Dear Colleagues in the Natural Products Industry:

I am writing this open letter to the natural products industry to share Xlear's experiences with the Federal Trade Commission (FTC) and the Department of Justice (DOJ) and to offer some cautionary advice. Simply put, if you haven't already been the subject of an FTC enforcement action or been sued by the FTC/DOJ, you probably will. Now is the time to take basic steps to prepare for this eventuality.

You may read that warning and think: "There is no way we will be sued." I get that. Xlear never imagined the FTC would come after us. We base all our advertising and marketing on published research. We only share information that our lawyers—and at one time the FTC—told us we could share. We followed the Guidelines that were in place at the time. We've been making—essentially—the same statements for decades. During that timeframe we have had no issues with the FTC or any other regulatory agencies.

But times are changing, and not for the better. The FTC as an agency has changed and is still changing and becoming more tyrannical. Most importantly, the FTC is arbitrarily making up and changing the rules that apply to you and our industry.

In 2022, the FTC issued new guidance, the "Health Products Compliance Guidance."[1] While the FTC admits this is "mere guidance" (things companies should bear in mind but are not legally required to meet), the Agency is aggressively, and unlawfully, seeking to enforce these guidelines as if they were law. In the FTC's view, this guidance applies to any health-related claim any product might make.

In the past, the standard for how much and what type of scientific data a company must have to make a health-related claim was much more flexible. However, for years, the FTC has been trying to impose a RCT rule on us. The 2022 Guidance now makes the RCT requirement the FTC's oversight and enforcement standard.[1]

What does that mean: Any health-related claim must now be backed by two randomized, placebo-controlled, human-clinical trials, using your specific product, showing safety and efficacy against the specific indication and providing the specific benefit the statement indicates. **Basically, you must now have as much or more data to make any statement than the Food & Drug Administration requires for new drug or medical device approval.**

According to the FTC, anything directly or indirectly suggesting a positive benefit to health is covered by this rule. For example:

- A humidifier ad that says it improves sleep: Covered.
- A probiotic social media post that says it can improve heart health or improve the gut biome: Covered.
- A supplement ad that says fiber improves bowel regularity: Covered.
- A knee brace Instagram video about improved joint stability: Covered.

[1] Even though the FTC's own staff readily admit it has never been promulgated as a legally binding rule.

- A juice company's social media post about lowering blood sugar levels: Covered.

You get the picture.

Additionally, according to the FTC, you don't actually need to claim anything. Such claims can be inferred. For example:

- Xlear posted links to published, peer reviewed, scientific studies regarding COVID-19. The FTC says the links on our webpage were implied claims.
- On our Facebook feed, Xlear thanked a leading, independent expert physician for a video he posted on social media telling people to use nasal hygiene to combat COVID-19. The FTC says that "thank you" linked to his post is a claim.
- Xlear ran an advertisement, which was titled "Stop the Spread"—and nothing else. The FTC says that ad is an implied claim.
- In another situation we are aware of, a product had the word COVID in its name. The FTC said any use of the brand name was a claim.

A few things to know when you are subject to an enforcement action and/or get sued:

1. **The government is a well-funded goliath. They have no incentive to reduce costs or settle things on a reasonable basis.**
2. **The government uses the regulatory, legal and litigation processes to both grind you down and punish you—from the get-go, long before anyone has been found guilty of anything.** In one case, a government attorney literally told defense counsel that, "[t]he process is the punishment."
3. **The process is stacked in their favor.** The rules in court favor the government. For example, all your routine corporate decision-making—e.g., the back and forth of emails about an ad text—is subject to discovery. The government's internal back and forth about taking action against you is protected from discovery and use by the "deliberative process privilege." Likewise, the FTC makes the rules, and the courts typically defer to the agency to say what they require.[2] The FTC Act, which is the basis for all these cases, says nothing about substantiation or RCTs. So why do courts impose this requirement? Because the FTC says that's what the law requires. Xlear hopes our case will shift this balance, but for now the courts give the FTC great latitude.
4. **The government officials who cast judgment on you and your actions have no real expertise in these fields—and they make no real effort to weigh the science.** In recent depositions in our case, we learned that the "science expert" at the FTC who determined our COVID-19 claims were not substantiated is a nutritionist. I have great respect for nutritionists—but I wouldn't go to one to help me with a novel, deadly, upper respiratory virus. Similarly, the FTC official who led the charge against Xlear has no science training—none. On the side he fancies himself a "consumer advocate." The more senior FTC official who made the decision to sue Xlear, the data suggests he never opened or read the studies we sent the agency to back up our statements.

[2] The Supreme Court has been reducing the level of agency deference in other areas, but the Court has not heard a "substantiation case" of late.

5. **The government officials who are making these nonsensical decisions are utterly unaccountable.** Their government positions make them immune from virtually all legal actions. Even if they act with supreme negligence, even if their actions are tainted by personal animus, they cannot be sued. The vast majority of them are civil servants; simply firing them is almost impossible. Even if the administration changes with a new president, the rank and file, and low and mid-level management doesn't change. The system grinds on.
6. **Even if you win, you're still left holding a big bill—and there's nothing you can do to get your time or money back**. Assume Company A gets sued by the FTC/DOJ for unsubstantiated claims. Company A fights the case and wins on all counts. The process—from early settlement discussions, through litigation—has cost Company multiple millions of dollars in legal fees and other associated costs (to say nothing of lost opportunity costs, damage to business goodwill; loss of business and the like). Company A has no recourse to recuperate that money back from the government.
7. **Odds are if you settle to "make it all go away," you will hurt yourself in the long run**. When the FTC initially sent Xlear a warning letter, we initially sought to work with the agency. However, the terms the FTC offered us were unworkable. The Federal Rules preclude me from discussing our settlement discussions. What I can say is, we determined what was offered was a veritable set up and lousy deal—even weighing the prospect of long and costly litigation.

If the Founding Fathers saw this tyrannical system in action, they would rollover in their graves.

Given all that, based on Xlear's experiences, here are a few tips as you navigate this changing landscape—yes, these have been cleared by Xlear's lawyer:

First and foremost, make sure you have a solid DNO insurance policy. If you don't have one, get one. A good DNO policy will help defray your legal costs if the government comes after you. I recommend a policy that doesn't require you to use the insurer's choice of attorneys. If you already have one, know the terms and conditions. Don't let the insurance company avoid paying your claim.

Second and equally foremost, implement a document retention policy. Ideally, your system should retain documents for no more than 60 days—and perhaps, in the case of routine stuff, as short as 30 days. Couple this with a review and archiving process to keep vital documents, such as contracts, as needed. Add to that a review of archived documents every year. During our litigation, the largest expense has been paying attorneys to read through 4 years of emails. After 20 years in business without any serious issues with government regulatory agencies we—like most companies—just kept our emails, years of them. When the government sues you, they will require you to turn over all your emails and other documents. Your attorneys will need to go through vast numbers of them before giving them over to the government. Reading through 30-60 days of emails is a hassle but paying attorneys to read through 4 years of them will cost hundreds of thousands of dollars and isn't worth the cost.

Third, have a lawyer on call and engaged (part time is fine). Xlear now employs what is known as a "fractional general counsel." This is a lawyer who we keep on a relatively small, fixed retainer to advise us on a host of matters. We use him to review things like press releases to ensure that we

aren't making claims that raise FTC issues. (He also helps us with a range of routine corporate legal stuff.) He has more in-depth knowledge of the company than most outside lawyers, which is valuable if you find yourself defending an FTC enforcement action. And he helps us manage the outside legal costs in our case. As lawyers go, this sort of representation is cost-effective.

Fourth, make effective use of disclaimers. I know, no one reads disclaimers. And disclaiming a marketing statement isn't a magic wand. It does not guarantee any statement is now legal to make. However, it does shift the burden on to the FTC to show the disclaimer was somehow ineffective or inadequate. In an enforcement action, the more you can muddy the government's arguments and increase the burdens on the agency, the better your chances of winning. Consumers already know their probiotic is not intended to cure their heart issues—so there is no real cost of adding a disclaimer.

Fourth, work with your lawyer and your marketing team to figure out what you can and cannot say about your product, then educate your people. When the government sues you, they will weed through every email, every PowerPoint presentation, and more, looking for evidence the company was making unlawful statements. The government doesn't care that the statement was an offhand comment made in an email by a junior employee—they will waive it around like the proverbial smoking gun. If your team knows what they can and can't say, you reduce your risks.

Fifth, pay attention to indemnification clauses in vendor contracts. Recall those boilerplate indemnification clauses in your contracts with your PR firm, your marketing agency, your distributors, your social media firm, your advertising firm? Probably not. When the government comes after you, all those vendors will get dragged into the discovery process. If their contracts have unlimited indemnification clauses, you will be paying their legal bills, on top of your own. Have your lawyer (see above) negotiate more limited indemnification clauses (or get rid of them if you can).

Sixth, get involved. Work as an industry to stop the FTC's unlawful regulatory scheme. Our legal team has analyzed the FTC's new regulatory scheme. They believe there are two ways it can be stopped: In court with a victory in Xlear's case or some other similar case (Xlear's facts are about as good as the industry can get); and/or, through Congressional action. Work with your association to get Congress to legislate against the FTC's unlawful health products compliance, substantiation scheme.

If and when those efforts to avoid the fight fail and the government issues you a warning of some kind or files suit, here are a few things to bear in mind:

First, provide your insurer with whatever notice is required in your DNO policy to ensure the matter is covered.

Second, as noted above, be cautious and hesitant to "negotiate" a settlement with the government. Even if you did nothing wrong—if you didn't make a false claim—they will try to push you into negotiating a settlement. The bureaucrats want a quick and easy scalp. They also use the settlement process to ratchet up the bar on you and the rest of the industry. If you did nothing wrong, please don't just roll over and obey. Not only will it hurt you, but it will hurt the industry,

and the American people in the long run. The only groups that gain from settlements are the government bureaucrats, "Big Pharma" and "Big Medicine" (e.g., hospitals). It may cost money to fight, but if no one fights, soon the government will have achieved their goal of shutting down the Natural Products industry.

Third, when choosing your attorney(s), choose carefully. Do not trust firms or lawyers who tout their experience of having worked at the FTC or FDA ("formerly-this" lawyer). These "formerly-this" lawyers are not just versed in the system; they are captured by it. You want lawyers who are willing to challenge the FTC dogma: "Just because this is what the FTC says the rules are, that doesn't mean that is the law." You want lawyers who aren't worried about currying favor with their former agency and colleagues. In our case these "formerly-this" lawyers cost us the most money by being incredibly inefficient (imagine that a government employee being inefficient). And, no, I don't believe these "formerly-this" lawyers are any more versed in the law than attorneys who have never worked at the FTC or FDA.

Along those lines, Richard Cleland, the lead FTC attorney who pushed the lawsuit against Xlear and who played a significant role in developing the new rules, has now left the FTC. He is currently employed at the law firm Arnall Golden and Gregory. He is looking to cash in selling his services to our industry. I recently heard his sworn deposition testimony—his views on FTC law and what it requires of our industry. Based on his testimony, I can say this: There is no way I would trust him to represent my company's interests.

Do not knee-jerk hire a firm in DC. Early on in our case, we hired a well-regarded Washington, DC firm. They were hard-nosed, top notch and very good at what they did. The problem is when the government sues you, they can bring the case to your home state. (Depending on the facts they may also bring it to DC.) If the government sues you in your home state, then you will need local counsel. You can find yourself needing two sets of lawyers, which quickly run up the legal bills.

That said, make sure your legal team has expertise in agency and administrative law. You don't need a DC firm, but you do need counsel who knows how official Washington works and how the law applies to Federal agencies. Ultimately, we hired a national firm with a significant Utah presence, and we augmented their team with an efficient, DC-based, solo practitioner who understands FTC law, knows the workings of government agencies and agency/administrative law, and is a tough litigator.

Make sure your lawyer also knows your science. These cases often turn on complex scientific facts and processes. For example, in Xlear's case, key issues include: the nature of the SARS-CoV-2 virus; blocking viral adhesion; ethical and other limitations on RCT trials; and, how xylitol functions in the nasal cavity. If your lawyer doesn't understand these types of scientific issues, they won't know what to look for in documents and studies, how to challenge the government's experts, and/or the like. Your lawyer doesn't need to be a PhD researcher, but they need to be capable of learning your science inside and out.

Fourth, stay involved in your case—nobody knows your business and your case better than you do.

Fifth, decide early on—ideally before you get sued—whether you are going to fold your cards and take it, or if you are going to do the right thing and stand up to government overreach. Deciding early on enables you to make a series of decisions that can help you reduce costs and prevail. For example, initially Xlear tried to work with the government to settle the matter and avoid litigation. Early in those talks it became fairly obvious that the FTC didn't intend to agree on a reasonable deal. At that point in time, we should have halted talks and saved the costs of extended, overly optimistic settlement efforts.

Sixth, find an industry group that can help you with litigation support (e.g., experts) and your legal bills—again, sadly, I think it's not a question of if, but when. There is strength in numbers. The time to build your community is now, before you face an enforcement action or lawsuit. Along those lines, I think that our industry should put together a legal fund to help with some of these expenses. A good defense in one case protects all of us.

Three final notes:

They say advice is worth what you pay for it. While my advice here is free to you, it comes at millions of dollars of costs, fees, and untold hours of frustration to me.

Second, I am not writing this open letter to scare you. Rather, my goal is to help you understand where things are headed and be prepared. Under the FTC's arbitrary new rules our companies have only three choices. We can stop telling consumers about our products. We can stop trying to educate consumers about their health in general. Basically, we can just close our companies. Alternatively, we can stay in business and keep informing the public about science-based health information. In which case, we (you) will most certainly violate the FTC's rules and find yourself subject to an enforcement action. It is what it is.

Third, taking on the government isn't as scary as it seems. Mostly it is a huge time suck, which is why I guess the government agencies do it. To make it seem appealing to simply give in and go along.

Thanks for taking the time to read and consider these thoughts.