Speaker 1 (00:00):

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Justin Prochnow (00:26):

Hello and welcome to Legal Food Talk. I'm your host, Justin Prochnow, a shareholder in the Denver office of the International law Firm, Greenberg Traurig. And this is a podcast brought to you by our food, beverage and agribusiness practice to give you some insights and knowledge about the world of food, beverage, and agribusiness.

(00:53):

Today I'm joined by a special guest, a longtime colleague for the 53 years of my life. My father, Jim Prochnow now, who also is a colleague of mine here at Greenberg Traurig.

Jim Prochnow (01:12):

My pleasure to be a part of this podcast.

Justin Prochnow (01:15):

Well, we have... I'm going to start by saying I'm going to give one of my New Year's resolutions before we even get there, which is more podcasts. I say that every year we had a sparse showing. This year we're going to get back on track with a bunch of podcasts next year with some other colleagues, some clients, some people from the industry. But we're going to do what's been a favorite the last couple years, kind of end of year podcast, recapping the year and also looking forward to 2023. So before we get going, Jim, what we can expect in 2023, any thoughts about 2022?

Jim Prochnow (01:56):

I thought this year what we saw as more regulatory activity on the part of the Federal Trade Commission and the FDA, which is consistent with the current administration, which fundamentally takes a position of being consumer oriented, which normally means more regulatory activity. Overall speaking, my sense is that, like the overall economy, sales are somewhat down, but because of the consumer's continuing interest in their consumer health, my prediction is that this industry will continue to be fairly strong throughout 2023.

Justin Prochnow (02:39):

One of the interesting things towards the end of the year was the FDA did what it frequently does, which was send out another five or six warning letters to companies regarding the use of CBD and hemp in various products. And this was several weeks ago. One of the interesting things about this volley of warning letters was that the FDA sent letters to a few companies, and in the past, probably the last hundred letters that the FDA has sent to companies regarding CBD and hemp, it's almost always been with the central focus on companies making improper disease claims, whether it will treat Alzheimer's or arthritis or any number of diseases. What was interesting in this set of letters was there were not disease claims being made by several of these companies, and instead the FDA focused on the delivery form being in beverages and teas, being in gummies, being in things that were potentially more attractive to children and also just more likely to maybe be consumed in higher amounts.

(03:53):

And it seemed like the FDA was focusing on that. Of course, everyone got excited about it. Still the FDA has continued to take no action outside of sending various warning letters, which oftentimes we view as FDA regulation by public announcement. They don't really intend on taking more aggressive action at this time, at least they haven't shown that, but they feel like if they send out some warning letters that will chill action by retailers and other companies. And so they send out letters immediately. Retailers who are maybe on the edge before now pull back, other companies pull back, even though the FDA historically has not shown that they're willing at this point in time to take more action over companies with CBD and hemp.

Jim Prochnow (04:44):

I agree with you. I would say this, one of the chilling effects that untitled letters oral warning letters do have is on sales to large purchasers of products who are reluctant to enter into the contracts or purchase the ingredients or products when there is a untitled or warning letter about it. A good example is with NMN, which is a precursor to NAD, which is good for cellular metabolism. In this instance, in mid-October, the FDA issued a letter to several companies which distribute this particular ingredient. And what the FDA said was, "We are not going to allow the NDI notification to be filed because you didn't prove to us, and we have evidence that NMN had been approved for study as a drug before it was sold as a supplement." Again, as Justin just pointed out, the FDA is unlikely to take any enforcement action like starting a lawsuit to prevent this, but it is creating a situation within the industry where people who buy or manufacture products with NMN are thinking twice about it. So it's having a chilling commercial effect to that extent.

Justin Prochnow (06:13):

And do you think... Has the FDA at this point shown that they're going to take action by pulling it off the shelves, or is that something you see? Where do you see that going?

Jim Prochnow (06:26):

What I see it going is that it's unlikely that the FDA will take any enforcement action, which they would have to start a lawsuit to take things off the shelf. However, probably most of all, because the industry itself through the trade associations is sending a lot of information to the FDA and communicating about them to get the FDA to change its position. However, I don't see the FDA taking enforcement action in court unless there's some safety issues involved in the particular situation in which they're involved.

Justin Prochnow (07:08):

It sounds somewhat similar to the situation with NAC earlier this year, where of course the FDA, and I guess it really went back to 2021, had sent a series of warning letters to companies making hangover claims, but that also had NAC in them and basically stating that NAC was not a legal ingredient in supplements because it had been approved as a drug and there was no evidence of it being used prior to being approved as a drug that had a big effect on sales, including online retailers pulling it off the shelves due to the fact that the FDA had issued these warning letters and then the FDA this, summer somewhat reversed its course, and issued a statement essentially saying it was going to exercise enforcement discretion and not take action against products with NAC in them as long as they were otherwise compliant with the law. I know it's early to tell, but could the FDA take similar action regarding MNM? What would be entailed in convincing the FDA that that's the course of action to go?

Jim Prochnow (08:24):

I think it's a very tough persuasive argument to be made because the FDA has dug in its heels on its position that the definition of dietary supplement, that is what I call the draconian clause that says something must be sold or marketed in or as a food supplement before it was approved as a drug, is continuing to be legislation that the FDA says that it will enforce. So I think this is a standoff right now between whether the FDA wants to expend its resources in going to court versus trying to accomplish it through what you've just described.

(09:09):

One other thing I'd like to bring up that's a little bit, that everybody should be aware of is in those letters in October about MNM, the FDA said, "When you submit an NDI notification, make sure that if you give us evidence of a sale prior to its approval of a drug, the evidence is of safe marketing, is of legal marketing." And the FDA pointed out in their letters that although there was some evidence it was not of legal sales before the time of the approval as a drug, which raises the bar a little bit and people must be aware of that. So I don't see there being any change. I continue there to be a standoff unless there's a safety issue involved.

Justin Prochnow (09:57):

Okay. Let's talk a little bit, kind of gave us a good lead into one of the things to look for here in 2023. One of the topics I wanted to bring up is the issue of there now being a ninth food allergen and that is sesame. Sesame became the ninth food allergen through the FASTER Act, which was signed into law in 2021 and essentially there have been eight major food allergens prior till now. We have soy milk, eggs, wheat, peanuts, and then three kind of categories of products, fish, crustacean, shellfish and tree nuts. And of course under the Food Allergen Labeling Consumer Protection Act, you must declare the presence of an intentionally added food allergen either through it being clearly disclosed in the ingredients list or in a separate contains blank allergen after the ingredient list. Sesame now has been added to that list. So as of January 1st, 2023, all food packaging that contains sesame must declare it either in the ingredients or in a separate list.

(11:25):

Just to be clear, it does not apply to products that are already in interstate commerce. So certainly products on retail shelves do not need to be pulled back to include a new sesame declaration, but if you are manufacturing products after January 1st, 2023, you need to make sure that it complies with the food allergen labeling requirements.

(11:50):

This is going to be a big deal. We've already been dealing with this with a couple clients and customers because sesame is a somewhat prominent ingredient in a lot of manufacturing, especially baking, and it's a little bit harder to rid equipment and facilities of the presence of sesame. So, if you are manufacturing in a facility that manufactures products with sesame, it's going to be a little harder to ensure that your products are completely sesame free, even with a good cleaning. It has become apparent that it is a difficult proposition to totally rid the area of sesame. So I think this is an area where we could even see some litigation regarding the presence of sesame if the people don't adequately warn of that potential issue.

Jim Prochnow (12:47):

Justin, I had two more developments, could I bring up that I forgot to mention before on 2023.

Justin Prochnow (12:55):

Well, sure. We're just going to go back and forth here. So what was your next one you wanted to talk about?

Jim Prochnow (13:01):

That is at the end of this year, there was a development that I think will reverse itself in 2023, and that's the golf scores between you and me. At the end of 2022, Justin won an end of the year long tournament by beating me for two strokes, playing really well last round. I see a different development for 2023 and predict a victory for Jim Prochnow at the end of 2023.

Justin Prochnow (13:33):

This is probably a good time. I might not have said it before, but the statements and opinions made by some of the people on this podcast are not reflective of Greenberg Traurig as a whole or the podcast host, and sometimes the information is just completely incorrect. So, take what you want with the previous comments, but I wouldn't plan on that for 2023.

Jim Prochnow (13:57):

The other development is I see the effort, an increased effort in continuing to regulate the sale of dietary supplements in general. This is evidence by Senator Durbin's continuing effort for registration of dietary supplements or ingredients and by various state legislature's efforts. For example, in both New York and New Jersey, there's pending legislation to limit the availability of muscle building dietary supplement products to folks under the age of 18 years of age. And this is in and of itself, was based upon studies made at Harvard University to which the trade associations have challenged, but so far the state legislature builds are progressing in each state. In New York, it's at the desk of the governor to sign, but there's been no finalization yet. It's just something that the people in this industry have to be aware of the continuing effort to erode the freed trade market system that currently exists for dietary supplements.

Justin Prochnow (15:12):

Let's talk about a few other developments. One of the other developments for 2023 that I wanted to talk about is the change in some of the bottle bill regulations. And for those of you not familiar, the bottle bill regulations are the bills in various states that require recycling of products. And so when you see on the top of a lid, the New York 5 cents or the California CRV, those are the related to the bottle bill laws and what type of redemption you can get for returning those cans. Connecticut is one of the 10 states that have a bottle bill law and in 2021, the governor passed a law expanding the Connecticut bottle bill law. So, prior to January 1st, 2023, the Connecticut bottle bill law really applied to non-alcoholic carbonated beverages and to products that were identified as water on the front of the packaging.

(16:32):

The new expansion of the Connecticut bottle bill law now essentially applies to any type of non-alcoholic beverage, including juices, including teas, really any sort of non-alcoholic product, and it will be 5 cents for each of those products. Then as of January 1st, 2024, it will be increased to 10 cents per product. So it leaves a lot of companies wondering what they're going to do because it'll be one year at 5 cents, then they're going to have to redo it again to 10 cents. The commissioner for Connecticut for the bottle bill passed a notice that indicated companies may simply put CTRV on there, which stands for Connecticut Redemption Value, and then the state will apply it as appropriate 5 cents in 2023, 10 cents in 2024 so that companies don't have to redo their packaging after having it out there for one year. So important

for those who are in the beverage world to make sure that your packaging is compliant and Connecticut essentially now will be one of the states that really all non-alcoholic beverages are going to apply.

(17:53):

When you look at these, again, there's 10 states. If you have a carbonated beverage, all 10 states apply. If you don't have a carbonated beverage, then typically it's going to be Connecticut, Hawaii, Maine, Oregon, and California, which will apply essentially to all non-carbonated waters. New York will also apply as long as it's not a sweetened water. So, certainly something we can help with, but take a look at those, make sure that you've got that because there is a big change to the Connecticut bottle bill law. Jim's going to talk about another topic that you just coming up here at the end of 2022 and have effect moving into 2023 here.

Jim Prochnow (18:40):

One of the things that happened during the end of this year was the issuance of the FDA guidance with respect to homeopathic drugs. Obviously a homeopathic drug is not a dietary supplement, but often companies look for ways to put a product on the marketplace for consumers without having to comply with the various regulations and statutes that are applicable to food or dietary supplements. What happened in early December of this year is that the FDA issued a final guidance document with respect to homeopathic drugs, and what they basically did is confirmed a 2019 guidance document in which the FDA... Which basically the FDA said the homeopathic guidance document consisting of many pages ACPG 400.400 is no longer in effect. We're going to approach homeopathic drug regulation in a different way.

(19:54):

On December 7th of this year, the FDA finalized their guidance and basically said 400.400 is no longer in effect. We're confirming it's no longer in effect, but we're going to tell you how we're going to go about regulating homeopathic drugs. And in actually a very short guidance document, the FDA laid out six factors that it will consider when deciding whether or not to take action against a homeopathic drug itself or against those that manufacture and sell it. What the FDA did emphasize is that at the present time, moving forward, the FDA regards, all homeopathic drugs that haven't gone through the FDA approval process as unapproved new drugs, which basically means all of the homeopathic drugs are going to be regarded as illegal unapproved new drugs.

(20:54):

However, as Justin pointed out as to other items that are regulated by the FDA, that doesn't necessarily mean the FDA is going to take any enforcement action, but rather they specifically laid out six exceptions. That is when they will take action, which they call high risk. I'm just going to recite a couple of them.

(21:18):

One of them is they're going to probably take action for products that are intended for vulnerable populations. For example, they say patient populations such as immunocompromised individuals, infants and children, the elderly and pregnant women may be at greater risk for taking homeopathic drugs. So if you sell a product directed at those populations, for example, cognitive function or something like that, you're just in a higher risk category for enforcement action and then they talk about products with significant quality issues. If you haven't been following the GMPs, you're much more likely to be at risk for enforcement action. So what I'm referring you to is the guidance document that was issued on December 7th. For those of you that sell or contemplating homeopathic drugs, I urge you to

get familiar with it because that is what the state of the law is right now with respect to homeopathic drugs.

(22:24):

On one other matter that I'd like to talk about is something related to supplements, and that is of course, we know that the advertising for supplements is jointly administered or regulated by the Federal Trade Commission and the FDA. The FDA itself works closely with the FTC. The FTC has been very active during this Biden administration and much more recently about really zoning in on earnings claims made for companies that are selling products to consumers. And this particularly has been in the forefront for multi-level marketing companies that sell food supplements because there has been a lot of studies done by the FDA and a lot of complaints for people that get involved as independent contractors that they are not making the money that they expected to be made from the sale of supplements that are involved in these sales organizations.

Justin Prochnow (23:29):

I'm sorry, did you say there've been a lot of studies done by the FDA about this?

Jim Prochnow (23:34):

I meant by the FTC, so thanks for clearing that up.

Justin Prochnow (23:39):

No, I was just curious because, so this generally is an area where the FTC is looking at, because it has to do with kind of the advertising. Has the FTC come up with a formal guidance of what's supposed to be said when talking about this?

Jim Prochnow (23:59):

Good question. Not exactly, but two items close to that deserve attention. One is that on my birthday, in commemoration of my birthday on September 22nd of this year, the FTC's Director of Consumer Protection issued a long speech to the Direct Selling Association about earnings claims. There they had a lot of interesting comments about their position about earnings claims, which are much more conservative than currently involved in that. So I suggest that you look at that speech because basically they're taking the position that a company has an obligation to be very transparent with all independent contractors that sell food supplements and others to make sure that the people who are getting involved are aware of what they're likely, what the typical person makes in the particular status that has in a direct selling association.

(25:03):

Also, earlier this year, the FTC issued a request for comments about earnings claims and whether it should adopt a regulation that deals with them, whether they're in multi-level market organizations or others, and they ask 28 questions to the public all about earnings claims, how they should regulate that. The comments were due in May. The FDA hasn't issued any rule yet, but I advise everybody to keep close tabs on that because it impacts a lot of companies in this industry.

Justin Prochnow (25:42):

Is a company required to make an earning statement?

Jim Prochnow (25:47):

No, there is no statute or regulation about earnings claims. It's all based upon whether or not your claims are deceptive or unfair to consumers, but the answer directly is no.

Justin Prochnow (26:02):

So if a company's not making any suggestions about what someone can potentially earn by selling their products either through the MLM system or something else, a company's not required to include an income disclosure statement. But the reality is that's how these businesses are directed is by telling people what they can make. So it seems unlikely there would be a scenario in which companies weren't making at least some sort of suggestion about what you can earn from selling the product.

Jim Prochnow (26:38):

You're absolutely right. We engage and represent multi-level marketing companies and it's the way that companies do business because each independent distributor is in fact a salesperson. So the issue is of course, always, what information is given to the consumers and what information is given by the company to the salespersons?

Justin Prochnow (27:00):

Great, thank you. One of the areas I want to talk a little bit about here as we wind up is a topic that seems to be somewhat ubiquitous around the industry, and you hear about it a lot and a lot of people might hear these, hear these term or these initials and not really know what they are, but it's PFAS and it stands for per- and polyfluoroalkyl substances. PFAS are something that has come up a lot in discussions and the belief from the Environmental Protection Agency and a lot of state areas that there's something we need to avoid. They're essentially manmade chemicals that have been around since the 1940s and are used in a lot of products to provide stain resistance, water and oil repellency and various other properties and are used a lot in packaging and there has been a big shift or movement towards removing those from packaging.

(28:10):

And while the FDA does not have any specific laws or regulations regarding PFAS, a number of states have started implementing state laws and regulations to prohibit the use of PFAS in packaging, especially in food packaging. So there's a couple states in particular that have laws and regulations going into effect as of December 31st, 2022 or January 1st, 2023 and it's two of the bigger states, New York and California.

(28:44):

New York's Hazardous Packaging Act takes effect on December 31st, 2022 and essentially prohibits any food packaging that's plant based from containing intentionally added PFAS. And the intentionally added language is important because PFAS tend to be something similar to BPA, which there are at least some studies that they're everywhere in the air. They're somewhat ubiquitous, at least in trace amounts. So it's actually somewhat hard to say something is totally free of PFAS even if you haven't intentionally added. So, most of the new laws specifically address intentionally added PFAS and it's for plant based packaging.

(29:37):

So the New York law in particular says it's intended for direct food contact packaging comprised mainly of paper, paperboard and other materials originally derived from plant fibers. It includes carrying cases, crates, cups, pales, trays, wrappers, bags, and tubs. So things like pizza boxes, pastry boxes, sandwich wrappers, soup cups, any of those types of things. It does not include glass, metal, plastic, and other

materials that aren't really derived from plant fibers. What you're going to start seeing, we've already started seeing it, is from a lot of retailers and other companies is getting a representation sent that they want signed that your packaging does not include any intentionally added PFAS. So similar to some of the things you've seen about GMOs or about compliance with Prop 65, if you are a finished package good manufacturer or brand owner, you are likely going to get something over the next couple months that is a statement professing that your packaging does not include any intentionally added PFAS.

(30:49):

California goes a little bit further as California usually does with everything that they do. They've decided they need to be even more specific. So they also include, in addition to intentionally added PFAS, you also may not have any, even if they weren't intentionally added, you must have a level below 100 parts per million. So even if you haven't added them in there, you need to essentially do testing to ensure that you don't have any PFAS that show up over 100 parts per million.

Jim Prochnow (31:23):

You've covered the PFAS area. There are some exceptions if PFAS are used as a manufacturing aid, but I have no further comment about that. But in closing, the comment I want to make is my personal comment about regulation that is in the effort to further protect consumers and dilute their responsibilities to make their independent judgements, there have been some evidences of real overreaching by the federal government that I think everybody listening to this podcast could be aware of, and it's exemplified by one of the statements made as I talked in the September 22nd speech by the director of the FTC Consumer Protection Agency. There, Mr. Levine said the following, "Companies will violate the FTC Act if they imply or state or allow their representatives to imply or state recruits will earn money if they work hard enough." To me, that's a good example of overreach of regulation. In my world, if you work hard enough, the inevitable result is that you're going to make more money.

(32:33):

I just bring that up in closing because I think, although there will be these attempted overregulation, we need to be very vigilant about that. I think the fact that there is going to be Republican controlled House of Representatives will cut back on the ability to overregulate, but I encourage this industry to be very vigilant as we approach 2023.

Justin Prochnow (33:00):

Okay, thank you. One final item I wanted to just touch base on is just two days ago, the FTC, speaking of the FTC, issued notice asking for public comment on the Green Guides. A lot of people might be familiar with the Green Guides, which kind of discuss how the FTC interprets section five of the FTC Act with regard to environmental marketing claims. These were last revised 10 years ago in 2012 with a lot of emphasis on some things like recycling, compostable, those types of claims. The FTC is looking at those again, again as we get more and more into some of these environmental issues about things like PFAS and other things.

(33:49):

So the FTC specifically called out looking for comment on carbon offsets and climate change. Again, on the term recyclable and whether there should be further parameters on what is meant by recyclable. We see a lot of companies these days wanting to talk about recycled content, and so they're asking about pre-consumer and post industrial content.

(34:13):

Some of these topics and then just a lot of the other terms like ozone friendly, degradable, compostable and sustainable are all claims that are being used more and more by companies. And I think as FTC sees more and more companies looking to make claims in this area, they feel the need, somewhat as Jim's talking about, to get more involved in it and make sure that companies are only making what they believe to be permissible claims.

(34:49):

So certainly look out for that. There's 60 days to provide comments on these. Once the notice gets published, it's going to be published in mid-January, and then there'll be comments for 60 days after that. So essentially till the middle of March, companies will have the opportunity to weigh in on some of those claims.

(35:09):

There's a lot more going on. We didn't even address the FDA's recent notice in September of 2022 about updating the healthy definition. We're going to see certainly a variety of different issues as we come through 2023. We're always here to help if needed. So we appreciate you listening today. We're looking forward to a great 2023. If you enjoyed this podcast, please like it on whatever platform you're listening to and tune in for our first podcast of January, 2023. Have a happy New Year.

Jim Prochnow (35:51):

Have a happy New Year. Justin, one last question. Do the Green Guides apply to golf greens?

Justin Prochnow (35:56):

Just me shaking my head as we sign off for 2022. Thank you.