How FTC's Broadened Health Ad Guidance Affects Marketers

By **Daniel Kaufman and Randal Shaheen** (February 6, 2023)

Daniel Kaufman

Randal Shaheen

In 1998, the Federal Trade Commission issued industry advertising guidance for dietary supplements that served as an important starting point for analyzing health claims for dietary supplements.

Of course, since that document was issued, the FTC has announced hundreds of cases challenging claims that companies have made for health products, and many of those cases contributed important information to the overall understanding of how the agency staff analyzes different health claims.

For some time, the FTC has hinted that an update was coming and that such an update was likely to tighten requirements around health claims substantiation. As all of us were collectively turning the calendar to 2023, the FTC announced a new and broader 42-page health products compliance guidance.

There is a lot to discuss about this new document, but for starters, if you are at all involved in analyzing or substantiating any health claims, or just want to better understand the issues involved, this is a must-read and must-retain document.

You may find that in some places it changes your understanding of what is or is not acceptable to the commission when it comes to substantiating health claims.

There may be unique cases, facts and issues that raise concerns about the breadth or applicability of the guidance, but this guidance does come with receipts. It is filled with real-life examples and hypotheticals, and the appendix makes it quite clear that most of these are based on real-life cases that the FTC has brought in the past.

In fact, anyone who has been working in this area will recognize specific cases throughout the examples and hypotheticals.

At the outset, what is fundamentally different here? Well, the biggest difference is clear from the title.

The prior version focused solely on dietary supplements and the new version makes it clear that it much more broadly addresses all health claims, not just those made by supplement companies. So pay attention, marketers of foods and over-the-counter drugs and device manufacturers.

The second-biggest change is that the new guidance more directly incorporates a lot from other areas of advertising law — how to properly use testimonials and disclosures.

And third, there is a far more extensive discussion on the science and what the agency expects to see. Not particularly familiar with the concept of p-hacking? Check out Page 18. Spoiler alert: The FTC isn't a fan of this practice, which is a form of post-hoc analysis of study data to uncover statistically significant differences that may not appear from the study as a whole.

So the guidance starts out with the necessary setup and background information, describing the agency's primary legal authority in this area, the FTC Act, and how the agency interacts with the U.S. Food and Drug Administration — they talk and defer a lot but approach things quite differently.

The next section of the guidance is more set up, explaining how the FTC approaches claims analysis — figuring out which claims are reasonably interpreted by consumers and how companies are on the hook for all such claims, regardless of whether they intended to make them.

For example, this section reminds advertisers that images of people wearing snazzy white coats will convey claims of clinical proof and that before-and-after shots can be quite effective at making strong efficacy claims.

The next section focuses on when and how to use disclosures properly and effectively, and reminds us about using disclosures to provide key qualifying information that can prevent an ad from being misleading.

For example, marketers should disclose whether a weight-loss product study also required diet and exercise, or whether a claim has limited applicability to the general population, such as a mineral deficiency that affects only 2% of the population.

A lot of this — particularly, how to make effective disclosures — comes from related FTC documents, such as the dot com disclosures guidance document that is currently being reviewed.

And then we get to the bulk — and probably most compelling part — of the document: how to substantiate health claims.

For those who have not been part of an FTC investigation that involved health claims, this discussion will give you a good sense of just how in depth the FTC staff get when analyzing studies and research.

Often, they are reviewing underlying study data as well as the formal study report, and the guidance makes it clear that they just might be doing that in your matter. And this part of the document is far more prescriptive than the prior guidance.

Over the years, there has been a lot of back and forth as to whether one study was enough, and for now, the answer appears to be that one good study will suffice, but another helpful one isn't a bad idea — and make sure that your one good study isn't at odds with what other studies have shown. A good study will take the form of a randomized, controlled human clinical trial.

And when it comes to studies, quality is more important than quantity. The FTC will consider other studies, such as animal or in vitro studies, or epidemiological studies, but animal and in vitro studies will not be adequate substantiation — except for claims about animals and test tubes — and epidemiological studies may just be adequate substantiation in quite limited cases.

This represents perhaps a slight walk back from the previous dietary supplement guidance, which stated that "animal and in vitro studies will also be examined," not only when human research is infeasible, but also "where they are widely considered to be acceptable

substitutes."

As for the quality of the studies, they should be controlled, randomized and double-blinded to the fullest extent possible, and results should be both statistically significant and clinically meaningful. It is not uncommon to encounter a situation where a study may achieve statistical significance but the actual difference that is shown by the study may be too small to provide real consequences for consumer health. And there is more.

Now, the FTC isn't saying that every study has to have the following, but it doesn't hurt and will be assessed as a factor: At the outset, the FTC is looking to see a clear and detailed protocol, with inclusion and exclusion criteria, that has been submitted for review to an institutional review board.

Also important are the size and duration of the study, how dropouts and noncompliance are handled, and, when applicable, the peer review process.

Of course, it's all about the totality of the evidence; studies are not reviewed in isolation. One decent study that shows a modest effect will often be outweighed if there are multiple studies reaching a contrary conclusion. As the guidance notes:

> Wide variations in outcomes of studies and inconsistent or conflicting results raise serious questions about the adequacy of an advertiser's substantiation.

The guidance also has something important to say about qualified claims — claims where there is some preliminary but not yet definitive evidence regarding the efficacy of an ingredient or a product.

FTC historians may recall that way back in 1984, then-Bureau of Consumer Protection Director Carol Crawford praised the Kellogg Co.'s high-in-fiber All-Bran cereal for the qualified claim that "there is growing evidence that may link a high-fiber, low-fat diet to lower incidence of some kind[s] of cancer."

Crawford stated, "We believe this advertisement and other advertisements like it can serve a valuable function in the marketplace." But what about today?

The new guidance suggests that it is very difficult to adequately qualify a claim based on limited and still emerging science, and suggests that words such as "may," "helps," "promising" and "preliminary" likely don't do the trick, in part because they sound too positive and fail to convey the significant limitations of the science.

Finally, we have a bit of a catchall at the end. The FTC reminds folks about using testimonials and expert endorsements properly, and that the well-known Dietary Supplement Health and Education Act disclaimer won't cure a deceptive ad.

The new guidance may also signal the death knell for traditional use claims for things such as herbal medicines, which have a long history of use but no definitive scientific support.

The original dietary supplement guidance permitted such claims without the use of a disclaimer if, in the context of the advertisement as a whole, the ad does not suggest "that there is scientific evidence demonstrating that the product is effective."

While the updated guidance continues to permit traditional use claims, it advises that such claims must be accompanied, likely in the claim itself, by a statement such as: "There is no

scientific evidence that it works." We wonder how many marketers will still find such traditional use claims attractive.

Finally, the guidance emphasizes the importance of not mischaracterizing the extent to which a product has been approved or reviewed by the FDA. We have seen a number of cases raising this last concern in particular.

Another important point raised in the document — and this is an issue that comes up frequently — is making sure that the claim you are making actually matches what the science is saying about the product.

We have seen many a company get into trouble because it might have a really solid study, but the claims either go beyond what the study supports or the study involves a different combination of ingredients — or perhaps a different dosage or formulation, or the inclusion of an ingredient — that isn't in the company's product. All these concerns will be analyzed and critiqued when your claims are being investigated.

There is quite simply a huge amount to digest from this guidance, and we have done only a bit more than scratch the surface. We recommend getting comfortable and setting aside a bit of time to review the full document.

And for the administrative law folks among us, this is a guidance document and not binding on anyone, but ignore it at your peril. Unlike other guidance documents, such as the Green Guides that are also under review, this guidance document is not voted on by the commissioners.

Again, this should not detract from the significance of this document — it is helpful information to know. And of course, unlike the Green Guides, the public was not asked to comment on changes to this guidance document.

Daniel Kaufman and Randal M. Shaheen are partners at BakerHostetler.