations, but represent FTC's views of certain practices.
  - Examples: The 1998 Dietary Supplement Advertising Guide (now the ***2022 Health Products Compliance Guidance***), or the Endorsements Guides.

- The 2022 Health Products Guidance sets out the basic advertising principles for a broad range of "health products."

Advertising Fundamentals Reiterated in 2022 Guidance

- As discussed in the new 2022 Guidance, Advertisements must:
  - Be truthful and not misleading
  - Be substantiated before disseminating ad; advertisers must have evidence to back up their claims
- Plus, "as a general rule…claims about the health benefits or safety of foods, dietary supplements, drugs, and other health-related products require substantiation in the form of competent and reliable scientific evidence."
- All parties that participate directly in marketing and promotion, or have authority to control those practices, have responsibility.
- FTC can issue a wide array of remedies: civil penalties, injunctions, restitution, corrective advertising.

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A Note on Verifiable Claims and Substantiation

Substantiation is required for any objective, provable claims (express or implied) made about a product or service in the ad. Examples: efficacy, quality, comparative claims.

Must have a reasonable basis for the claim ***before*** making the claim in advertising.

When an ad lends itself to more than one reasonable interpretation, there must be substantiation for each interpretation.

Basis/substantiation for claim should be disclosed in ad as appropriate and should be kept on file.

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FDA vs. FTC Advertising

- FDA primarily responsible for claims on *labeling*, whereas FTC has responsibility for claims in all forms of advertising.
- FTC does not distinguish between types of health-related products or claims.
- While FDA considers dietary supplements, food, etc in separate categories, FTC does not.
- FTC does not distinguish between a structure/function claim or another kind of claim.
- However, health claims that meet FDA's scientific standard are presumed to be substantiated.

Overview of 1998 Guidance

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Basics of 1998 Guidance (*Dietary Supplements: An Advertising Guide for Industry*)

- Informed the status quo of claim substantiation for dietary supplements for the last 25 years.
- Sought to allow for "sufficient" flexibility in achieving substantiation (no rigid or fixed formula), including by considering varying types of evidence (e.g., *in vitro* and animal studies).
- Focused on dietary supplements, in light of the recent passage of DSHEA at the time, included several example claims accordingly.
- Provided FTC expectations regarding identifying claims, when disclosures and qualifications may be needed, and how claims may be substantiated and what kind of evidence is required.

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Basics of 1998 Guidance (*Dietary Supplements: An Advertising Guide for Industry*) (cont.)

- Clarified expectations for disclosures and qualifying language
  - "Clear and prominent" disclosure
  - ***Example***: A marketer promotes a supplement as a weight loss aid. There is adequate substantiation to indicate that the product can contribute to weight loss when used in conjunction with a diet and exercise regimen. The banner headline claims "LOSE 5 POUNDS IN 10 DAYS," the ad copy discusses how easy it is to lose weight by simply taking the product 3 times a day, and the ad includes dramatic before-and-after pictures. A fine print disclosure at the bottom of the ad, "Restricted calorie diet and regular exercise required," would not be sufficiently prominent to qualify the banner headline and the overall impression that the product alone will cause weight loss. The ad should be revised to remove any implication that the weight loss can be achieved by use of the product alone. This revision, combined with a prominent indication of the need for diet and exercise, may be sufficient to qualify the claim. However, if the research does not show that the product contributes anything to the weight loss effect caused by diet and exercise, it would be deceptive, even with a disclosure, to promote the product for weight loss.

Examples Used in 1998 Guidance (*Dietary Supplements: An Advertising Guide for Industry*) (cont.)

- Clarifies several other guidelines for other claims
  - Traditional use claims
  - Consumer testimonials and expert endorsements
  - Third-party literature
  - DSHEA disclaimers

1998 Guidance: Traditional Use Claims

"Claims based on historical or traditional use should be substantiated by confirming scientific evidence, or should be presented in such a way that consumers understand that the sole basis for the claim is a history of use of the product for a particular purpose."

Example

The advertiser of an herbal supplement makes the claim, "Ancient folklore remedy used for centuries by Native Americans to aid digestion." The statement about traditional use is accurate and the supplement product is consistent with the formulation of the product as traditionally used. However, if, in the context of the ad, this statement suggests that there is scientific evidence demonstrating that the product is effective for aiding digestion, the advertiser would need to include a clear and prominent disclaimer about the absence of such evidence.

1998 Guidance: Consumer Testimonials

"An overall principle is that advertisers should not make claims through either consumer or expert endorsements that would be deceptive or could not be substantiated if made directly."

Example

A best-selling book about the benefits of a supplement product includes a footnote mentioning the most effective brand of the supplement, by name. The manufacturer of the brand cited in the book has an exclusive promotional agreement with the author and has paid him to reference the product by name. The manufacturer's ad touts the fact that its product is the only brand recommended in this best-selling book. The ad is deceptive, since it suggests a neutral endorsement when, in fact, the author has been paid by the manufacturer to promote the product.

1998 Guidance: Third-Party Literature

"Although the FTC does not regulate the content or accuracy of statements made in independently written and published books, articles, or other non-commercial literature, FTC law does prohibit the deceptive use of such materials in marketing products. The determination of whether the materials will be subject to FTC jurisdiction turns largely on whether the materials have been created or are being used by an advertiser specifically for the purpose of promoting its product."

Example

An author publishes a book on the curative properties of an herb. The book title is "The Miracle Cancer Cure." The book does not endorse or otherwise mention any particular supplement brand. The author/publisher does not sell the herbal supplement and does not have any material connection to any marketers of the herb. As non-commercial speech, the book itself would not be subject to the FTC's jurisdiction over advertising. However, if a marketer of the herb referred to the book in advertising materials (for instance, by quoting the title and using excerpts to describe the anti-cancer benefits of its product), such references would likely be considered advertising. The advertiser would be responsible for substantiating any claims about the advertiser's product that are conveyed by these references.

1998 Guidance: DSHEA Disclaimer

"…inclusion of a DSHEA disclaimer or similar disclosure will not cure an otherwise deceptive ad, particularly where the deception concerns claims about the disease benefits of a product. In making references to DSHEA and FDA review, advertisers should also be careful not to mischaracterize the extent to which a product or claim has been reviewed or approved by the FDA."

Example

An advertisement for an herbal supplement includes strong, unqualified claims that the product will effectively treat or prevent diabetes, heart disease, and various circulatory ailments. The advertiser does not have adequate substantiation for this claim, but includes the DSHEA disclaimer prominently in the ad. In the face of the strong contradictory message in the ad, the inclusion of the DSHEA disclaimer is not likely to negate the explicit disease claims made in the ad, and will not cure the fact that the claims are not substantiated.

Overview of 2022 Guidance and Key Changes

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Basics of 2022 Guidance

- Covers "any health-related product," not just dietary supplements (food, drug, device, supplement, etc.).
- Broader swath of claims is covered, including S/F claims, health claims, or drug claims.
- This represents a broadening of FTC focus, but also a broadening of potential private litigation challenges.
- Several topics are updated:
  - Substantiation standard
  - Discusses adequacy of clinical studies and interpretation of results (p-hacking)
  - Continues guidance on consumer testimonials and expert endorsements (clear disclosures of material connections)
  - Disclosures and qualifying language ("Vague qualifying terms are inadequate")

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Updating the Substantiation Standard

- Competent and Reliable Scientific Evidence (**CARSE**)
- Previous guidance more readily suggested flexibility – new guidance describes substantiation standard as "rigorous" and no longer uses the term "flexible."
  - Previously, FTC's 1998 guidance stated that "The FTC's standard for evaluating substantiation is sufficiently flexible to ensure that consumers have access to information about emerging areas of science."
  - This is updated to: "It is designed to ensure that consumers can have confidence in the accuracy of information presented in advertising."
- FTC explains that generally, "substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific standard"
- Plus, for example, "research supporting a claim about heart benefits would need to meet accepted norms of research in the field of cardiology."

Updating the Substantiation Standard (cont.)

- Historically, the CARSE standard permits full and careful consideration of a wide range of relevant scientific evidence.
- Double-blind, randomized, placebo-controlled studies have not been explicitly required for dietary supplement advertising. *See, e.g.*, *FTC v. QT, Inc.*, 512 F.3d 858 (7th Cir. Jan. 3, 2008).
  - "Reasonable scientific inferences and extrapolation are methodologies regularly used and relied upon by experts in the field." (*Basic Research v. FTC*, No. 09-cv-779 (D. Utah Nov. 25, 2014).
- Indeed, the *Bayer* court, for example, found it instructive that the guidance allowed marketers to extrapolate from the research to support the claimed effect without a single study on the entire formulation, even given significant discrepancies between the research conditions and the real-life use being promoted. *United States v. Bayer Corporation*, 2015 WL 5822595 (D.N.J., 2015).
  - Private litigants may eagerly test the legitimacy of *Bayer* and the previous standard based on the new guidance, as FTC states that "The case law both before and after Bayer has consistently applied an RCT standard in cases challenging health-related advertising claims as unsubstantiated."

Adequacy and Quality of Clinical Studies

- FTC strengthens its position on the standard that must be met to be considered CARSE. Studies need to meet certain criteria with respect to:
  - Control group, randomization, double blinding, statistically significant results, and clinically meaningful results.
- Includes other possible factors for clinically meaningful results, including the clarity of the protocol, submission of protocol to an IRB, registration of the clinical trial in a public database, duration of the study, dropout rates, noncompliance, dose-response relationship, and more.
- Also note from an example: "clinically tested ingredient" implies not just that the ingredient was tested, but also that the test results prove a benefit.
- FTC's approach to the substantiation standard here raises the bar for substantiation

Adequacy and Quality of Clinical Studies (cont.)

Example

"The marketer of an at-home brain stimulation device conducts a randomized, controlled, double-blind study of the effects of its device on subjects with depression. The study uses eight validated measures to assess the impact of the device on symptoms of depression. Subjects show statistically greater improvement in the treatment group compared to the control group on one of the eight measures. The other seven measures reveal no difference between treatment and control group. The study doesn't include any statistical correction for the use of multiple tests. The fact that only one outcome out of a total of eight showed statistical significance could be the result of chance."

Quality of the Evidence: Interpreting Study Results

- FTC warns against the practice of selecting individually significant results or post-hoc analysis to find meaningful results in otherwise less significant studies (p-hacking): "a *post hoc* analysis of data – one that departs from the original study protocol – can be an indication that the researchers are engaging in data mining or "p-hacking" in an attempt to find some positive result to report from a study that otherwise failed to show any treatment effect."
- Depending on how this is interpreted by private litigators and courts, this could encourage challenges to reliance on studies and research papers currently lending support to credibly substantiated claims.

Quality of the Evidence: Interpreting Study Results (cont.)

Example

The marketer of a liquid protein and vitamin shake commissioned a study to evaluate whether the shake is effective in treating symptoms of osteoarthritis. The 200 subjects had all been diagnosed with mild to severe osteoarthritis. The study was randomized, placebo-controlled, and double-blind, and used a validated measure of osteoarthritis symptoms, assessing subjects at regular intervals over a 90-day period. The study author reported that subjects using the shake showed a statistically significant improvement in symptoms from baseline to day 90. This result, however, doesn't substantiate a marketing claim that the shake can treat symptoms of osteoarthritis, because it doesn't compare improvement in the treatment group to improvement in the control group. In fact, both groups saw some improvement on the measure over time and the treatment group improvement wasn't statistically greater than that of the control group. The marketer then searches the data from the study for statistically significant outcomes, looking at comparisons that weren't part of the original protocol. This post hoc analysis of the findings shows that, for a small subgroup of subjects diagnosed with the mildest osteoarthritis, there is a statistically greater improvement in symptoms in the treatment group compared to the control group. The post hoc analysis of the data doesn't provide reliable evidence of a benefit for subjects with mild osteoarthritis. Further research on subjects with mild osteoarthritis should be conducted to verify a benefit in this population.

Disclosures and Qualifying Terms

- Disclosures must be "***clear and conspicuous***" and if the relevant claim is made both visually and audibly, the disclosure should be made both visually and audibly ("a simultaneous visual and audible disclosure is more likely to be clear and conspicuous").
  - In social media formats, the disclosure should be "***unavoidable.***" Hyperlinks are considered avoidable by FTC.
- The ultimate test of whether a disclosure is effective is the net impression that consumers take from an ad with the disclosure.

Disclosures and Qualifying Terms (cont.)

- Qualifying information explains or limits the applicability of an ad claim, but FTC believe this is difficult when it comes to complex scientific concepts: "It is very difficult to adequately qualify a claim based on limited and still-emerging science to make clear to consumers the uncertain and limited nature of the support for the claim."
- FTC goes further, stating that qualifying modifiers such as "promising," "preliminary," "initial," or "pilot" are positive, and thus do not operate as disclaimers about the state of the science behind a claim.
    - Statements like "Results not typical" may not be enough in endorsements
- Therefore, is it possible that FTC is going too far with respect to the modifier terms? Does language such as "promising" clearly suggest that more evidence is necessary and could neutralize the initial findings? Private litigants are likely to test FTC's position.

Disclosures and Qualifying Terms (cont.)

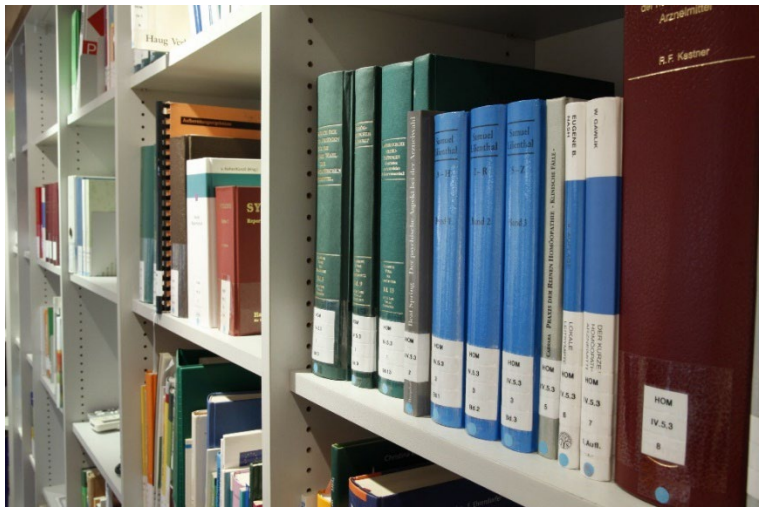
Examples

1. A company has results from two studies suggesting that its supplement helps to maintain healthy cholesterol levels. There are, however, significant limitations to each of the studies and a better study is necessary to confirm whether the effect is genuine. The company makes a claim in advertising that "promising, preliminary scientific studies show that our product may be effective in reducing cholesterol." The use of the words "promising," "preliminary," and "may" is unlikely to sufficiently convey the limitations of the science.

2. The marketer of an unproven weight-loss supplement, through the use of medical images (e.g., people dressed in lab coats, use of the caduceus symbol) and medical terminology (e.g., "medical innovation" and "research center") on its website, conveys a false claim that the product's efficacy is backed by scientific proof. A fine print disclosure in the "Terms and Conditions" section of the website states that "no clinical study has been performed on the product." The statement is inadequate to correct the false scientific proof claim both because it directly contradicts the claim and because it is not clear and conspicuous.

Third-Party Literature and the Two-Click Rule

- FTC does not buy into the two-click rule: the idea that if it takes consumers multiple clicks to go from scientific literature information to product information, there is enough distance to separate implicating potential claims from the product being sold.
- Claims implied by directly or indirectly referencing third-party literature will not prevent FTC from holding the marketer accountable for substantiating any implied claims made.
- This raises the risk of private litigators scouring websites for references and implied claims based on literature citations.



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Third-Party Literature and the Two-Click Rule (cont.)

Examples

1. Advertising for a weight-loss supplement includes references to what appears to be an independent website discussing the risks of gastric bypass surgery and referencing the advertiser's supplement as a safer alternative. In fact, the advertiser created and owns the gastric bypass website and does not disclose that financial relationship. The website is not independent third-party literature. The advertiser is responsible for the accuracy of claims made on the site and must clearly and conspicuously disclose its ownership of the site.

2. The marketer of the herb described in Example 50 provides a link to a web page that in turn links to the "Miracle Cancer Cure" book. The fact that the book is "two clicks" away from the marketer's own website doesn't insulate the marketer from responsibility for substantiating any implied claims that consumers may take from the indirect reference to the book. The FTC will evaluate the marketer's website, the description it provides in linking indirectly to the book, statements appearing on the linked page, and other elements of the marketing to determine whether the marketer is using references to the book to promote its product.

Traditional Use Claims

- FTC now lays out several steps to avoid communicating misleading messages about product efficacy or the scientific basis for any health benefit:
  - Same formulation, strength, and dose.
  - Include a ***disclosure*** that there is no scientific basis for the traditional use,
  - Don't undercut the disclosure with other positive statements,
  - Conduct a copy test to confirm that consumers understand the limited nature of the claim
- FTC says it will look closely at how consumers perceive a traditional use claim.

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Effect of Guidance on Other Regulatory Activities

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State Attorneys General

- State unfair competition and consumer protection laws ("Baby FTC" and "Baby FDA" acts)
  - Can be brought by state-level or local prosecutors
  - Examples
    - California:
      - Sherman Food, Drug and Cosmetic Act
      - Proposition 65
    - New York:
      - Consumer Protection from Deceptive Acts and Practices Law
    - Florida:
      - Deceptive and Unfair Trade Practices Act

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Private Plaintiffs

- Some state consumer protection laws allow for both state-initiated lawsuits and private rights of action
  - California:
    - Sherman Food Drug and Cosmetic Act, Unfair Practices Act, and Consumer Legal Remedies Act
  - New York:
    - Consumer Protection from Deceptive Acts and Practices Law
  - Florida:
    - Deceptive and Unfair Trade Practices Act

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Self-Regulation Challenges

- National Advertising Division
  - Voluntary self-regulatory body under the Better Business Bureau
  - Reviews advertising for truthfulness and accuracy (i.e., **substantiation**)
    - Product performance claims
    - Superiority claims
    - Scientific/technical claims
  - Handles ~150 cases per year
  - Generally a faster and more specialized option for handling advertising disputes
- May refer matters to the FTC in cases where there is a failure to participate or comply with an NAD recommendation.

Questions?

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