Cooley

FTC Revises Health Products Compliance Guidance

March 2, 2023

In December 2022, the Federal Trade Commission released its **Health Product Compliance Guidance**, updating and replacing its 1998 industry advertising guidelines on dietary supplements. Unlike the 1998 guidelines, the new guide expressly applies to advertising for **all health-related products**[1] to ensure that claims about the benefits and safety of not only dietary supplements, but also foods, over-the-counter medicine, homeopathic products, health-related apps, health equipment and diagnostic tests, are truthful, not misleading, and supported by appropriate substantiation. The basic legal framework the FTC uses to evaluate these issues has not materially changed in the intervening 24 years, but the standards the commission applies have been clarified and refined by its prosecution of more than 200 cases involving false or misleading advertising claims for health-related products. The guide incorporates the FTC's collective views based on that work. Although the guide deserves careful review, particularly of the many examples of permissible and prohibited advertising conduct that may apply in particular situations, a few key points stand out.

Key insights

Substantiation standards

In an effort to dispel what the FTC refers to as "**urban myths**" about the substantiation required to make health-related claims, the guide unequivocally states that the commission will rigorously enforce the requirement that advertisers have "competent and reliable scientific evidence" for any health-related claims. Regardless of whether an ad makes an express claim about the level of support (i.e., "tests show"), generally competent and reliable evidence for health-related claims consists of "randomized, controlled human clinical testing" conducted by experts in the relevant disease, condition or function. In evaluating the reliability of such testing, the FTC will consider several factors, such as sample size, duration and outcome measures.

The guide also urges advertisers to consult with independent experts to assess whether a study was well designed and well conducted, and whether the data was properly analyzed. Only then can advertisers confidently say that their health claim is supported by competent and reliable scientific evidence. Although the FTC does not require a specific number of reliable clinical studies, replication by one or more additional studies adds to the weight the commission will give to the evidence. The guide notes, however, that "quality of research is more important than quantity." Further, the guide cautions that animal and in vitro studies cannot, standing alone, substantiate health claims, nor can surveys of consumer experiences. And the FTC will accept epidemiological or observational studies only where experts in the field consider them an acceptable substitute and clinical studies aren't otherwise feasible (e.g., nutrition studies that would take decades to complete).

Quality of evidence

The FTC not only looks at the type and amount of substantiating evidence, but it also analyzes the internal validity of each piece of evidence. The guide directs that the following basic requirements should be present in any competent and reliable scientific evidence:

- A control group
- Randomization
- Double blinding

The study also must result in statistically significant and clinically meaningful results (i.e., results that would actually matter to users). Moreover, the guide cautions against post hoc analysis of data, or "p-hacking," rejecting it as a way to substantiate a claim where the original protocol did not show meaningful results. In addition, the guide sets out a number of factors that the FTC will consider when analyzing the quality of the underlying evidence – factors that all advertisers and their research partners should carefully consider when designing substantiating clinical trials. Even where advertisers have valid internal studies to support their claims, they must consider the totality of the other research in the field, including studies that show different results, to assess whether a claim is substantiated. And advertisers must be sure that the research they are relying on is truly relevant to the specific claim they are making.

Clear and conspicuous disclosures

Many ads require disclosures of qualifying information to avoid deception. The guide reaffirms that such disclosures must be clear and conspicuous, or "difficult to miss," and easily understandable by ordinary customers. The guide also clarifies that disclosures must mirror whatever medium the ad is conveyed in – so if the claim is made visually and audibly, the disclosures also should be made in both mediums. For claims made via social media, the guide offers new guidance that disclosures necessary to prevent deception must be "unavoidable" and, it pointedly notes, "hyperlinks are avoidable." Notably, the guide contains new cautions that if, despite the disclosure, a "significant minority" of consumers take away a misleading claim, then the disclosure must be modified, or the claim should be discontinued.

Indeed, the guide describes certain disclosures that are unlikely to, or will not, meet the FTC's "clear and conspicuous" standard. Claims about emerging science, for example, are described by the guide as "very difficult" to adequately qualify for a general audience, given the complex scientific concepts at issue. Moreover, the FTC rejects the use of vague terms such as "may," "helps," "promising," "preliminary," "initial" or "pilot" as adequate qualifiers for such claims. The FTC's misgivings regarding emerging science claims, as expressed in the guide, should give any advertiser pause before making such claims. Further, the guide reconfirms the long-standing rule that a disclosure that directly contradicts the express or implied message conveyed by advertising copy is ineffective. As an example, the guide notes that even an express disclosure that "no clinical study has been performed on the product" cannot cure the misleading impression of scientific support conveyed when an ad displays images of individuals in lab coats and/or uses the caduceus symbol, in combination with terminology such as "research center."

Consumer testimonials and expert endorsements

The guide reaffirms the basic principle that advertisers cannot make health-related claims through consumer testimonials or expert endorsements that they cannot separately substantiate with appropriate scientific evidence – in other words, the FTC views testimonials and endorsements as if the advertiser were making the claims directly. Further, if the testimonial reports results that are not typical, it is likely deceptive and cannot be cured by disclaimers such as "results not typical." Instead, the ad must clearly and conspicuously disclose the results a consumer can actually expect. Lastly, advertisers must be sure to disclose clearly and conspicuously any "personal, financial, or similar connection" between the expert/consumer and the advertiser.

Traditional use

The guide is clear that there is no exception for homeopathic and alternative medicines, as they too must meet the competent and

reliable standard to make health-related claims. However, it also clarifies that advertisers may make carefully qualified claims that describe a product's traditional or historic uses, as long as those claims do not misleadingly imply the product's efficacy and/or health benefits. To do so effectively, the guide includes specific guidelines, including:

- Clearly disclosing within the ad that there is no scientific support for the health-related benefit.
- Avoiding positive statements, endorsements or images that might undercut that disclosure.
- Urging advertisers to consider conducting consumer research on the ad, to ensure consumers understand the limited nature of the qualified claim.

Regardless of the above, the guide cautions that advertisers cannot make traditional use claims regarding the treatment of serious medical conditions, which could put users at risk even if carefully qualified. For example, a claim that a folk remedy is traditionally used to shrink tumors is prohibited, regardless of clear disclosures that there is no scientific support for the claim. This is in sync with the FDA's approach to view such claims as rendering such a product an unapproved new drug under the Federal Food, Drug and Cosmetic Act (FDCA), including **the FDA's recent draft guidance on homeopathic drugs**.

Third-party literature

The guide notes that it will carefully scrutinize ads that use third-party literature, such as books, newspaper articles or abstracts of scientific studies, to market their products, as such materials impact how consumers interpret an ad. Advertisers will be responsible for any claims implied by reference to the materials. For example, where an ad for a dietary supplement contains a link to a book entitled "The Miracle Cancer Cure," which describes the purported curative properties of an herb that also is used in the dietary supplement, the marketer is responsible for substantiating the implied efficacy claims. Note that such cancer claims would render the product an unapproved new drug under the FDCA and pull the product outside claims permissible for a dietary supplement.[2]

Dietary Supplement Health and Education Act disclaimers and FDA approval

The guide notes that the disclaimer required under the FDCA for dietary supplements, (i.e., that statements regarding dietary supplements have not been evaluated by the FDA, and that the product is not intended to diagnose, treat, cure or prevent any disease) does not cure an otherwise deceptive ad. The guide also notes that advertisers must carefully avoid implications that their products or claims have been approved by the FDA. For example, where a Class I or Class II medical device has received FDA clearance, a label in an ad saying "FDA Approved" is deceptive, as it overstates the FDA's review of the product, conflating the agency's "substantial equivalence" determination for low- to moderate-risk devices with the more rigorous approval standard the FDA applies to Class III high-risk devices. Thus, referencing the phrase "FDA Approved" for a device cleared through the FDA's 510(k) pathway may falsely imply that the FDA has reviewed and approved of any accompanying marketing claims.

In sum, while the guide offers parameters to meet the FTC's stringent requirements for health-related claims, advertisers must keep in mind the separate FDCA requirements, which govern premarket applications required before certain categories of products can be marketed, as well as strict labeling requirements that vary depending on the product category.

If you have any questions or concerns about FTC or FDA compliance, please contact one the lawyers listed below.

Notes

1. For these products, the FTC shares jurisdiction with the US Food and Drug Administration, and companies that promote and distribute such products will have to ensure compliance with both agencies' regulations,

with the FTC primarily regulating the advertising for such products, and the FDA regulating the labeling. As the FTC's **recent guidance explains**, "[s]ome forms of marketing may constitute both labeling and advertising under the two agencies' laws. For example, a website where a dietary supplement can be purchased would fall within the FDA's definition of labeling in addition to being advertising under FTC law." The FTC and the FDA have a long-standing memorandum of understanding in place to harmonize the enforcement of these regulations. The FTC's jurisdiction does not extend to certain health-related product areas, such as prescription drugs and restricted devices.

2. 21 USC §§ 321(ff); 343(r)(6).

Key Contacts

Megan Donohue San Diego	mdonohue@cooley.com +1 858 550 6085
Scott Dailard San Diego	sdailard@cooley.com +1 858 550 6062
Sonia Nath Washington, DC	snath@cooley.com +1 202 776 2120
Shawn N. Skolky Washington, DC	sskolky@cooley.com +1 202 776 2127