# Misguided: The FTC Attempts to Redefine the Law with its Health Products Compliance Guidance

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Yesterday, the FTC's Bureau of Consumer Protection released its Health Products Compliance Guidance—a sweeping overhaul of the 1998 Guidance, *Dietary Supplements: An Advertising Guide for Industry*. Unlike the recently announced effort to review its Green Guides, the FTC did not seek public comment prior to issuing this update.

According to an FTC blog post that accompanied its release, the new Guidance purports to "correct misunderstandings" and "urban myths" that have circulated about FTC substantiation standards. In actuality, however, the new Guidance represents a recitation of some of the positions the agency has taken in health-related enforcement matters over the last decade, continuing a stark departure from the prior "flexible" approach to substantiation set forth in the 1998 Guidance.

While FTC guidance does not have the force and effect of law, if a person or company fails to comply with a guide, the Commission might bring an enforcement action alleging an unfair or deceptive practice in violation of the FTC Act. This makes the new Guidance a must-read for any company operating in the food, supplement, personal care, health equipment or app, or related industries.

While there is quite a bit of material to digest in this new Guidance, including a new definition of what constitutes a clear and conspicuous disclosure and an entirely new section addressing advertisers' mischaracterization of FDA approval, here are two main takeaways:

***First*, the 2022 Guidance encompasses a far wider industry scope than its predecessor.** While the 1998 Guidance was, by title and content, focused on dietary supplement products, the 2022 Guidance purports to guide advertising practices for "any health-related product," including dietary supplements, foods, over-the-counter (OTC) drugs, homeopathic products, devices, health equipment, diagnostic tests, and health-related apps."

The agency is also expanding the types of claims that fall within its scope. While the 1998 Guidance was issued to answer questions that arose from the passage of the Dietary Supplements Health and Education Act of 1994 ("DSHEA"), specifically its allowance of "structure/function" claims without prior FDA approval, the 2022 Guidance purports to apply regardless of whether the claim would be considered a health claim, a structure/function claim, or a drug claim under FDA law.

While FTC enforcement over the last decade has involved all of the industries referenced in the updated Guidance, this updated Guidance synthesizes the agency's approach and seeks to put

broad swaths of the health and personal care industries on notice that FTC staff is attempting to raise the bar for substantiation, even though prior attempts to do so through litigation have been rejected by various courts.

***Second*, the 2022 Guidance departs from the FTC's prior, "flexible" interpretation of the "competent and reliable scientific evidence" standard.** By its own terms, the 1998 Guidance sought to be both "sufficiently flexible" and "sufficiently rigorous" to ensure that consumers have access to information about emerging areas of science, while protecting them from inaccurate or misleading information. Accordingly, the 1998 Guidance did not apply a fixed formula for either the number *or* type of studies required to substantiate advertising claims. Rather, the agency focused on the totality of the evidence and considered *all* kinds of evidence, including animal, *in vitro*, and epidemiological evidence, while recognizing that well-controlled human clinical studies are the "most reliable"—but not the only—form of acceptable substantiation.

Those who have been following the FTC's enforcement efforts relating to health claims over the last decade know that, since approximately 2010, the agency has been skeptical about certain health claims and has attempted to apply a drug level substantiation standard to a range of non-drug products. This is echoed throughout the 2022 Guidance with obvious references to prior enforcement (and pending litigation) matters in the advertising examples. This march toward a more stringent "competent and reliable scientific evidence" standard continued through the *POM Wonderful* litigation to the present day.

Indeed, the previously "flexible" definition of competent and reliable scientific evidence is completely absent from the 2022 Guidance.

- Instead of simply recognizing that RCTs may be the "most reliable" form of evidence, as set forth in the 1998 Guidance, the new Guidance provides that RCTs are the *only* form of evidence that will suffice, regardless of whether the claim would be considered a health claim, a structure-function claim, or a drug claim under FDA law: "[a]s a general matter, 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 evidence standard."
- Additionally, while the 1998 Guidance stated that the FTC would accept epidemiologic evidence when supported by other evidence, such as research explaining the biological mechanism underlying the claimed effect, the updated Guidance states that the FTC will now only accept "high-quality" epidemiologic evidence in "limited cases where (1) it is considered an acceptable substitute for RCTs by experts in the field; and (2) RCTs aren't otherwise feasible."
- Finally, where the 1998 Guidance specifically provided for consideration of animal and *in vitro* studies, those are now off-limits because, according to the FTC, they have "limited value" in predicting benefits in humans.

With echoes of *POM Wonderful* ringing through the paragraphs, the 2022 Guidance explains the FTC's views on *how* RCTs should be designed and conducted. Specifically, a study is "unlikely to yield reliable results, and generally won't meet the FTC's competent and reliable scientific evidence standard" unless it utilizes a control group, randomization, and double-blinding, and unless it returns results that are both statistically significant and clinically meaningful.

The 2022 Guidance then goes a step further, identifying "other factors" the FTC will consider in assessing the quality of research, including the existence of "a clear and detailed protocol," submission of the protocol to an Institutional Review Board, registration of the clinical trial in a public

database, performance of an "intent to treat" analysis, evidence of a dose-response relationship, and a rigorous, and unbiased peer-review process (including a warning that research that has not been through peer-review "will be subject to greater scrutiny"). But without further explanation of *how* these elements will be factored into the FTC's substantiation determination, companies are left with more uncertainty about how to design their research in a manner that will be acceptable to the FTC.

Finally, in addition to imposing requirements regarding the design and conduct of the now-mandatory RCTs, the FTC has also weighed in on how RCT data should be *analyzed*. Specifically, the 2022 Guidance warns against "*post hoc*" analyses of data, particularly ones that depart from the original study protocol. According to the FTC, *post hoc* analyses suggest that the researchers are engaged in data mining or p-hacking and do not "generally" provide reliable evidence to substantiate an advertising claim.

In practice, this new prohibition on *post hoc* analysis ignores that significant scientific discoveries (such as penicillin and Viagra) have been made based upon incidental findings. This blanket statement may have the unintended consequences of discouraging data analysis that is not specifically laid out in a study's protocol and squelching future, unintended discoveries. Moreover, the FTC's equivocation on this point—that *post hoc* analyses "generally" do not provide reliable evidence to support a claim—injects further uncertainty as to whether a *post hoc* analysis could *ever* substantiate an advertising claim, either on its own or with an appropriate disclaimer.

**How Should Companies React To The Updated Guidance?** As a starting point, it's important for companies to understand the context in which the updated Guidance was issued. The updated Guidance is a synthesized recitation of the agency's positions over the past decade and much of what is included was already imposed on individual companies subject to FTC consent orders or litigation. The 2022 Guidance is not law, but rather provides insight into staff's increasingly restrictive views on competent and reliable scientific evidence and disclosure practices.

Further, staff's positions are subject to challenge and there is existing law that directly calls into question the validity of the staff's restrictive interpretation of competent and reliable scientific evidence. The *Bayer* case, in which the court found that Bayer's practice of regular review and analysis of clinical studies involving specific probiotic strains in conjunction with digestive health claims, remains good law. The FTC attempts to dismiss the importance of the holding in *Bayer* as an order violation case, but cannot ignore that because of the company's FTC order, the company was subject to the same definition of "competent and reliable scientific evidence" referenced in the updated Guidance.

It is also worth noting that the staff's positions continue to be subject to legal challenge, including in a case that will likely go to trial in the Southern District of New York in 2023 involving Quincy Bioscience, for whom Kelley Drye serves as counsel.

In the meantime, as marketers generate new content for the new year, we have two suggestions:

- First, review claim substantiation and disclosure practices with an understanding that the FTC staff is continuing its efforts to impose a less-flexible substantiation standard and more stringent disclosure practices. Closing substantiation gaps can be tricky and may be a longer term investment, but disclosure practices are frequently easier to address.

- Second, to echo the FTC's blog post, put down your phone, get a cup of cocoa, and watch this space. In the coming weeks, we will provide further insight on the gaps between the 1998 Guidance and the updated Guidance, and the daylight between the law and FTC staff's

positions.