(00:13):

Hello, and welcome to Greenberg. Traurig's legal food talk. I am your host, Justin Prochnow. Now 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

(00:38):

Wide range of topics in the food and agribusiness industries. So we hope that you can join us for this one and check back in the catalog for some of the other episodes that we've both done and are going to do in the future. Last time we talked about immunity claims here in the COVID era. And today I have a special honored guest that I know pretty well. He's got the same last name as me. It's my father, Jim Prochnow now hello, Jim. My pleasure in being here today, you know, one of the things before we get into it is of course, everyone finds it interesting that I work with my father. I'm sure that you work with your son and I get a lot of, uh, I, I admire that. I don't know if I could do that with my father. You know, I think it's been, uh, been mostly good times.

(01:25):

Anything unique that you can share with us about working with your son? Yes. I have three distinct factors to bring up. One is this. We worked together really well from the standpoint of this. I'm an exceptionally early morning riser. I get up at five 30 every day, turn on my computer and I'm ready to respond to people at 5:45 AM, mountain standard time. However, I usually shut things down at the end of the day at six o'clock my son, on the other hand, uh, I often get emails at 1:00 AM or midnight or 11:00 PM, but at that time I'm long gone into sleep. So we compliment each other really well. Uh, second thing is this, or occasionally not every week, but maybe every third week I get a call from somebody that says I heard there's a Justin involved. Is he your, is he your father, your brother, your son, who's he relationship to?

(02:20):

And I always am pleased when they believe that I'm his son or the brother instead of the father. But I guess it's because of my youthful talk, uh, in whatever we have a good time. We get emails mixed up in the sense that I get his emails. He gets mine. I think he gets the better part of this. And he's got a lot more business because they think they're calling me, but who knows? It could be the other way around in all. It's been a great experience. And, uh, personally speaking, I've really enjoyed it because Justin really knows the law and we have similar approaches to the and how we handle things.

(03:01):

Thank you. I would say this it's true here at Greenberg Traurig with respect to the email. Uh, most people have their last name. And first initial, since you beat me to the firm by a year, you have Prochnow J and mine, Prochnow JJ, but a lot of people just assume that I'm proc now J and so you get a lot of my emails. I don't get as many of yours. And so I always tell people that, um, you know, it's one thing if someone else is getting your email, but when it's your father, that's getting your email. You have to be a little more discriminant about who you hand out your email address to.

(03:41):

You know, I agree

(03:42):

The same. We work very well together. Um, generally agree on most things and, and it's always great to have someone to bounce things off of. And, uh, ironically, even though we work in the same office, sometimes we'll go a while without seeing each other during COVID. We've probably seen each other more than ever, because we've both gotten into a par three golf and play during the summer two to three times a week. And, uh, that's been kind of a nice way to still connect in this, uh, kind of year of, uh, hard connectivity. So we're going to get into it today. And our topic today is a topic that has really kind of caught fire in the food beverage supplements, cosmetic industries, uh, over the last, certainly the last two years, but even as far back as the last four or five years, and that's the topic of hemp and CBD, I guess I never really thought that I would be a hemp and CBD lawyer, but because of the fact that it has become the most popular ingredient in the history of mankind, uh, we have both found ourselves being hemp and CBD lawyers, as well as, uh, food and beverage.

(04:54):

My first recollection of getting involved was with a company, uh, that is still a client of ours, Bluebird botanicals here in Colorado and Brandon, the founder and CEO contacted me back in as early as April of 2014. And at that time, I didn't know a whole lot about CBD. Um, we really, you know, I, I give Brandon a lot of credit because he was really on the forefront here of kind of looking at the products as supplements, wanting to be compliant with the FDA law for supplements. And we really treated it as no different than any other sort of botanical at that time. Uh, obviously things have changed in the last five, six years, but Jim, do you remember when you first kind of got involved in the hemp CBD or at least when it became, you know, a more central part of what you were working on? I think

(05:45):

Same time, I first got involved doing FDA work in March of 1990 in a supplement company in castle rock Colorado. I can guarantee you, nobody thought about CBD at that. Um, I do think about the same time as when I first was involved with CBD with a company called CBD distillery, which is now about himself botanicals, a major CBD, uh, retailer in Denver. And since that time, things have sort of blended together because it exploded all of a sudden, so that now occupies a significant percentage of my business and that of Justin's, but I think your about right about when it started taking off.

(06:32):

And at that time, I don't think there was a lot of confusion about the legality of hemp and CBD because there was really no guidance from FDA, um, nothing published. It was really the first time that we really started hearing from the FDA on these things was with a series of 10 warning letters issued to companies in early 2015, in which the FDA sent warning letters out for claims being made, as well as testing the levels of hemp and CBD that were claimed on the labels and finding some deficiencies in those was really the first time we heard it. Um, and so we got lots of calls from companies as to, you know, is it legal for me to sell? And I know when I look at hemp and CBD, I kind of look at the watershed moment as being the 2018 farm bill and really regulation of products, pre 2018 farm bill and post 2018 farm bill. Can you tell us a little bit about, you know, we hear him talk about the farm bill all the time and what the farm bill did. You'll, you'll see right after it happened, we saw all these, uh, you know, emails and things about how the 2018 farm bill made hemp now totally legal in all 50 States. What did the 2018 farm bill really do? First of all, it, what it did.

(07:54):

It was, it took out of the jurisdiction of the DEA CBD basically, and products that contained 0.3% or less of Delta nine, THC. It actually was a watershed moment in time. The dietary cellphone act health and education act of 1994 was a gigantic, uh, moving point in this industry. And I would say the farm bill was the second one. It covers not only retail sales of products or ingredients of CBD and THC, but talks about the ability for the transportation of CBD products across state lines and talks about regulations being developed from the federal level for the cultivation of hemp products that contain CBD cannabis products. Basically it was a major piece of legislation. What it didn't do is this, it didn't amend a provision in the federal food drug and cosmetic act that is causing a significant concern for the industry and the FDA at the present time in the federal food drug and cosmetic act, the definition of dietary supplement and food. Basically what it does is it excludes from those definitions ingredients that is articles that had been authorized for study as a drug before that ingredient or article was used in a dietary supplement or food, the end result, or what I'm saying this in non-legal is, is this, it is still non-compliant with federal state statutes to market products, those to sell products that contain CBD.

(09:50):

Let me stop you there for a second. Cause I guess I would say certainly companies in the industry would take the position that it is the FDA's position, that it is illegal to do it, but a lot of companies in the industry would argue that the law does not necessarily mandate that. And I suppose it's because of this, there is no specific law or regulation, which specifically addresses hemp or CBD. So the FDA has taken the position in various guidance and other documents that hemp and CBD well, that CBD is not a legal ingredient for the reasons you stated, because it was investigated as a new drug, but that is essentially the FDA's interpretation of the law based on what has happened and not necessarily a specific law that says it. And so companies in the industry would say, well, the ingredient investigated back in 2007 and maybe again in the early 2010s is not the same ingredient that they're using now because the ingredient investigated was a CBD isolate. And the ingredient that, you know, a company may be using is a broad spectrum, hemp extract with, you know, some amount of CBD and other ingredients. Um, how does that interplay work

(11:10):

It this way? First of all, is this in some respects, it's a, um, intellectual argument only because at the present time, the FDA's position as an enforcement of the federal food drug and cosmetic act is that it's illegal to include CBD, but their informal position is they do not intend to take any action against a CBD containing product, as long as there aren't any, uh, obvious noncompliant with good manufacturing practices. And if you comply and or unless the claims being made for the product are clarity disease. So at the present time we have this kind of conundrum, but still a somewhat clear position in that is that I it's an uphill battle for the, for people to believe the law doesn't exist. On the other hand, the government is not going to take any enforcement action at the present time, unless one of those two instances takes place. What in my judgment has to be done though, is there has to be an amendment to the federal food drug and cosmetic act to make it clear for everybody what the law is because this industry needs clarity, both from a financial and other standpoint, as we move forward until then the industry will continue to thrive. It just would be in the best interest of everybody to have an amendment to the law itself.

(12:46):

So it sounds like we have a little bit of a technically versus practically situation here. Technically the FDA has said they don't believe it's a permissible ingredient, practically their enforcement actions and other

statements have indicated that their focus has been on companies that make egregious disease claims or potentially have manufacturing issues, which could cause a product to be unsafe.

(13:15):

You're absolutely right. I might say another major change by the farm bill. I'm glad you brought this up, is that now there is much more opportunity for scientific research for companies to conduct clinical trials. There's human trials about the safety and efficacy of their products before the enactment of the farm bill. Uh, the DEA really had control over scientific research and had to approve applications for research. That still is true for everything for cannabis companies, for example, where the THC level is higher, but it makes it a challenge for this industry that the industry should accept, because there's really no reason now for not doing real studies to support the claims. And we need to rise to that challenge.

(14:06):

So if we go back just a second to, to kind of summarize the 2018 farm bill, what it really did was potentially give companies that are looking to get involved in this area a little bit more comfort, that as long as they comply with the terms of the 2018 farm bill, with respect to the levels of THC, that the DEA is not going to show up and potentially walk some people away in handcuffs, which, which really was the concern of companies before, because of course the definition of marijuana prior to the 2018 farm bill was any parts of the cannabis sativa plant, other than the mature stocks, the un-germinated seeds, or the paced oil or residents from those two parts of the plant. So you had companies with CBD products and as those in the CBD industry know, most of CBD comes from the flowers and the leaves. You're not getting CBD from the un-germinated seeds of the plant. So CBD was coming from the parts of the plant that prior to the 2018 farm bill, the DEA considered to be marijuana. So there was a real risk. The company selling the tincture of CBD could be charged with selling a schedule, one controlled substance. And now with the farm bill, at least that part of the equation has been removed

(15:29):

100%. That's really a good summary of it all. I think that the only other comment I would make about the current state of affairs is that companies really need to pay attention to the claims that they're making. I know most companies do now, but because of some recent speeches made by rich Cleveland or the FTC who's in the advertising division of the FTC and the overall attitude of the FTC is that whatever action the FDA is taking or not taking is really not of a consequence to the FTC. They are going to take enforcement action in this area. Particularly if you make anything, that's an obvious disease claim. And as Justin knows, and we inform our clients, getting investigated by the FTC is much more significant than getting a warning letter from the FDA,

(16:25):

Right? And to be clear, the FTC doesn't take action just because you're making a disease claim, because of course they're not the ones in charge with regulating whether you can or can't make a disease claim. But what it does do is it makes them very skeptical that you will have the science necessary to make it. So just as a callback to our first episode, when we look at claims for companies and a large portion of our day is spent reviewing packaging, labeling website materials, other information in the claims that companies are making and helping them devise appropriate claims, both the FDA and the FTC are looking at claims. And the FDA primarily looks at claims to see is this the type of claim that's permissible for the type of product. So the FDA is really the one who says, Hey, you're selling a non-drug product.

(17:17):

You cannot make a claim that suggests a product will diagnose, treat, cure, or prevent a disease. So they are looking to see whether you are making disease claims or not. On the other hand, the federal trade commission, they actually don't care whether you're making a disease claim or not, because they're not tasked with the responsibility of determining whether that's an appropriate claim for that type of product. They are tasked with making sure that all advertising is truthful and not misleading, fair and substantiated. So what disease claims do is while they don't make the determination of whether it's permissible or not, their general feeling is if you're making a disease claim, you probably don't have the substantiation, because if you did, you'd be selling that product as a drug and making however many millions or billions of dollars selling that product as a drug. So it's kind of a, a yellow to orange, if not red flag to the FTC that, Hey, this company is making disease claims. We want to see the science and more often than not companies not going to have it,

(18:25):

No, no trade commission standpoint. All of you should know that really what prompts most investigations is not what we're talking about. It's talking about not doing the right thing with your normal customers, with respect, to responding to complaints, they have to the continuity plans that often food supplement companies have where you buy things on a monthly basis and not being clear about, uh, invoicing and purchase orders. The FTC always includes in their consent decrees, almost the last 10. I've looked at provisions that talk about the need for companies to do the right thing. With respect to the basic business of selling a product, not with the claims. The claims are always an important part of this, but every consent decree or settlement agreement talks about doing the right thing for customers with respect to normal business operations.

(19:28):

Jim raises a good point here. You know, there are a number of different ways in which you can come up across the radar of regulators, class action, plaintiff lawyers, and others looking at your products. Um, it might be just the claims made on your website, but as Jim indicates more often than not, it's other means it's a competitor who says, Hey, we've worked hard at making sure we're making permissible claims Lake. Shouldn't be able to get away with making these claims that we know they don't have science for, because we don't make them because we looked and there's no science for it. We see those types of actions started. We see actions from customer complaints. You know, there's a variety of different ways in which these can can come across the desk of regulators before we get too far here towards what regulators are doing.

(20:23):

I want to talk a little bit about another, uh, kind of area that companies have to be wary of. And that's state law regulations on hemp and CBD. Uh, it's kind of a unique area here compared to, you know, uh, some of the other areas where for the most part, the food drug and cosmetic act covers a lot of the areas of food and supplement labeling. And of course, if the federal government has covered it, then States are preempted from, uh, passing laws that are different than what the federal government has decided. But since there is no federal law right now on hemp and CBD, the States have taken upon it themselves in many States to regulate the, uh, growing sale and, uh, processing of hemp and CBD in those States. And we see a very wide range of regulation from, uh, you know, we tend to look at the States on kind of a green, yellow, red light level of, there are some States that have clearly said, it's okay to have hemp and CBD in there.

(21:28):

They've passed specific laws, allowing it certainly where we are Colorado was kind of one of the first that, um, has looked towards doing it. But you have other States like Kentucky and even more recent States that have passed laws, allowing for the growing and, uh, processing and sale of hemp and CBD. Then we have other States that have specifically said, we don't want any part of, uh, hemp and CBD, um, States like Hawaii, uh, States like Idaho, which doesn't want any THC in any of the products South Dakota for a long time until recently was, was a big, no. So we have this very wide range and States that have passed very different laws. How are companies supposed to try to follow both the federal law and all of these individual state laws by hiring a good lawyer like you,

(22:20):

Besides that fact it is a conundrum or a challenge for everybody. Uh, keep in mind that basically the structure of our whole government on a federal basis is that state's rights are the laws to be followed. And the federal government will fill in the gaps, uh, such as national defense, uh, and items like that, that States where you really need a uniform law. So where we stand right now is this with respect to the sale of products. That is the marketing of products. You're pretty much in my judgment going to be okay if you follow the statutes, uh, dealing with the type of food product you're selling or that the dietary supplement regulations or the food regulations with respect to labeling and things like that on local matters like cultivation and growing and getting licenses for transportation outside of knowing what the law is in all 50 States, you should focus on the state in which your principal place of business is.

(23:28):

And then look carefully at maybe the next five States where you expect to have the most sales and focus on them to see what kind of regulations specific regulations you may have to take into account when labeling your products to date, basically laws of the States that deal with land, things that are local in nature. You need to follow the state laws in order to avoid a regulatory action by state authorities and to get approval. For example, for licensing and other things, the federal law is more geared toward the labeling of products and the, uh, transportation of products and interstate commerce. It's not an easy task at all in sometimes it's impossible for a company to anticipate what state may raise an issue, and when it's raised, then we have to deal with it. But it's the challenge that will always be there. I doubt if there's ever going to be any uniform law, and we'll just have to deal with this on a case by case basis.

(24:37):

Never right now, when companies come to me with a product for sale, it is a difficult task because if a company really tried to comply with each individual state requirement, and there are a lot of them, you know, Colorado requires a statement on the label that says this product has not been evaluated by the FDA for safety or efficacy. Florida requires a very specific statement that the product does not contain less than 0.3% Delta nine tetrahydrocannabinol by dry weight. Some States require a declaration of the amount of, uh, THC and CBD. Some States specifically prohibit statements about the level of THC. So it's virtually impossible to comply with both. And if you complied with all of them, you would have one of those, uh, accordion style labels like you see for, for drug products, with, uh, with the drug facts panel. So I agree, you know, as a general rule, there's probably less risk for online sales right now than there are for brick and mortar sales.

(25:41):

Your biggest risk is that, you know, a state department of health official walks into a brick and mortar retail location and says, Hey, these are not compliant with our laws. So I think that's good advice to, you know, kind of highlight the States in which, you know, you're going to be having a lot of sales in them. And then, um, and then go from there before we get to kind of some, some conclusions, I did want to cover one other area. Um, and that is the difference with cosmetics and topical products versus ingestible products. And we we've talked a lot about the FDA's position on hemp and CBD as a legal ingredient in food beverage and supplements. Um, of course we see a lot of topical products out there with hemp and CBD in them. Do you want to kind of address what the FDA's position is on those? Or do you want me to take that one?

(26:33):

I'm just going to make a preliminary comment, unless you eat your cosmetics, assuming you apply your cosmetics to the skin or spray as intended, of course they'll cosmetics or topically are applied products. Aren't subject to when I called the draconian measure that we talked about previously, where if something was first approved as a drug, it can't be used in our food. So again, if you don't eat your cosmetics, you're not subject to that law. And so at that point in time, basically what we're dealing with is whether or not basically we're dealing with the claims, uh, part of the product. Uh, there are other things about cosmetics, but cosmetics to date are the least regulated part of the product that's in our practice, where the FTC pays the least attention of things. But just add on some of your comments about topics.

(27:29):

I have good news. Cosmetics are topicals, so you may not eat your cosmetics. So, um, the good news is topical products in the United States can only really be sold in one of two ways as a cosmetic, AKA personal care product or as a drug. And really the dividing line is the type of claims that you're making cosmetics are products applied, sprinkled, rubbed into the skin to cleanse beautify, promote attractiveness, or otherwise alter the appearance. Anything else makes the product that drug. So in the area of CBD and hemp, you can have the hemp cream and you can say it has hemp in it, but you can't really talk about what the hemp does or the CBD does, because anything that you do is likely then going to be viewed as making that product, a drug. So topical products that are offered for pain and inflammation for anxiety and stress for sleep, which are generally the three main categories of claims for hemp and CBD products. Those products are drugs because those are claims that do not relate to cleansing, beautifying, promoting attractiveness, or altering the appearance of the skin. So it really comes down to claims for those products. And, you know, if you're making those types of claims, you've got to look at them as either somehow fitting them into one of the over-the-counter drug monographs or selling them as a prescription drug.

(29:06):

I would say, in addition to that is it's going to be impossible. There are no, uh, regulations or monographs for CBD. So if you were thinking about trying to sell the product as an over the counter drug, it's not an Avenue you'd have to go through the prescription drug process. So you do need to be careful about that. Again, the claims that I've seen out there in the marketplace about CBD, and there are tons of them in all of the major cosmetic stores. Uh, it's just the gut to what Justin said is letter book law do not make any claim for sure that affects any serious disease. You have no defense to that situation. Let's kind of wrap up here a little bit with using our kind of crystal ball here and looking to 20, 21 and beyond, and seeing what we have in store for the future.

(30:05):

Um, of course we represent a lot of companies in the industry, um, both squarely in the CBD hemp industry, but also a lot of retailers, um, and just general food and supplement companies that are looking to sell products with hemp and CBD. Where do you see things going? I know there's been a lot of hope starting back in 2019, where the FDA held a hearing in may of 2019, uh, you know, where over a hundred people got up to give their kind of 2 cents worth about how hemp and CBD should be regulated. The FDA, uh, initiated a special, uh, advisory group to kind of look into this, um, obviously 2020, and COVID put a stop to a lot of different things. And I think it really slowed the momentum on kind of that, uh, investigation and look into further regulation of hemp and CBD. But as we near 2021, where do you see things kind of moving in this area?

(31:09):

I have two points I'd like to make and observations about the future. One is I am positive that the industry will be given better guidance about what the FDA's position will be about the percentage of THC once it's harvested and is, uh, either, uh, in extract form or even not an extract form or put in products that are being transported. That exceed 0.3%. I do believe we're going to get better guidance than currently exists at the present time. That's one thing I'm confident about from an overall standpoint. I think there will be a change in the legislation that will exclude or take away or delete that troublesome provision in the federal food drug and cosmetic act. I think it will take place in the next eight years, hopefully in the first four years with a change of administration and overall better acceptance of CBD and its familiarity with Congress persons and their staff. So overall, I see a bright future for the industry. I also see the industry participants themselves of doing more scientific studies to support claims that can be made. So from an overall, I see a bright future ahead for the industry, Justin.

(32:40):

Yeah, I, it seems inevitable that in some form or fashion, the FDA is going to, uh, officially approve the use of hemp extract and CBD in some form, whether that is approving broad spectrum hemp extract, you know, at some percentage, uh, it just seems a little bit like, uh, something that has gained so much momentum that it's really hard to put a full stop on everything and the way that the FDA has regulated, it has somewhat indicated that if they really were interested in putting a full stop to everything, that that's what they would have done. So I think they're looking for a way to come up with some sort of compromise to, uh, make it legal, to do so. And hopefully as we start, uh, putting COVID behind us, hopefully this year, there will be a shift in more focus back to some other areas of the law.

(33:43):

I have. One final comment is I do believe it might take 15 years. I do think overall there will be a movement toward adoption of a more liberal position about cannabis products in general, much like the California cannabis statute that was enacted, uh, effective, uh, early 2019, where basically we have cannabis products in general with the limits on THC are much different in the federal food drug and cosmetic act and the farm bill. It won't happen immediately, but as more acceptance takes place, I think you'll see a rise in the 0.3% or maybe even an elimination of them, but I think that's for the next decade and not this one. Alright, well, hopefully for those of you tuning in, uh, that was a little bit of insights into the world of hemp and CBD. If you have any questions, you can certainly look us up on, uh, the firm's website at gtlaw.com of course, look for one of the Prochnow. So you can email us at, uh, PROCHNOWJ@gtlaw.com for Jim at another J and make a PROCHNOWJJ@gtlaw.com for me. And if you

enjoyed the podcast, give us a favorable review on whatever platform you're listening to this. So without any more, we will sign off and we hope you join us for our next episode. Thank you amen.