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Hello, and welcome to Greenberg Traurig's legal food talk. I am your host, Justin Prochnow. I'm an attorney and shareholder in the Denver office of the international law firm, Greenberg Traurig. And this podcast brought to you by me and my colleagues in the food beverage and agribusiness practices at Greenberg was launched to provide our listeners some insights and knowledge regarding a wide range of topics in the food and agribusiness industries. For those of you who haven't heard of Greenberg Traurig,

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It's a law firm that started in Miami in 1967 and is now become an international law firm with 40 offices dispersed throughout the U S and around the world in places like London, Warsaw, Amsterdam, and Mexico city. Just to name a few of them with over 2100 lawyers, we have someone who could probably assist you with whatever legal need you have. But for this podcast, we're going to focus on eating, drinking, and growing in the manner of speaking with my colleagues, Rick Shackleford and Arlene Naan. I co-chaired the food beverage and agribusiness practice here at Greenberg, which is a really diverse group of lawyers that assist companies in those industries with everything from regulatory assistance to employment law, work to mergers and acquisitions to the growing number of class action litigation. And through this podcast, we hope to introduce you to some of the members of our group and some of the unique clients that we work with.

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And also maybe drop a little knowledge along the way. So without further ado, let's get talking today. We're going to start off with a topic that I think most of you would agree has been on the forefront of everyone, uh, over the last year. And that's immunity claims while 2019 in many respects, at least for my practice was the year of CBD and hemp. 2020 has been the year of the immunity. And of course, with the big shadow hanging over of COVID-19, uh, immunity has been at the forefront of everyone's minds here at Greenberg. I am, I guess you would call it the regulatory guy. I spend the majority of my days looking at labels, websites, social media sites, and other marketing and advertising materials, and working with companies to help ensure that they stay within the boundaries of the law and permissible claims for their products.

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Of course, it's sometimes hard to stay within the boundaries when you don't know what those boundaries are. And to be honest, it, isn't always easy to tell. So that's where I come in. And today I will be your muse as we discuss how to make permissible claims during this unprecedented time and focus on immune health. So when I talk to companies about claims, and again, my practice is 100% representing companies in the food beverage, dietary supplement, cosmetic, really any FDA regulated product space. So when we're looking at claims for products and I'm talking to companies, we're really looking at two main federal regulatory agencies that are responsible for regulating claims, the food and drug administration and the federal trade commission. Those are really the two agencies that are going to be looking at the claims that you're making for products. When we talked about the food and drug administration, the FDA is really looking at your labeling and advertising to determine whether you're making appropriate claims for the type of product that you're selling.

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And today we're going to really focus on non-drug non medical device products. So food beverages and dietary supplements and how you can make appropriate immunity claims. We're not going to talk about topical products because it's important to understand that if you're making immunity claims for topical products, you're selling drugs because in the United States, you may only sell topical products in one of two manners as drugs, or as cosmetic slash personal care products and cosmetic slash personal care products may only be sold to cleanse beautify, promote attractiveness or otherwise alter the appearance of the skin. So if you're making immunity claims, those claims obviously don't fall into one of those categories of cleansing beautifying, promoting attractiveness, you're selling a drug. So it's really important to understand immunity claims plus topical equals drug. So we're going to focus today on ingestible products, uh, food beverages and dietary supplements.

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So the FDA looks at those and decides, are you making appropriate claims for the type of product that you're selling? On the other hand, the federal trade commission looks at products and marketing and advertising to determine A is everything that is being said truthful and not misleading. B, is there anything unfair about what's being said and C, does the company have appropriate substantiation to back up any claims? Those are really the two different categories that the FDA and the FTC are looking at. So we're going to focus first on the food and drug administration. And this is probably one of the most important parts of Mark. This point of the podcast, come back to it. If you don't remember anything else from this podcast, remember this, you may not sell a non-drug product to diagnose, treat, cure, or prevent any disease. That is the number one mantra you should keep in mind.

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When you're making claims for products, you cannot sell a non-drug product again, to diagnose, treat, cure, or prevent any disease. It doesn't matter if you have all the science in the world, if Albert Einstein could have done the clinical trial himself. Congress simply decided if disease claims equals drug. So any of the claims that you make have to stay within those boundaries of not suggesting the product will diagnose, treat, cure, prevent disease. And oftentimes that's pretty easy to determine if you're making a claim that your product will treat cancer. Guess what? You're making a disease claim. If you're saying that your product will help prevent COVID-19, that's making the claim that you will help prevent a disease, but sometimes it's not always as easy to tell. And so where I start with clients, when I walked through appropriate claims is making sure that they understand what the definition of diseases, because it's a little bit more expansive than what you would typically think of when you think of disease.

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So the definition of disease is actually codified in the code of federal regulations at 21 CFR one Oh one point 93, subsection G subsection one. I'll leave it to you, whether you think that's a sad statement of my life, that I knew that by memory and not by looking at it. Um, but it's something that, uh, those of us who work in the industry have become very familiar with. And so it's really important that we understand what that definition is. And that definition of disease is damage to an organ part structure or system of the body, such that it does not function properly or a state of health leading to such dysfunctioning. So what does that mean? I mean, again, damage to an organ part structure or system of the body. Again, when we think of classical diseases, cancer, diabetes, Alzheimer's arthritis, pretty clear that those all involve damage to the body, but we have to really think about that definition.

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When we're talking about claims. If I'm selling a supplement with calcium to help build back strong bones after breaking your leg, that's actually a disease claim. Because if you think about it, a broken leg is damaged to a part of the body such that it does not function properly. So following up that definition of disease in that regulation, 21 CFR 10193 G is subsection two, which includes 10 different categories of disease claims ranging from express mentions of diseases. Like we've talked about the signs or symptoms of disease, things like high blood pressure, low blood sugar, heart pain. Um, any of those types of things are also going to be viewed as disease claims. And they go on to other things like, uh, offering the product up as a alternative to a drug therapy. So sometimes you see products that are advertised as that natural Prozac or, um, herbal Viagra.

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I mean, those are actually drug claims because you are saying essentially that your product will do the same thing as a drug. So we have to keep that definition of disease in mind as we're formulating claims, so that we don't go over those lines into permissible claims. So when we're talking about immunity, you know, what type of diseases are we talking about with respect to immunity? Well, obviously the big one out there is COVID-19 and you have to be very careful these days about COVID-19 because the FDA and the FTC have been very proactive in taking action against companies, making claims that either expressly or implicitly, uh, make claims about COVID. And that's an important concept to keep in mind is that claims can be both express and implied. And we'll talk in a little bit about what other types of claims are implied claims, but we've got COVID-19, you know, we've got, of course, you know, any sort of respiratory issue, we've got colds and flu, um, you know, the FDA considers flu and colds to be disease conditions, allergies, or disease conditions.

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So any of those types of claims are going to be considered disease claims by the FDA, but COVID-19 is certainly at the top of the list of claims that the FDA and the FTC are likely to get involved in the quickest way to get the FDA or the FTC involved is to mention that you have the solution to a pandemic outbreak. Um, a lot of times people might have complaints of the federal government moves at a, at a slow pace. Um, but if you say you've got the cure for, uh, COVID-19 or a couple of years ago, Ebola, or the, uh, bird flu, uh, that's where you're going to see Swift and prompt action from the FDA and FTC. So we stay away from the express claims, what can we say? And again, as I said, you know, 2019 was the year of CBD and hemp 2020 has certainly been the year of immunity.

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I've had so many clients come to me and say, they want to launch a skew or a line of products that have added ingredients like zinc or vitamin D or elderberry and make immunity claims, and what type of immunity claims can they make. So let's talk about it first from the FDA perspective, what types of claims would be permissible and would not be viewed as suggesting the product will diagnose, treat, cure, or prevent a disease. When we're talking about claims, we typically look at them in terms of maintaining or supporting health, uh, when we're making permissible supplement food and beverage type of claims and not talk about lowering or increasing output. So again, claims like this product will help maintain good immune health. This product will help support, uh, normal immune function. Those are likely going to be permissible claims. When we get into things like this product will help increase immunity.

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This product will help bolster in immunity, defense. Those are still probably okay, but we're getting closer to kind of that line that differentiates permissible claims versus non permissible claims. Let me give you an example, you know, typical, uh, claim that I've been getting these days, we'll start with something that kind of vaguely suggests why you might want immunity without specifically saying, so something like never, has it been more important to have a healthy immune system now, obviously we can probably guess that there's at least an implied claim there that we're referencing COVID, but we're not saying anything we're saying, Hey, it's important to have the immune health. That's probably okay. Where companies run into trouble is when they say something like that. And then they add because, and I always know that that's going to be the problem, the language after, because so it would be something like never, has it been more important to have a healthy immune system because a weakened immune system makes you more susceptible to viruses and other disease.

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And it's that language after, because that's going to get companies into trouble. Again, viruses are at the top of the list of no-nos. And along with that, any of the antis antibacterial, antiviral anti-microbial, those are all going to be viewed as indicative of disease claims by the FDA. So when we're making these claims, where do companies typically run a foul, uh, when I'm looking at their marketing and advertising materials, again, as we talked about, it's talking about the repercussions of having a weakened immune system, cause it's hard to do that and not get into the discussion of disease. I would say one of the other big areas that I think it's really just more of a lack of understanding from companies than really intentionally trying to do something, is companies talking about ingredients in the product and not understanding that claims about ingredients are going to be viewed as claims about your product.

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So for example, let's say I have Justin's immune support. And two of the main ingredients are vitamin D and zinc. And on my website, I don't really say anything on my product, but on my website, I have all this information about how vitamin D has been shown to help prevent COVID-19 and I'm citing various, uh, websites and other materials. Even if I'm not saying that my product will prevent COVID-19. If I'm talking about one of the main ingredients in my product and how that ingredient has been shown to prevent COVID-19, that is going to be viewed as an implied claim, that my product with that same ingredient will also help prevent COVID-19 because the FDA's position is the general consumer. The takeaway is going to be, Oh, if this ingredient does this and that product has that ingredient, then that product is going to do that.

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And of course that's why those claims are being made is for consumers to make that logical leap. So it's important to understand, because I find that happens a lot. I look at a website, someone's got descriptions of ingredients, and then we find out that actually, you know, those claims are impermissible because you're making disease claims for those ingredients and those ingredients are in your product. So descriptions of ingredients is one of the main areas where I find people, perhaps not having a clear understanding of the repercussions of that. I would say customer reviews is another area where the FDA has certainly increased their focus. It's important to understand that when customer reviews are incorporated into advertising, those reviews become adopted statements of the company. So again, we go back to, if I have Justin's immune support product that I'm selling and I don't make any, I say, you know, it helps maintain a healthy immune system, all permissible claims.

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And then my customer reviews include a bunch of reviews from consumers saying, wow, Justin's immune support product is great. I never get colds and flu anymore. Or I took Justin's immune support. Everyone else in my office got COVID-19, but I didn't, I'm sure it's because of taking Justin's immune support, those types of reviews. If those consumers make them on their own Facebook or social media feeds, that's fine. But if I incorporate them onto my website or they make those in customer reviews on my pages, then I'm responsible for those claims. So it's important if you do have a section of customer reviews on your website, that you review them from time to time and make sure that consumers are not making impermissible claims because they could be attributed to the company itself. Social media is an area that the FDA has looked at increasingly. Um, you don't have free license to say whatever you want to on Twitter and Instagram and Facebook.

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Uh, pretty sure people aren't saying anything on MySpace anymore. They are. I don't think a lot of people are looking at it, but you do have to be careful what you're saying there again, the FDA has definitely been viewing, uh, company web pages, especially YouTube pages that have videos and making sure that companies are towing the line on those claims. And then the last, which kind of segues into the other agency is scientific information. And if you provide scientific information about ingredients in your product, that also suggest the treatment of disease that is also going to be viewed as an implied claim, that your product with those ingredients will help treat disease. So we've seen warning letters to the FDA for products as simple as chocolate or blueberries, but on the website of the product, there were scientific articles talking about how chocolate will help reduce the risk of heart disease or how the antioxidants in blueberries will help with heart disease posting those studies or links to those studies on your website essentially makes your product drugs because you are implying that your product will have those benefits.

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So it's again really important that you sit down and have a discussion with someone who knows these issues to make sure you're not going over the war. And that issue of scientific information. It's a good segue into the other federal regulatory agency. We talked about, which is the federal trade commission, the federal trade commission doesn't actually care whether you're making disease claims or you can make a disease claim. And the FTC doesn't look at it and say, well, you can't make that type of claim for that type of product. That's not their purview. What they're looking to see is, is the claim truthful and do you have proper scientific information to back it up? So the standard, the FTC standard is competent and reliable scientific evidence. And there's really no definition for that FTC case. Law has defined us tests, analyses, research studies, or other evidence based on the expertise of professionals in the relevant area that has been conducted and evaluated in an objective manner by persons qualified to do so.

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Using procedures generally accepted in the profession to yield accurate and reliable results. So back when people actually went to conferences in person, or you used to do a bunch of webinars or presentations, and I would read that definition and then ask people to raise their hands as to who had a better understanding now of competent a reliable scientific evidence. So I'll ask that rhetorical question now and assume that the very few hands have gone up, uh, around, you know, it's not a helpful definition. Uh, the reality is the real definition is whatever the federal trade commission decides on that

particular day is the requisite scientific evidence required. Typically the gold standard is a double-blinded placebo controlled clinical trial on your formula or product. Oftentimes that's just not possible that a company has that. So you look for as much information as you can find about the ingredients in your product.

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I would say the number one area where companies fall short is they want to talk about ingredients in their product. Again, things like vitamin D things like echinacea, things like elderberry or zinc, and they want to talk about these ingredients, but what's really important is to make sure that you have an efficacious amount of that ingredients in your product, what the federal trade commission doesn't want to see is companies putting in what we call, uh, in the industry, a fairy dust amount of an ingredient. Like you sprinkle a little zinc in there. You sprinkle a little vitamin D so you can talk about them. But the reality is that you don't have enough in there to actually provide those benefits. And what the federal trade commission has said is you shouldn't be talking about ingredients in your product. If you don't have enough in there to actually support the benefits you're talking about.

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So what that really means is you shouldn't be talking about ingredients, unless you have science that actually supports the amount in your product you give for example. So I've got all these great, you know, I want to talk about zinc and all of the great benefits of has, but in looking at the studies, you know, all of the studies suggest you need at least six milligrams of zinc in order to, uh, provide any of these benefits. And I've only got two milligrams in my product. Then the FTC would say, it's misleading to talk about zinc when you only have a third of what's necessary to provide those benefits. So again, really important to make sure that you have the science to back up those claims. So that's really the two areas that the FDA and the FTC looks at it. I mean, at the end of the day, you know, companies come in and say, well, what's the big deal.

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I mean, you know, what's the real repercussions of if I make claims what's going to happen well in this day and age, um, one of the big issues is, are you saying anything about COVID because if you're saying anything about COVID, you can expect pretty immediate and aggressive reaction from the FTC and the FDA during this COVID time. And really just in 2020, the FTC has issued 381 letters to companies making COVID claims and 104 of those have been joined FDA FTC letters, and your typical FDA warning letter, you have, you know, the FDA says, we believe you're making impermissible claims. You're giving 15 business days to let them know what you're doing and try to figure it out. These letters, you have 48 hours to take down the required information, or the FTC says they will take aggressive action. And we've seen other repercussions from companies that have received these letters cancellation of better business Bureau, registrations, you know, a variety of different repercussions for making these claims.

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The letters are very aggressive. The FTC says, you know, you must have competent, reliable, scientific evidence. And for COVID-19 no such study is currently to exist for the products that are being identified. There's no way that you have the science and you must take it down immediately. That kind of brings us to our last kind of group that monitors these types of things. And that's our friends, the class action, plaintiff lawyers, and, you know, FDA and FTC warning letters are like roadmaps to class action, plaintiff letters of what they should, uh, bring their next class action about because they scour the FDA website

and the FTC website to look for what the FDA and FTC are taking action on. And that just provides the skeleton for their next complaint. So getting a warning letter from the FDA and the FTC has a variety of consequences, including action from the agencies, you know, other types of parties that are viewing those and the class actions from plaintiff's lawyers.

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So really important that you stay off the radar of all of those organizations. That's kind of our reader's digest version for today. Uh, maybe just to recap, kind of what we've talked about. Again, I go back to what I said, the number one mantra when you're making claims and really our discussion today, while I've talked about immunity, it applies to any types of claims that you're making. When we talk about these kind of general principles at the end, number one, if you're selling a non-drug product, you can not sell it to diagnose, treat, cure, or prevent a disease. Just can't do it. That's the number one mantra. If you stay clear of that, you're a long way towards making permissible claims. Number two, if you're making any health claims, you have to have competent and reliable scientific evidence to back up those claims. Most importantly, make sure that you have enough of those ingredients in your product, that you have science that can back up those claims.

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And then just understand that the FDA and the FTC are looking at anything you put out there about your product. The FDA takes the position that if you have the website address on the label of your product, or you sell products on your website, everything you have on that website is going to be viewed in a similar way to it being on the label of your product. So I have some companies who come to me and say, well, we don't really say much about our product on the label we use. We, we save that for the website. Well, anything you say on the website is going to be viewed the same way as on the label. So you can say things on the website, but you have to look at it in the same lens as if it was on the label of your product. Again, don't diagnose treat, cure, or preventive disease. Remember that endorsements and testimonials, including customer reviews become adopted statements of the company when you use them, make sure that your social media is also being viewed under the same lens because the FDA and the FTC are looking critically at those types of things. And that's it. That's easy. All right, well that wraps up our first

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Podcast. Hopefully you learned a little about immunity claims. Certainly if you have any questions or you can reach me by email, it's my last name Prochnow. Now that's PROCHNOWJJ@gtlaw.com. Or you can call me at (303) 572-6562. And if you liked it, give us a good rating on whatever podcast streaming service you have. We hope you join us for our next session, which will include a guest that I'm pretty familiar with. Same last name, my father, Jim Prochnow. Now who works with me here at Greenberg Traurig and all things, food beverage, and agribusiness. And we'll be talking to you about the wonderful world of CBD and hemp. So we hope you join us again and have a great Holiday. Thank you.