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Justin Prochnow (00:24):

Well, welcome to 2022. Today, we're joined here by myself, Justin Prochnow, and my two colleagues, Jim Prochnow and Michael Goodman. Michael and Jim, welcome to Legal Food Talk.

Michael Goodman (00:39):

Our pleasure to be here.

Jim Prochnow (00:40):

Thanks for having me, Justin.

Justin Prochnow (00:42):

All right. Well, today we're going to talk a little bit about some things that we see on the horizon here in 2022. But before we get to 2022, I'll leave it to the group, anything you want to say about 2021?

Jim Prochnow (00:58):

I do, that is I'm glad 2021 is behind us and we're looking forward to 2022.

Michael Goodman (01:05):

Yeah. I sort of wish that we were back in the '90s, but now that we're not, at least we can get 2021 over with.

Justin Prochnow (01:13):

2021 was an interesting year because after a year in 2020 where everyone was at home for most of the year, I think there was obviously a start to get back out. We saw some new things kind of being launched, and now it seems to some extent, like we're back where we were in 2020. Today, we're going to... I thought we'd each bring up a couple things that we see on the horizon here in 2022, things that people in the industry here might have an interest in and things that they might see on the horizon.

Justin Prochnow (01:52):

Michael, do you want to start us off? What do you see coming up here as being some topics of interest for our clients and people in the FDA regulated industries?

Michael Goodman (02:03):

Yeah. I think that the biggest thing that's going to be happening in 2022 is the reduction of hand sanitizers. Obviously with the start of COVID, hand sanitizers were liquid gold. And what happened was is that the FDA basically waived most of the drug requirements that are attached to hand sanitizers. As of March 31st of this year, retailers can't sell the old hand sanitizers that they sold before that were not manufactured under good manufacturing practices, weren't registered with the FDA. And now we're kind of going to where we were in 2019.

Justin Prochnow (02:46):

Are you talking about the emergency kind of rules that the FDA issued that allowed your local distillery or whoever to make some hand sanitizer, FDA is revoking those as of March 31st?

Michael Goodman (03:01):

Yep, that's absolutely right. If they can't comply with the drug manufacturing practices, then they can't make the product anymore.

Justin Prochnow (03:11):

That sounds like a significant deal because in order to do that, you have to be registered, I assume, as a drug manufacturing facility, be compliant with all the good manufacturing practices for over the counter drugs. I take it that a majority of the companies that might have been initially making these kind of emergency hand sanitizers just won't be able to be compliant with those rules.

Michael Goodman (03:39):

Yeah, yeah. And we can kind of date this back to the interesting thing of World War II when companies really had to pivot to meet the needs of the US government fighting overseas. It sort of looked like that again, where we didn't have enough hand sanitizer and everybody wants it now. Distilleries were the best source to make 80%, well, 100% ethanol and put it into a really simple solution and use it on the hands.

Michael Goodman (04:12):

That's being pulled now. I think during the whole COVID thing, the epidemic, these manufacturers were protected by the PREP Act, which everybody kind of knows, the Public Readiness and Preparedness Act, where they were...

Justin Prochnow (04:30):

I can tell you that the majority of people do not know that that's what the PREP Act is. So I'm glad you explained that.

Michael Goodman (04:36):

No. One of the problems that a lot of these companies were facing was that they were going to meet the needs of the US government and the US population, or even the world population, but they needed to make sure that they weren't going to be sued for any problems that arose from making a hand sanitizer that wasn't quite up to the drug stand. The PREP Act, in theory, immunized a lot of these companies from future lawsuits.

Michael Goodman (05:08):

And then they also had the Public Health Service Act, which meant that the FDA wasn't going to bring any, any actions against these companies either.

Justin Prochnow (05:19):

What do you expect will happen with all of this product out on the market? Do you think FDA will still wait a little while? Do you think it depends on how Omicron and other variants are going as to how

aggressive they are? I mean, what do you think the odds are of these companies who are making the hand sanitizer now as of April 1st? Are they going to start pulling it off the shelf? What do we see here?

Michael Goodman (05:45):

That's what the FDA is saying. They gave the warning in October of 2021 that in March 31st of 2022, they were going to start pulling these off the shelves. Now, whether they do it or not, whether they have the resources to do it is another question. But it doesn't look like right now is three months away that the FDA is willing to pull that decision back.

Justin Prochnow (06:13):

I suppose, again, we'll see what happens in the next 90 days as to the whether there's an additional deferral.

Michael Goodman (06:22):

Yeah. The other thing that... I want to make a big prediction of 2022, and we're starting to see this sort of rev up at the end of 2021, but I think it's going to get bigger in 2022, as the world opens up and these hand sanitizers are sort of pulled by, is that I believe that plaintiffs attorneys are going to start targeting these hand sanitizers more. Now, I just told you, Justin, that the PREP Act immunized these companies from any lawsuits in the future, obviously, right?

Michael Goodman (06:49):

That could be any sort of injury other than death, which we're not really worried about. But the problem is that there was a specific menu or a recipe that the FDA prescribed that these manufacturers could use. It turns out that it needed to be 80% ethanol or I believe 72% isopropanol. A lot of companies found that that was really expensive. What they did was they skipped the good manufacturing practices part and they manufactured a lower percentage of ethanol or isopropanol in their hand sanitizer.

Michael Goodman (07:27):

Obviously they declared it honestly, but that's not really fitting within the PREP Act. They are really subject to potential litigation, whether that could be in false labeling. One thing that I'm really interested to see and I think it may be coming down the pike is that people who caught COVID could start potentially bringing class actions because they used hand sanitizer. But unfortunately, it didn't stop them from catching the disease.

Michael Goodman (08:02):

Even though hand sanitizers never advertised that they could stop COVID, that was really the intent and that was why they were brought on. In 2022, I think we're going to see that, we're going to see more plus actions about hand sanitizers.

Justin Prochnow (08:17):

Interesting. That will be interesting to see how those... I can just imagine the depositions in this case. How many times a day did you use the hand sanitizer? Did you use it every day? Interesting. All right. Well, I feel a little bit like the sports reporters. We're going to go around the table here to Mr. Prochnow here. Jim, what do you see on the horizon here for '22?

Jim Prochnow (08:42):

I see four or five definite things I'd like to talk about or bring up topics. First of all is I think there will be an increased activity by the Federal Trade Commission with respect to social media advertisements in the food supplement industry. I say that because the amount of opportunities and venues for social media is increasing and the use of social influencers is becoming more rampant.

Jim Prochnow (09:12):

The FTC has been continuing to be interested in the use of testimonials and product reviews. That's one thing I see. The second thing I see...

Justin Prochnow (09:22):

Before we go, before we go further, I mean, obviously the FTC issued some revised guidelines about three years ago in the space of social media and advertising, specifically related to influencers, bloggers, things of that nature. From the perspective of your clients, have you seen that action by the FTC in those announcements several years ago quelling the amount of social media use, or do you think that's just something that they view as part of the territory and they continue to move forward without really worried about that too much?

Jim Prochnow (10:01):

In my judgment, most companies aren't even aware of the guidelines of the FTC. If they are, it's in a general way. They have their either in-house or contracted for social media companies or marketing companies who really are unfamiliar with the actual guidelines of the FTC. Now, the larger companies are somewhat more familiar.

Jim Prochnow (10:28):

But in my experience, most of the clients do not have a good grasp on really how to implement and carry out the guidelines, which are the way the FTC regulates under section five of the Federal Trade Commissioner Act. My view is it's still kind of unknown territory for most companies.

Justin Prochnow (10:50):

It sounds like more people should have attended my presentation at SupplySide West in I believe October, November of 2018, where I gave a presentation on the new changes. Actually also from the Legal Food Talk Podcast 2021, we did an episode on using endorsements and testimonials in advertising and social media. If you want to learn and more about that, check out our previous podcast about social media advertising.

Jim Prochnow (11:23):

The second area still of interest intensely is the CBD industry.

Justin Prochnow (11:31):

Heard of it.

Jim Prochnow (11:31):

The CBD industry continues to be of great interest to companies who want to get into it. We still have the over... Let's put it like this. We still have the kind of dampening of it from a legal standpoint because

of the provision in the Dietary Supplement Health and Education Act that we call the exclusionary clause. However, most companies that want to get into it are even unaware of that. They come to us hopefully before they've hit the product on the marketplace, and we explain to them the reach of that exclusionary clause.

Jim Prochnow (12:11):

As you and I discussed, the reach of that exclusionary clause, which fundamentally prohibits the inclusion of an ingredient in a dietary supplement if it was first approved or studied as a drug, is under fierce attack from the major trade associations with respect to the dietary ingredient NAC. There's a lawsuit pending that was filed in December by the Natural Products Association against the FDA.

Jim Prochnow (12:43):

That was the case with NAC, where briefly NAC was used both as a drug and a supplement or as an ingredient in a food supplement before the enactment of DSHEA in October of 1994. And fundamentally, the Natural Products Association is arguing that if an ingredient was on the marketplace before DSHEA was enacted, that the exclusionary has no retroactive effect and wouldn't apply. We'll see where that comes out. There are a lot of related issues involving citizens petition and the effect of that on CBD.

Jim Prochnow (13:27):

But I think this year we're going to get more input from the FDA, both in a lawsuit and in public speeches about the application of the exclusionary clause.

Justin Prochnow (13:40):

Obviously this whole issue with NAC started really in 2020 with the issuance of seven warning letters to companies selling products that were allegedly making the hangover claims. It happens that N-acetylcysteine, which is the scientific name for NAC, helps with hangover symptoms. In those letters, the FDA really for the first time ever, or if not ever, at least in a number of years identified NAC as potentially a non-permissible ingredient, which was a big surprise to the supplement industry because NAC is a very prevalent ingredient probably in thousands of products.

Justin Prochnow (14:35):

It was a surprise to everyone the FDA was now taking this position that they had never taken before. That kind of led to a number of different actions, including Amazon taking NAC off the shelves and where at one time there were hundreds of products with NAC as an ingredient. You now go to Amazon and there are no products with NAC on there. Obviously it caused a lot of concern for companies in the supplement industry. There are various working groups at different trade organizations, NPA, UNPA, CRN, that are all working on this topic separately.

Justin Prochnow (15:15):

As part of this whole issue, the FDA called for comments from the industry as to submitting evidence of safety for the ingredient. Those are due at the end of January. I know a lot of the trade organizations, as well as individual companies are going to be submitting information on the safety of NAC and its use in both supplement and food products. Certainly an interesting and ongoing issue.

Justin Prochnow (15:47):

I think as you alluded to, a lot of companies and the industry groups see this as potentially a precursor to how the FDA might treat other ingredients like CBD that have a similar argument about them being excluded, pursuing to the exclusionary clause. While there is certainly an interest in NAC, I think the interest in NAC also carries over to potentially how FDA is going to address other ingredients.

Jim Prochnow (16:18):

Excellent. I just have two other comments. One is I do believe that given the effect of COVID-19 or pandemic, that there's going to be more of an interest in plaintiff's lawyers and the Federal Trade Commission in the regulation of multilevel marketing companies. People are staying at home developing their own business, which is really what multilevel marketing or direct selling companies are all about. This is not only in the United States, but in Europe and Asia as well.

Jim Prochnow (16:52):

My last is about as I see a developing matter that's irrespective of the COVID is increased interest in what I'll call biologic, or I'll just say stem cell products and their use in treatment of patients. It's cutting edge science. We have clients that are involved in that. We have background in that. It's just cutting edge science where people are looking for ways to deal with unusual and serious conditions. It seems to me that the regenerative medicine and the products they need are going to be greatly expanded during this coming year, which will draw increased interest from both the FDA and the FTC.

Justin Prochnow (17:43):

Thank you for that, Jim. I want to go back to what you were talking about with CBD because kind of a tangential issue to CBD I think is the growing number of, for lack of a better, derivatives or variants of hemp ingredients that are truthfully in some cases taking over a lot of the space that just CBD products are, in particular, the one probably more than anything is Delta-8, which has received a lot of attention, both from a state level and to some extent from a federal level.

Justin Prochnow (18:18):

Delta-8 is another form of THC. Delta-9 being the main form of THC that was addressed in the 2018 Farm Bill. But we're seeing a lot of sales of Delta-8, which is very similar to area you're familiar with, Jim, about the DMAA and whether it came from, I believe, a geranium oil or not. Delta-8, while it is a derivative of hemp, typically does not come in prevalent enough amounts to use the naturally occurring amount. Typically, Delta-8 is created by processing or synthesizing Delta-9 into Delta-8.

Justin Prochnow (19:07):

There's a lot of question from the industry as to whether the DEA will consider processed Delta-8 from Delta-9 as a Schedule 1 controlled substance since THC is a controlled substance. There has been a lot of back and forth as to whether... Since the 2018 Farm Bill exempts hemp and derivatives of hemp that are at 0.3% or below Delta-9 THC, whether this Delta-8 created from industrial hemp is also exempt or not. I would say that the issue is far from resolved.

Justin Prochnow (19:50):

However, In November of 2021, the DEA did send a letter to one of the state board of pharmacies addressing this very issue. And it is interesting. It's one of those cases of depending on what side you're on. The letter was very clear in saying that Delta-8 derived from Delta-9 is not going to be a Schedule 1

controlled substance, while others seem to believe that the letter is still very unclear as to whether that's the case, whether it's Delta-8 or Delta-10 or we've seen CBDO, THCO, CBDP, CBDV.

Justin Prochnow (20:36):

There are a lot of different variance and derivatives, and until the FDA... We've been waiting now for three years since the 2018 Farm Bill was passed for the FDA to issue some sort of further guidance on the use. Obviously I think COVID slowed that down a little bit, but the continued variance and derivatives of this, I think, are going to continue to make it a challenging area for companies in determining how to be compliant and stay adrift of both state regulation and federal regulation.

Jim Prochnow (21:18):

Don't you think the FDA's position would be that Delta-8 is not a dietary ingredient for the same reason they felt DMAA isn't because it wasn't available in nature in a usable amount and that's why they got involved in a lawsuit with the makers and manufacturers of DMAA?

Justin Prochnow (21:38):

I mean, it certainly could be. I mean, there are a variety of different tax the FDA could take. They could take a position similar to CBD or others, which is, at the very least, it's a new dietary ingredient for which a notification should be filed. Of course, we saw what happened with that earlier in 2021 when two companies filed an NDI for CBD, only to have those rejected. Again, the whole area of CBD and hemp regulation and those derivatives is going to continue to be one that deserves a lot of attention in 2022.

Jim Prochnow (22:19):

I think the biggest challenge from my perspective as a practitioner is not talking about it or just giving advice to clients. But the rubber hits the pavement when you're asked for a legal opinion, either by an investment company or a group or bank or a potential buyer. That's where more guidance from the agencies would be helpful.

Justin Prochnow (22:47):

One other topic I want to get into and we'll go around the room one final time for some closing thoughts is as of January 1st, 2022, the bioengineered ingredients regulations become mandatory for compliance with the USDA. These are the rules issued several years ago that require companies that have one or more bioengineered ingredients in the product to have a decoration on the label which indicates that the product contain bioengineered ingredients.

Justin Prochnow (23:33):

These are ingredients that are typically thought of as being coming from crops that were bio-engineered. So things like corn, sugar beets, canola, cotton soybeans. If your product has one or more of those ingredients in the product, then the labeling as of January 1st, 2022 needs to include a declaration that it contains a bioengineered ingredient. Now, There are some exceptions to this rule.

Justin Prochnow (24:07):

If it is derived from a bioengineered ingredient, but it's non-detectable in the testing of the finished product, then you are exempt from having to include that declaration, but you do have to have records

that either back up that you've done that testing or records from an ingredient supplier that indicated it contains a non-detectable ingredient.

Michael Goodman (24:32):

Justin, that's an interesting topic. Do you see that in 2022 and maybe in the years subsequent that there's going to be quite an uptick in litigation because of the genetically engineered? What we used to see was one crop with bioengineered product floating over to another farm of nut, and then lawsuits well upstream. Do you think we're going to see downstream effects from that?

Justin Prochnow (25:01):

100%. I mean, if our friends, the class action plaintiff lawyers, if it's any indication from what they've been doing, we will start to see those types of litigation right away. Now, I guess the biggest issue is you have to have at least... I mean, it's debatable, depending on some of the letters we see from plaintiff lawyers, but you're supposed to have some amount of damages. Right now the amount of damages is only based on five or six days of sales.

Justin Prochnow (25:34):

We'll probably wait at least six months before we really see significant sales that would warrant a plaintiff lawyer taking action on those types of things. But I think we will. That kind of brings up a good point, which is the growing number of class action lawsuits that we see in various types of labeling claims for our types of clients. In 2021, we saw certainly an increase in claims over protein.

Justin Prochnow (26:10):

In particular, there's a law firm in San Francisco that has been suing companies over the daily value percentage declaration for protein and whether it's been properly adjusted based on what's called the PDCAAS, which is the protein digestibility converted amino acid score.

Jim Prochnow (26:31):

This is a pretty nerd conversation.

Justin Prochnow (26:34):

That's what we're here for. Of all the things we've talked about, it probably touches on more of our clients than anyone else. Because if anyone has a label that has a protein declaration, and especially in the era of plant proteins, you need to make sure that your protein declaration is adjusted based on the PDCAAS score. And in particular, if it's collagen protein, your PDCAAS score is zero. You could have 20 grams of protein from collagen, your daily value percentage is zero.

Justin Prochnow (27:08):

There are law firms that are out there just looking to ensure that not only are you making that declaration, but some of these law firms have gone a step further and taken the position that it's misleading to declare the number of grams of protein on the front of your label without qualification if it's an adjusted daily value percentage based on PDCAAS. Where those go, we'll have to see, but it's certainly something to be aware of. The protein declaration has been a frequent source of class action litigation.

Justin Prochnow (27:41):

The other one that we've been seeing a lot of are natural and artificially flavored declarations. This has always been kind of an ongoing thing, depending on if you say a product is peach instead of having actual like peach juice or peach tea and has peach flavor. But lately plaintiff lawyers have been going after certain ingredients in the product, most notably malic acid, and arguing that even if you have natural flavors, if you also have malic acid in your product, that the product should be labeled as naturally and artificially flavored and taking the position that malic acid is an artificial flavor.

Justin Prochnow (28:22):

Because when you go to the ice cream store, you always order that malic acid ice cream, right?

Michael Goodman (28:27):

That's my thing.

Jim Prochnow (28:28):

I do it frequently. Yeah.

Justin Prochnow (28:30):

Again, these types of things are issues we deal with all the time. You get a letter from a class action plaintiff lawyer, and they're typically characterized as we believe you have been egregious doing this. That being said, we're willing to talk settlement. If you want to pay us somewhere between 40 and $100,000, depending on who the letter is coming from.

Justin Prochnow (28:55):

We've had some that say, "We're willing to settle this right now for either seven to $8 million on a classwide basis or $450,000 on an individual basis," which I agree. That would be a great thing for them if someone is willing to do that. We will continue to look at these labeling issues and address them as they come up, but I don't think that class action lawsuits are certainly going anywhere.

Jim Prochnow (29:25):

You didn't mean a great thing for the defendant. You meant for the plaintiff.

Justin Prochnow (29:28):

No. I mean, that's what I'm saying. The plaintiff lawyer, I imagine they would love to have a $450,000 settlement for the amount of time that it took them to switch the names on that letter from the last letter that they sent out and do something. We're going to kind of wind it down here and we're going to go around the table one last time here to see how people are looking at 2022 and any final thoughts. Mr. Goodman?

Michael Goodman (29:55):

Yeah. I have a final thought. I have some legislation to look for. In 2019, there was the VALID Act to change laboratory developed tests to make it more regulated with the FDA. That kind of fell by the wayside mainly because of something called the coronavirus. Well, it's being brought up again and it's always been a point of contention. I get a lot of calls about laboratory tests and advertising them direct to consumers and you just can't do it.

Michael Goodman (30:30):

But then what is a laboratory test as compared to an in vitro diagnostic test? The FDA, well, through legislative act, through the legislature, they're going to start to clarify the difference between an in vitro diagnostic and a laboratory developed test. It will make things a little easier to understand.

Michael Goodman (30:48):

But at the same time, if this passes, there's going to be some obligations that a lot of these clinics that use LDTs with no oversight other than CLIA, the Clinical Laboratory Improvement Amendments, which is really state regulated in most cases, it's going to, again, clarify, but there are going to be some obligations. Let's look forward to that in 2022 and then on to see what happens and if this passes.

Justin Prochnow (31:26):

All right. Thanks.

Jim Prochnow (31:29):

A couple of my last comments are this. First of all, in my judgment, one of the things on a practical basis that we're going to recommend or I'm going to recommend to my clients this year is from time to time to... When you use a laboratory or in-house laboratory, to get an independent test to confirm that the people who are running your test in-house, or if it's independent contractor are using the right equipment, the right standards, everything else.

Jim Prochnow (32:04):

Because there's so much now, as Justin was talking about in the realm, whether we talk of bioengineered foods or otherwise, where lab test results are so important. One shouldn't just rely on the testing that you've always done or the people you've always used. You can continue to use them, but periodically a double check should be made of those.

Jim Prochnow (32:27):

From a broader standpoint, I think one of the unknowns yet is how some of these spaces within the FDA are going to be filled with respect to policy makers and litigation matters. Bob Charrow is a partner in our DC firm, who is the former general counsel of health and human services. That spot hasn't been filled. The head of litigation of the chief counsel in the FDA has not been filled. Carl Welsh is the acting director of the office of dietary supplement programs.

Jim Prochnow (33:03):

The filling of those spaces will be important is the Biden administration continues to try and fill some of those things and those could have a big effect on things. In closing, I want to say that follow up to what Justin said, there's been an increasing number of demands by plaintiff's lawyers for technical violations of the Federal Food, Drug, and Cosmetic Act.

Jim Prochnow (33:28):

My own view is these claims are not being brought for the public good, but just as a method of generating more income for the people that are bringing them and the lawyers. I think they're a scourge on our industry, and I'd like to see legislation that would ban them under certain circumstances.

Justin Prochnow (33:47):

I'm sure that last comment will be met with a lot of cheers from people in the industry, because it has continued to be one of the biggest sources of frustration I know for clients that I hear is the continual just onslaught of these types of actions over things that try to make a technical labeling violation, which maybe would be akin to jaywalking on a country road with no one around and making it seem like it's first degree murder.

Justin Prochnow (34:24):

For now, we will conclude. Like us if you liked the episode or send a review on your various social media platforms that you're listening to this. And look out for more upcoming episodes here in 2022. Thank you. Cheers! Happy 2022.

Michael Goodman (34:44):

Happy new year.