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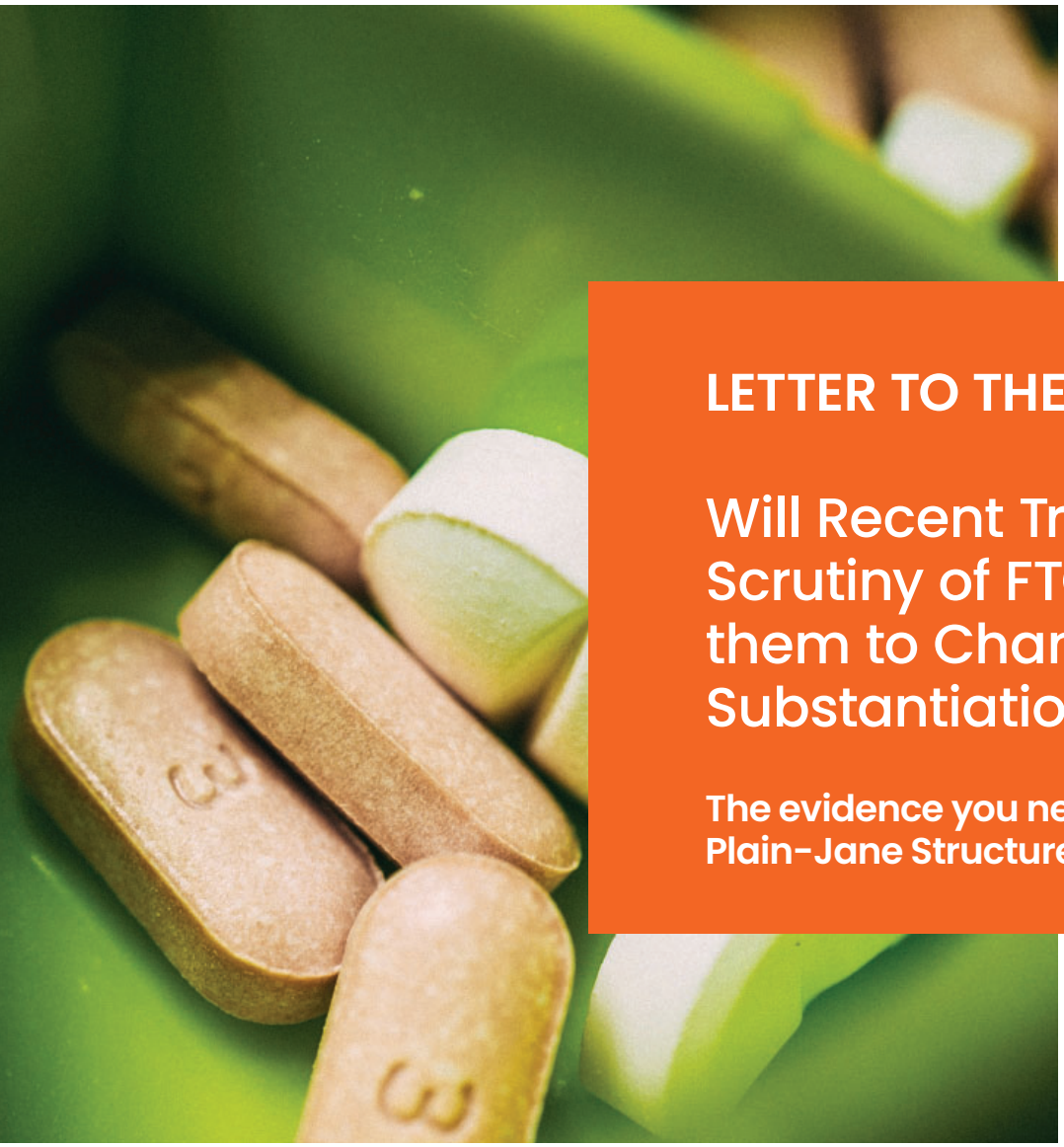

LETTER TO THE INDUSTRY

Will Recent Trade Press Scrutiny of FTC Force them to Change Their Substantiation Standard?

The evidence you need for the Plain-Jane Structure Function Claim

"FTC 'clarifies' claims substantiation of Health Produce Compliance Guidance" was the title of a recent trade press article from Nutraingredients. It definitely created a splash just before the industry's largest trade show, SupplySide West - Mission Accomplished. It will be the talk *du jour* no doubt in Vegas.

The problem is that the article was confusing for a multitude of reasons.

1. The language used throughout the article was just not precise. Let's take health claims and health-related claims. We still don't know what a "health-related" claim is as it is not defined anywhere in our copy of the statute. Was it talking about substantiation for a health claim, which requires alignment to the Significant Scientific Agreement? The intent wasn't to talk about health claims, which also encompasses authorized health claims and qualified health claims, but it sure used the term health claim all over the place. And health claims typically require 2 RCTs so the effect is independent and verifiable. Furthermore, health claims are targeted toward claims involving risk reduction of disease and not therapeutic claims.

2. The article suggests that there are "serious health claims" and then there are "structure-function claims". I don't know what qualifies as a "serious health claim" as opposed to just a "Plain Jane Structure Function Claim." FDA has never delineated a serious structure function claim vs a non-serious structure function claim in the January 6, 2000 final rule.

3. It seemed to lump serious health claims and structure-function claims as being in the same type or category, except one required substantiation while the other claim did not. These two types of claims are completely different. The only commonality is that they are both regulated by FDA's Center for Food Safety and Applied Nutrition. The main difference is they are regulated by completely different groups at CFSAN. Here is the reality: they both require substantiation and that does not change.

4. The takeaway message was that FTC was not going to sue anyone for making structure/function claims in isolation. Well, this seems to be a quote taken from FTC out of context. While FTC may have offered up the quote, the transmission of that quote to the masses with no further dialogue seems irresponsible.

5. The article says, "FTC has focused its resources and enforcement efforts on health claims involving serious medical conditions and diseases." There are lots of claims FTC has gone after: disease claims, structure function claims, comparator claims, etc. I don't even see the term 'disease claim' used anywhere in the article. Companies are not permitted to make disease claims (FDA jurisdiction), and the article makes it seem as though structure function claims do not need substantiation. So, someone who makes a disease claim will certainly incur the wrath of FDA and FTC in that case (box checked).

FTC provided clarification to the TanSheet:

"Choosing which claims to make," an advertiser "affects the amount of substantiation required. A structure function claim, supports digestive health, may require a different level of substantiation than if you choose to make the claim, prevents diarrhea," says FTC attorney Christine DeLorme.

Well, this is probably another poor example because FDA does not permit you to make unqualified diarrhea claims on dietary supplements. A diarrhea claim, if left unqualified, would be a disease claim. One would have to qualify and limit the scope to "occasional diarrhea" in order for it to remain a structure function claim.

So, what exactly is FTC saying and what is the trade press not saying?

It does not take a law degree to know you need substantiation for a structure function claim or any type of claim for that matter. The question seems to be over 'how much evidence'. There are structure function claims, disease claims,

nutrient content claims, classic nutrient deficiency disease claims, comparator claims, mechanism of action claims, statement of fact claims, and there are probably a few more categories we can come up with if we sat here pondering for another hour. The POM Wonderful and Phillips' Colon Health decisions both said that randomized clinical trials were the gold standard. You probably only need one of those, but there could be circumstances where the totality of the evidence was sufficient where you might not even need an RCT. However, working out the criteria for that might be more challenging than completing the RCT itself. You only saw 'two RCTs' on the back end of consent decrees after companies were litigated.

So, FTC's standard is not changing. They have never come out and stated you always need two RCTs. Rich Cleland had never once said possessing two RCTs is the competent and reliable scientific evidence standard, end of story. Having one RCT with statistical significance and a clinically relevant effect in a well-designed trial is sufficient, unless there was competing evidence from another study that showed no effect. Totality of the evidence is key along with quality of the evidence, relationship of the evidence to the claim and meaning of the claim. All are factors in the FTC claim analysis. What can one conclude from FTCs guidance and position on substantiation? There is nothing to see here. There is nothing new. FTCs guidance remains unchanged. The more things seem to change around us, the more they stay the same.

This takes us back to the articles over substantiation from the trade press. Why now?

FTCs updated thoughts in their December 20, 2022 "Health Products Compliance Guidance" seemed to have induced 'occasional indigestion' with the industry.

Companies are worried that FTC could be secretly applying a higher scientific standard (2 RCTs here). The other concern seemed to be that FTC failed to mention the acronym CARSE, referring to the substantiation standard for needing to have competent and reliable scientific evidence. A quick search shows that there are 25 mentions for this substantiation standard all throughout and 5 citations where it is mentioned in the Endnotes. That argument is a real head-scratcher.

While the mention of RCTs repeatedly, may worry industry, RCTs have always been the gold standard for supporting claims with CARSE. With Citizen Petitions flying in September, why did it take some 9 months to respond to FTC's updated substantiation guidance?

The real battle is over the flurry of Notice of Penalty Offenses, sent to 700+ companies from FTC in April some 4+ months after releasing their guidance, and the pressure on trade associations to respond in turn for their members, who may or may not have been caught up into that wide dragnet. The issue here is how much evidence is required to substantiate the claims at the center of these letters and the concern that FTC will impose a more heavy-handed drug standard of applying more than one RCT to structure claims for dietary supplements.

Several organizations decided to push back on this attack procedurally so as to say that this generic attempt by FTC to call broad brush penalties for unsportsmanlike activities by companies is inadequate for obtaining monetary gains for the US Treasury. The letters are non-specific and do appear as mafia-style shakedowns, but those are the first communications to those companies. Communication #2 will be much more tailored to each company over the exact claims in question, as well as the ingredients and/or products the claims have been made.

Takeaway Message to the Industry:

- FTC's Recent Guidance was an attempt to simply increase the number of examples given in comparison to their previous guidance from decades ago - the guidance did not offer any glaring changes and it is "business as usual".
- FTC will not reverse course on their newly minted substantiation guidance - it represents their current thinking and collection of 20+ years of example enforcing against non-compliance to the competent and reliable scientific evidence standard.
- Do not expect any future surprising FTC clarification to the industry, indicating that firms do not need to substantiate structure function claims.
- All structure function claims need to be substantiated with competent and reliable scientific

evidence - the FTC and FDA substantiation standard has never changed. Trade press article(s) took FTC comments made at industry trade shows from agency personnel out of context, implying there is no need to substantiate structure function claims - choice of terminology in those articles was very imprecise (e.g., "health-related claims") and led to much confusion.

- The gold standard for substantiating a claim will always consist of a randomized, placebo-controlled clinical trial.
- FTC has never imposed a 2 RCT standard to any companies in compliance making substantiate structure function claims - they have imposed a 2 RCT standard on the back end of consent decrees to firms found to be in non-compliance to FTC's competent and reliable scientific evidence substantiation standard.
- Recent case law has stated that the overall totality of all of your evidence will be evaluated and having 1 RCT with statistical significance and physiological relevance is enough (e.g., a half-pound of weight loss that is statistically significant after supplementation for 9 weeks may not be physiologically relevant to the consumer).
- Disease claims are not permitted on any dietary supplement product.
- The amount of evidence required to substantiate your claims depends on the structure function claim itself - you may need more evidence to substantiate "helps with occasional pain after vigorous exercise" than you would need for "helps with metabolic and liver health".
- Having *in vitro* or animal data alone is not sufficient to substantiate any structure function claim because the competent and reliable scientific evidence standard implies you have evidence in intact humans.
- Trade Associations remain vital tools to fight Agency overreach in areas that require greater clarification from government agencies. We encourage membership in trade associations that align with your business.