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. 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.

(00:55):

Welcome to another episode of Legal Food Talk with Greenberg Traurig. Again, I'm your host, Justin Prochnow. Very pleased today to be joined by a friend and colleague in the industry who I've been on panels with before, seen speak at a number of shows, and happy to have him here today, Bill Bookout from the National Animal Supplement Council. Welcome, Bill.

Bill Bookout (01:19):

Thank you very much. I really appreciate the invitation and always enjoyed talking to you. And anytime we have the opportunity to get together, I look forward to it, Justin. Thanks.

Justin Prochnow (01:30):

So I know when we were talking about setting this up, you're usually based in Arizona. It's been a little hot in Arizona this summer. So you said you were in ... and I think you put the abbreviation AK, and this goes to an interesting thing. I immediately thought Arkansas instead of Alaska. And it reminds me, I was listening to this comedy presentation and a guy was talking about how they came up with the state codes, and some of them seem very apparent. Obviously Idaho, there's only ID, you immediately jumped to that, but some of them are not as apparent as others. And they were talking about, well, when they first created them, the first one, this will be easy. We've got AL, Alabama. And they're like, okay, next one Alaska. Oh, now what are we going to do? So they went to AK, which you don't normally maybe associate with Alaska. So what brings you up to Alaska this time of year?

Bill Bookout (02:35):

So we do the snowbird thing. We're in Phoenix in the wintertime and Alaska in the summertime. So we have a place in Alaska on the Kenai Peninsula. I have a [inaudible 00:02:44] office here. And funny enough, I have faster internet connection here and faster internet speeds in Alaska. Although we're 35 miles outside of Kenai, Alaska in the middle of the Alaskan Bush, I'm connected with higher speeds here than I'm in my office in Arizona. So with technology you can really operate from ... you're not constrained geographically anymore as we used to be in offices. So yeah, I can operate just as effectively from Alaska where I am right now and get out of that 110 degree heat that's plagued Arizona this summer.

Justin Prochnow (03:18):

Well, I was just there this last weekend, and it was actually a balmy 95 degrees. So it was kind of nice, but as we read about signs melting and things, I think I was out there obviously for the National Animal

Supplement Council annual meeting, which we'll talk about later, but that was probably the last bearable time in Arizona for a while.

Bill Bookout (03:43):

Yeah, it's been an incredibly hot summer. I connect with people who stay down there all summer and yeah, it's been a scorcher this year, but it's a dry heat.

Justin Prochnow (03:54):

That's right. That's right. I think is was Garry Shandling who used to say, "So is an oven, but I don't stick my head in the oven either." Well, let's talk a little bit. Again, our podcast here touches on a wide range of topics affecting companies in the food, beverage, supplement areas. And we had an interesting one last time with one of my colleagues, Barry Schindler, talking about AI in food, but as I said in the intro, you're the figurehead right now for the National Animal Supplement Council. Tell us a little bit about your background. What did you do before arriving at NASC and how did you end up participating in the NASC?

Bill Bookout (04:37):

Yeah, starting a trade association?

Justin Prochnow (04:38):

Yeah.

Bill Bookout (04:40):

Yeah, so my background is I was in the human medical device and drug industry. I was a business executive. I'm an MBA entrepreneur. And before I got into the animal side, I was chief operating officer for a $500 million medical device and drug company on the human side. So I'm used to regulatory stuff. We did drug approvals, device approvals. I was based in Denver, lived in Elizabeth, Colorado, your neck of the woods when I went -

Justin Prochnow (05:10):

I didn't know that.

Bill Bookout (05:10):

Yeah, it was Marquest Medical Products in the Denver Tech Center area. So we lived in Elizabeth and worked there, and then there was a lot of M&A activity so those companies got scooped up and changed names and became affiliated with QE. But anyway, that's another story. But I was raised in Wyoming, so I'd always had dogs my whole life, and I had dogs with a couple problems. I had two Labrador retrievers. One of them had hip dysplasia and the other one got cancer. So I was looking for help with my own dogs. So I had two total hip replacements done on my lab with hip dysplasia and treated for cancer. So I got out of human medicine in the mid 1990s and took a slot as CEO for the third largest specialty companion animal referral center in the US. It was in Fountain Valley, California, which I had migrated to California with a startup medical company.

(06:03):

So I made a career change. Human medicine felt like it was trending more towards patient processing rather than patient care, and I was just more gratified and fulfilled by the animal side. So I took a slot as CEO for the animal referral hospital and did that for three years. In the course of that experience, cancer comes back second time around on my own dog, 11 and a half year old laboratory retriever. And I worked with all these high-powered oncologists, and he was given a three-month prognosis with chemotherapy, and I just wasn't going to do that for an 11 and a half year old dog, so I'm looking for help. So I find a veterinarian formulated product, changed his diet completely, and he lived two and a half years, good quality of life, which wasn't long enough, but I was thankful for that. But I thought out of that experience, I thought, well hey, I should start a company selling supplements for animals because they'd made a tremendous impact on my life, and I see human dietary supplements out there.

(07:02):

So you would think that if anybody out there could figure out what the regulatory environment was, it'd be me, because I'd dealt with FDA, I was used to operating in a highly regulated industry. And I made every mistake that you can possibly make, it seemed like. So started my own company, didn't realize that [inaudible 00:07:22] doesn't apply to animals, which we can talk further about. And the products were actually in jeopardy of being removed from the marketplace back in 2001 with a publicly announced initiative. So we founded NASC with 26 companies initially. 18 of them stuck with us. And in 2001, and NASC has become the largest trade association in the world representing companies that sell products that are similar to human dietary supplements, marketed for dogs, cats, and horses. So that's kind of a long-winded thumbnail [inaudible 00:07:57] to my background and how I got into the transitions I went through and got into the business. Sold our company in 2012, so I'm president and founder of NASC, and that's my only focus.

Justin Prochnow (08:11):

So I know you celebrated the 20-year anniversary either last year or maybe the tail end of 2021?

Bill Bookout (08:19):

Right.

Justin Prochnow (08:20):

So of course you raised the ... I don't know if it's the elephant in the room, but the big issue here, which is you are the founder of an organization for a category of products that technically the FDA doesn't recognize.

Bill Bookout (08:36):

That's right.

Justin Prochnow (08:37):

Because as many people may or may not know, the Dietary Supplement Health and Education Act here, educational note, was founded in October 15th, 1994, but it only applies to products intended for humans and not for animals. So for a category of products that technically is not recognized by the FDA, it's a very large category of products. And I'm sure you can probably provide some numbers on how many products are out there, but it's a awfully large industry for something that's not technically recognized by the FDA. So maybe talk a little bit just about that interesting part. How big of an industry is it? Do you have any numbers on that? It doesn't have to be exact, but ballpark numbers?

Bill Bookout (09:31):

Sure. Yeah, ballpark numbers. When we started ... and remember, our focus is specifically to products that are similar to human dietary supplements that are marketed for dogs, cats, and horses. So when we started back in 2001, 2002, the industry was estimated at consumer spending level about $800 million. Just to deviate a little bit, what people don't realize is besides the fact that the Dietary Supplement Health and Education Act doesn't apply to animals, we are also regulated at two levels. We're regulated potentially at the federal level by FDA Center for Veterinary Medicine, and also at the state level through the Department of Agriculture, depending on what the statutes in any particular state recognize as either animal food or animal remedy products.

(10:24):

So when we started, it was about $800 million. The industry was threatened. They began removing products from the marketplace back in 2002. So NASC stepped forward and said, "Listen, we will engage the regulatory agencies," meaning states and feds, "And provide what we think is a solution based on self-regulation with the cooperative approach," meaning acting transparently, asking for input in this category, because technically on the animal side, you've only got two choices. You've got animal food or animal drugs. That's it. So we've developed a system of self-regulation that has allowed the industry to thrive, also addressed an issue that FDA and the state regulators couldn't figure out a solution to. And the industry has grown in the last 20 years under this program and really our collective and cooperative oversight to approximately now $2.6 billion in consumer spending for dog and cat supplement products and about $800 million for horse products.

(11:33):

So I would argue ... and I've made this statement before and I'm interested in your comments, I've asked the question, how do you regulate quality and compliance into an industry? Any industry. How do you regulate? How do you mandate? How do you regulate quality and compliance? I think the answer to that question question is it's very difficult. I don't think you can, but when you have the majority of the industry, which is who we represent, working cooperatively with the regulatory agencies to define, develop, and implement a responsible solution, then I think that's how you maximize the outcome and the benefits really through a private, public cooperative effort. FDA likes us, and I credit the regulators a lot with the success that we've had and the industry success, because without the cooperation of the regulatory agencies cracking down on bad actors, we don't have any regulatory authority as a trade association. We have influence with our members, certainly, but if you have bad actors out there, you need regulatory oversight and regulatory action to make sure that the people here that are responsible participants in the industry can contribute positively.

(12:52):

So what has happened over time, Justin, is the industry self polices, the regulators see that that works in a cooperative joint approach. It makes their life easier and they can focus on more important issues. So I would say based on the benefit of 2020 hindsight, I'm biased of course, but I personally think we're a Harvard Business School case study about how to take an issue that could be extremely problematic and work cooperatively with the government and regulatory agencies for a positive outcome. And I would not only cite our accomplishments, but if I look back retrospectively, there haven't been any significant issues that have affected the animal supplement industry, and that's not true for the pet food industry, meaning the complete and balanced diet industry with melamine back in 2008 or even human dietary supplement industry. So am I proud of our accomplishments? Yes, I am. And I think that I can base that and underpin that with results.

Justin Prochnow (13:59):

You raised a good point. So to be clear, I mean this is a self-created industry policing ... I don't know policing necessarily, but to some extent to try to show to FDA look, we're trying to do what we can to make it as clean as possible. But at the end of the day, I mean it's clear that just because a company works with the National Animal Supplement Council and has the NASC quality seal on its label, doesn't mean that the FDA still couldn't take action against anyone here, because at the end of the day, you try to do what you can to get companies in line, but it's still subject to either FDA or state regulation. Then they could take action at any time if they wanted to.

Bill Bookout (14:54):

And they can and do. And we encourage that, because like you said, I think the industry ... it's always dangerous to paint with a broad brush, but I think you can classify the industry broadly as there are really three categories of participants in the animal supplement industry. There are NASC members that are trying to do the right things right to find a responsible path forward and do that cooperatively and transparently. There are certainly companies that are not NASC members that are responsible companies and make quality products. There aren't very many of them left out there, but there's a couple.

(15:34):

But there are opportunistic participants that may not care about quality or claims and are curing everything from parvo to cancer, and they give the industry a bad name. So those companies should be highlighted. They shouldn't be in the industry, in our view. So when you have the majority of the industry or responsible participants differentiating themselves from opportunistic providers, then I think it makes everybody better. And at the end of the day, as you said, we operate with the philosophy that a rising tide floats all boats. And if we can establish a foundation that paves the responsible path forward, then everybody has a fair and equivalent opportunity to gain market share and grow their own business.

Justin Prochnow (16:24):

What would you say the interaction is with ... well, let's start first with the FDA. I mean, how much interaction is there with you and NASC and FDA?

Bill Bookout (16:37):

I would say we routinely communicate with FDA. We have routine meetings with FDA once or twice a year. If there's something that comes up that we think the agency needs to know about. In some of our systems, we have early warning systems through our adverse event reporting system. So if there's anything that we identify ... we never want the government or any regulator to be blindsided if there's something that comes up. So we communicate with them. I would say routinely, and I serve on a number of committees in another association, the Association of American Feed Control Officials that FDA always participates in as well.

(17:17):

But just to back up one step, as I mentioned earlier, there's really, on the animal side, two categories. There's animal food or animal drugs. At the end of the day, a lot of the products, probably 80% of the products that you see out there, are regulated under or fall under specifically 201G1C in the Food, Drug, and Cosmetic Act, which says articles other than food, if intended to affect structure and/or function of the body [inaudible 00:17:48] or other animals, but that means that FDA does have oversight, but the

fact is these products are allowed to be marketed under enforcement discretion provided that companies act responsibly.

Justin Prochnow (18:02):

This is the category I think that we've talked about, which would be the low risk animal drug product.

Bill Bookout (18:08):

That's right. That's right. So at the end of the day, we always hope that we would put a foundation in place that if these systems ever did need to be recognized formally, meaning statutorily through Congress or even states, that we would have the foundation in place that they could really recognize what the majority of the industry is already following, that the regulatory agencies have had input into developing, and we push the implementation side.

Justin Prochnow (18:41):

Has there been a push at all from the NASC or others to actually get a more formal recognition of animal supplements in the same way as [inaudible 00:18:57] or something else? Have there been various bills or things put forward? Or are you comfortable with being in this FDA doesn't really take a lot of action as long as everyone kind of stays in the middle there?

Bill Bookout (19:15):

And in the absence of a safety concern. That's always -

Justin Prochnow (19:18):

Right, of course.

Bill Bookout (19:18):

- a regulator's first and primary concern is you want to be sure the products aren't doing harm and they're safe, low risk.

Justin Prochnow (19:28):

Is it a goal to try and get some more official recognition? Because otherwise you're kind of obviously always operating in a little bit of a gray area where, hey, we believe we're doing everything, but still at anytime ... I mean, this is an industry that you have to be able to operate with some comfortability that there's always going to be some level of risk.

Bill Bookout (19:52):

Yep. Here's the answer to that. When we first started, we initially started to charge down the pathway of we're going to go to Congress and we're going to pass [inaudible 00:20:04] for animals. Here's the complicating factor, and the thing that people don't realize is we have to deal with 50 different state regulators as well as the layer at the federal level with FDA Center for Veterinary Medicine. So you really have 51 different sets of regulatory departments that are potentially involved. That's a big difference from [inaudible 00:20:27], where you have national legislation for an industry that you don't have all these different states to worry about. That's not true on the animal side.

(20:38):

So an answer to your question is we have been active in working with state legislatures, cooperatively with departments in states to formally recognize these types of products. Vermont and Florida are two recent examples of legislation that's been passed through the state legislature to recognize dosage form animal health products for a non-nutritional benefit that would be similar to joint products with glucosamine, chondroitin, MSM, turmeric, or lutein for eye health or co-enzyme Q10 or things like that.

Justin Prochnow (21:16):

It's interesting that Florida is one of them, because truthfully, Florida has been one that in the past has been somewhat aggressive in going after companies that were selling animal supplements and saying that they're not really compliant. So interesting to hear that now they're one of the first to have actually passed some legislation recognizing it a little more.

Bill Bookout (21:38):

That was a bit of a tortuous pathway, but I think we ended up in the right place with the department in Florida, but it didn't start out as a joint friendly, let's work together to address this issue responsibly. It didn't start out that way, and it was really mystifying to me, because when you get an industry coming to someone, whether it's at state or federal level that says, "We want to be regulated. We're not opposed to being regulated. We just want to be regulated responsibly, fairly, and we'll help you do that."

(22:20):

To put a group of products under your purview and have the state be resistant to that, that was a bit of a ... I didn't truly understand that, as opposed to Vermont, where we got dosage for animal health products for non-nutritive benefits, recognized that we did that very cooperatively and jointly in testimony at the state legislature. But at the end of the day, we've come out, I think, in a good place and with the right answers. But to have to have the issue addressed nationally, the really big factor is you've got 50 different sets of states with 50 different sets of state statutes to deal with, and that's a big difference between [inaudible 00:23:08] and the animal side.

Justin Prochnow (23:09):

Sure. I suppose that's one of the impetus for you being on the AFCO ... you said it's a committee on various AFCO committees, is to kind of stay involved on those issues on the state side as well.

Bill Bookout (23:27):

Yeah. Yeah, for sure. And some states have animal remedy laws that cover the non-nutritional products, but every state except California through the Department of Agriculture has oversight on animal food products, and that's both good and bad. You don't want a national industry to be subjected to subjective -

Justin Prochnow (23:56):

Interpretive state laws.

Bill Bookout (23:57):

- regulate ... yeah, you've got 50 different sets of interpretations of statutes and subjective opinions. So there's some discussion about that. And consistency, especially on the pet food side, is really important. And also, because you have the Association of American Feed Control Officials, which is a nonprofit like

we are and they do provide a really good and valuable service because they try to promote consistency, but as you know, the more people you get involved, typically the slower the processes are. So AFCO is often criticized for being the ... they call themselves deliberate, they're a deliberative organization. What that means is slow. But regulators never move as fast as industry most of the time, unless there's something negative happens and then that bubbles to the surface and causes more immediate action.

Justin Prochnow (25:00):

Well, let me talk a little bit about one of the topics that I know always is an interesting one. Obviously I've come out and spoken along with my friend Todd at Venable and Kim Pearson on some of the regulatory legal panels at some of the annual meetings. And the topic of CBD and hemp always comes up, because of course it's ubiquitous through all industries, although I would say I'll be curious to hear what you think on the pet side of things. There's definitely been a drop-off after the initial surge at the end of 2008 when the Farm Bill was passed, and it kind of opened the floodgates a little bit. Certainly 2019 was the year of hemp and CBD, and then all of a sudden COVID came in. That kind of slowed the role on everything a little bit.

(25:53):

And now we've really kind of seen it settle down into the companies that are really both feet all in on hemp and CBD because the FDA has declined to enact any legislation specifically on CBD and passed it off to Congress. Most mainstream companies have just said, "It's just not worth it to us with this being such a gray area." So it's really filtered back to the companies that that's what they do for a living, is they do hemp and CBD. But it's very popular in pet products, especially for anxiety. You see all sorts of products related to anxiety from fireworks or from being left home alone and things of that nature. Where is NASC currently on hemp and CBD in animal products?

Bill Bookout (26:50):

Yeah, let me back up a step and thank you for being on the legal panels at the NASC annual meeting. You're always a real value add, Justin, and well respected in the industry and a go-to guy in this area for Food, Drug, and Cosmetic Act laws, so I just want to personally thank you for our relationship over the years and your support of the organization on the panels and so forth.

Justin Prochnow (27:14):

You read that email I sent you perfectly, Bill. Thank you.

Bill Bookout (27:20):

I do what I can.

Justin Prochnow (27:21):

I appreciate it.

Bill Bookout (27:23):

So you're right, in 2018 when the Farm Bill hit and CBD kind of got a [inaudible 00:27:29] hold and so did hemp and it took off, a lot of people misinterpreted that they thought it made all the products legal and it really just legalized the growing of the agricultural commodity. So I provided testimony in FDA's public meeting in 2019, and in that meeting, FDA said ... and this is pre-COVID, which set everything back and kind of derailed it, but FDA said it's going to take them a couple of years to come out with any kind

guidance or definitive information on hemp and CBD. And I said in my testimony in '19 that the industry can't wait for two years, because we're in a state of really nebulous existence.

(28:14):

So I said at that meeting, which I think it was the end of June, first part of July, something like that, I said to the representatives at CVM, I said, "We are going to come back to you, FDA, in December, and we're going to present to you what we believe is a responsible path forward for both hemp and CBD in products that are not intended for nutritional benefits, but it's going to be limited to only non-human food chain animals."

Justin Prochnow (28:44):

It's been pretty clear it seems that AFCO has taken the position, and most state departments, that they don't want hemp and CBD in animal feed.

Bill Bookout (28:54):

Yeah, that was the original position. And I was on ... I'll give you a little inside baseball. I was on a meeting one time with AFCO, I think it was an ingredient definitions committee meeting, and hemp is proceeding through the ingredient definitions process right now, but again, it's a slow and deliberative process. So I was in on this meeting and there was a whole bunch of regulators on the meeting and they said, "Well, we need to start taking action." AFCO had a position statement on hemp, on approved ingredient, but it really rests with the states to take enforcement action. And they said, we need to start taking enforcement action. And that was ... I'm just ballparking it, but I think it was 2021. And I said in this meeting, it was a whole group of people, I said, "Listen, I should probably keep my mouth shut, but I just can't be quiet anymore."

(29:44):

I said, "You guys are kidding yourselves if you think you're going to go out there and just start taking regulatory action and these products are going to come off the market and everything's going to be fine." I said, "The consumer demand is too great, the industry has developed too significantly, there's too much economic impact, and the political charge is too significant. So we better figure out a way to deal with these products because they're out there, and if you try to take a strong heavy enforcement hand here, all you're going to do is create a black market industry. States are going to go out and start passing legislation at the state level to allow these types of products to be marketed in the states. And some of that's already happened. You're going to have a hodgepodge of different regulations, inconsistency, and people on the animal side are going to turn to human products, maybe from dispensaries that are not provided by responsible animal companies, and they're going to guess at what to do.

(30:43):

They're going to self-diagnose, self-treat, be educated by Dr. Google, and you're going to actually wind up hurting the exact animals that you say you want to help. So really, that's kind of a little bit of a deviation. We went back to CVM in 2019 and presented what we thought was a responsible path forward. So we have labeling guidance, testing guidance, GMPs like we do for all of our other products. Hemp is percolating its way through the animal feed approval processes now, and hemp can and will show benefits as a fiber source or through hemp seeds, essential fatty acid source. And these will eventually happen. It won't happen as quickly as people want it to, necessarily, but CBD on the other hand, FDA said because of some of the research that they had is they were always concerned about safety, potential liver complications.

(31:39):

We talked to FDA and we said, "Listen, in all the data I've ever seen, I've never seen any data that would support CBD as a nutritionally beneficial ingredient. Meaning maybe some nutrients that are required as a part of daily vitamins, minerals, or to help sustain life and have a complete balanced diet, I've never seen any research that supports CBD as a nutritionally beneficial substance." So we said to FDA, "What do you need?" Because these products are in demand, the market is growing. And they said, "Well, safety is our big concern." So we commissioned through the NASC board, with the support of our members, a long-term safety study. What does that mean?

(32:23):

The FDA said, "We want to see a 90-day study." So we commissioned a safety study on CBD in 32 dogs. We had CBD-A, CBD-G, CBG, and a control group, the carrier was MCT oil, that was a 90-day study with a two-week washout period, so it was really 104-day total, that evaluated animal consumption at once a day being administered at five milligrams per kilogram body weight of the animal, assessing the risk or safety. And that study came out very positively. We had press releases on that.

Justin Prochnow (33:00):

That was the one we talked about in May?

Bill Bookout (33:03):

That's right. Yeah, that's right. The study is ... I can't say too much about it because it has been submitted for peer review, but we did have a press release that summarized that. So we positioned CBD as any other botanical extract that's beneficial that you see out there all the time. CBD is a naturally occurring substance in cannabis sativa L. So if you have a naturally occurring botanical extract that can be beneficial for a non-nutritional purpose that we've demonstrated is low risk, as many other ingredients that are being marketed today.

(33:42):

There's 1400 ingredients out there, Justin, that are marketed in these types of products. And about 800 of them are approved or defined as being nutritionally beneficial, common ingredients that we know of every day: glucosamine, chondroitin and MSM, CoQ10, SAM-e, stuff like that, but it doesn't mean that thousands of animals die or are injured or harmed by these products. So that involves all the other things that substantiate quality conduct in an industry: process control, supplier qualification, good solid raw materials, post-market surveillance, adverse event reporting, limitation on claims. Nobody is out there curing everything from parvo to cancer.

Justin Prochnow (34:29):

Right. I mean, you generally take the same position as you would for a drug product that you can't promote these products to diagnose, treat, cure, or prevent the disease, or it's going to be viewed as a straight animal drug?

Bill Bookout (34:47):

That's right. Yep. And if you mention any disease, and that's under 201G1B, as you well know, either overtly stated or implied, then that can be violated and the company could receive a warning letter. And I subscribe, as I know you do, to warning letters. You get them every week. And you can learn a lot about what the agency is thinking by subscribing to the warning letters and reviewing those. But you're right, our box is defined as supporting the normal healthy structure and/or function of the animal.

Justin Prochnow (35:21):

I think you raised a good point, which is for the most part, the FDA ... look, they've got a lot of stuff to worry about. And the reality is animal supplements aren't at the top of their list. With other things that they've got got going on, now they're even focusing on cosmetics with the new Modernization of Cosmetics Act, MoCRA, coming out last year and starting to be implemented. I mean, they're stretched thin. So for the most part, the action that the FDA has taken has been when there's, as you indicated at the beginning, safety issues, whether it's, again, aggressive disease claims where it's noncompliant or when there's contaminations. There've been some salmonella contaminations of products from time to time or some undeclared ingredients, but the reality is, I would say the biggest focus on supplements and even animal food has been from class action plaintiff lawyers.

(36:31):

And how much do you get involved with companies if they get one of these letters? And if you go back through all of our episodes, I've probably mentioned class action plaintiff lawyers at least once in each one, because it's one of the biggest issues that companies putting products out on the market face is it might be regulatory compliant, maybe it's low risk, but am I going to get a letter from some class action plaintiff lawyer wanting to get some of the money I made? How much interaction do you have with those, or do you then direct them to a knowledgeable attorney who might assist them?

Bill Bookout (37:12):

That's exactly what we do. So we don't get involved in substantiation of claims, even if they're a structure function claim, which would be within the allowable box from FDA as being regulatory compliant. But as you well know, the law extends to truthful, not false and misleading to the consumer in any particular. So you've got potentially FTC, but more often a plaintiff lawyer that questions substantiation of a claim. So companies need to have and be sure that they can back up with reasonable scientific data that they can substantiate the claim for the purported benefits that they make on their products, even if they are within the structure function boundaries.

Justin Prochnow (38:03):

So I guess maybe that's a good [inaudible 00:38:06]. When someone sees the NASC seal on packaging, what does that mean that the NASC has done? How do you get an NASC seal?

Bill Bookout (38:17):

Yeah. So you can't just pay your money, join NASC, and use the seal. To join NASC, you have to have a direct interview with either myself or Chief Operating Officer Ryan Cargo to ... first of all, we want to be sure that we can help you, that your products fall under the scope of what we address. And secondly, that the company is willing to comply and abide with our guidelines. And that includes labeling, formatting, claims, good manufacturing practice standards, vendor qualification if they don't manufacture the product directly, having SOPs that do provide oversight and structure for the processes that they are directly responsible for in their company, and then entering their products and ingredients in our adverse event reporting system for post-market surveillance and risk monitoring and management through adverse events.

(39:12):

So companies have to pass the hurdle of joining NASC, you're willing to comply with our requirements and also that we can actually help you, but you can't use the NASC seal until you implement all of our systems and pass an independent audit. So that audit would be similar to any other audit that you see

from an independent auditing body where we verify the company has actually implemented what our requirements are, and we check that. So we operate, like Ronald Reagan said years ago, trust but verify. So it means that the company has been reviewed and in compliance. A lot of times companies make a mistake and I say, "Do you have a written quality manual?" And they say, "Well, no, but our manufacturer does," because a lot of pet companies are not fully vertically integrated and don't manufacture their own products, but it's the supplier of record, meaning the purveyor of the product that's responsible for really everything that happens, whether they directly perform that operation or depend on somebody else to perform the operation, like manufacture the product for them.

(40:20):

They have to qualify that vendor and they're going to have things that they're responsible for, like labeling, claims, to how do you take an order, how do you fill an order, release criteria for batches that are manufactured. So you want to be sure that your manufacturer is performing all the operations that you expect them to be and that they're following the CGMP. So we say, "Do you have a written ..." so you have to have a written quality manual. God forbid you ever had a recall. That's the responsibility of the company. So written quality manual is required for every company, because they're the supplier of record. Ultimately anything that happens that company is responsible for, as you know.

Justin Prochnow (41:04):

So to get the seal, I assume that there's occasionally some companies who might have the seal and then divert from the NASC guidelines and guardrails.

Bill Bookout (41:21):

Yeah.

Justin Prochnow (41:21):

I assume that there's a process of revoking the seal.

Bill Bookout (41:25):

There is.

Justin Prochnow (41:28):

How does that happen? When does that happen?

Bill Bookout (41:30):

Yeah, that hasn't happened very often, but it has happened occasionally. I'll give you an example. There's a contract that companies sign when they join NASC that's a code of conduct document. So these are the rules of the road that apply to everybody, and it's been vetted by legal counsel and everybody's held to the same standards. So we also independently test products. So we had ... and I forgot what the ingredient that we were testing for, but we had a company that was a longtime NASC member, audited member, had the seal, and came up significantly light of label claim on the product.

(42:09):

So we sent them a letter and we said, "Listen, there may have been something happened that you didn't realize. Could have been a mistake. We wanted to bring this to your attention, and we need a written investigation and corrective action on what happened because you're 78% of your label claim and that's

not acceptable." And they sent us back a note and said, "We're not going to give that to you. We think you're getting in too deep in our business and that's out of the scope." And we said, "Listen ..." if I can summarize in one word why NASC has been successful and why we have a positive relationship with the regulators of the positive relationship that we do, it's one word, Justin, credibility.

Justin Prochnow (42:50):

I was going to say, I knew it was going to be credibility or integrity. Yes.

Bill Bookout (42:54):

That's right. That's right. So in that particular case, they said, "We're not going to give you written corrective action. That's our business and you're getting too deep in our business." And we said, "Then you're no longer a candidate for NASC membership," and we terminated their membership. And then there's a process. They're using the seal, they have a certain amount of time to get it off all their packaging materials, website, any references. So we're serious about it and we walk our talk and integrity and credibility are two really solid words that I think apply to the organization that we live by.

Justin Prochnow (43:31):

Well, look, I mean if you're going to sell the existence of it to the FDA and to others, it's not just going through the things, but it's also demonstrating that if there are people that go outside of the lines, that you're not going to allow that either. Again, as you said, going to credibility, because otherwise -

Bill Bookout (43:52):

I'll give you another example that happens that we don't throw people out for. Any company can make a mistake. Let me give you an example. Somebody gets a new ad agency or they get outside of the claims box. That happens sometimes. And sometimes it's an honest mistake. Somebody makes a claim that they shouldn't make. Well, in the industry, you get the majority of the industry, you kind of develop watchdogs. Everybody else watches everybody else and keeps them within the same boundaries. So if something gets brought to our attention, we call the company up and say, "Hey, you're probably not aware of this, but you need to change this because it puts you at risk and it's outside of the boundaries in our guidelines." And usually companies, they didn't know about it. They got a new person, turnover. So we're not ... I mean, we're reasonable people and we're also business people, that we try to help companies be successful without them feeling like they're trying to win the marathon wearing ankle weights.

(44:56):

But we've never had an NASC member, an audited member receive a warning letter from FDA. And we've never had any significant regulatory action, even from FDA inspections that have been conducted in companies participating in our industry. So we haven't had any negatives with the regulators, even though you're right, technically the category, we're under enforcement discretion. But I think, again, based on results ... and I always credit the regulators. Without the help and support of the regulatory agencies, both state and federal level, we wouldn't be where we are today. So that's why I think that we're a really good model. Am I biased? I certainly am, but I think based on results -

Justin Prochnow (45:49):

It's a good coexistence. As we wrap up, is there any one particular topic that you've been hearing a lot from members or an issue that ... obviously, again, for a number of years it was hemp and CBD, and

that's always there, but is there another one that you think is either on the horizon or that you're dealing with now that's going to be a big thing here in 2023 and maybe 2024?

Bill Bookout (46:18):

Well, I think the market shifts are ... COVID really propelled and changed the entire marketplace. It really elevated the eCommerce channel much higher than anybody ever anticipated, and much more rapidly than anybody ever anticipated. So I think with the five primary channels to market, those things are shifting. ECommerce is growing more rapidly than any of the other channels. Some of the other channels like pet specialty, the small mom and pop pet specialty stores are becoming more stressed. So I think there's some things in the marketplace that are going to change. From a regulatory standpoint, I don't see any big regulatory landmines that are on the horizon that would disrupt the industry. And again, I think based on results. I don't that based on subjective opinion. I say that based on results. I think our effectively working with the regulators and implementing responsible programs in the industry over the last 20 years have really paid dividends. I think that the pet industry will continue to grow. I don't think we'll have the robust growth as we saw in the COVID era of where we grew at 10-20%.

Justin Prochnow (47:38):

Everyone had their pet's home every day, and everyone that didn't have a pet bought a pet. So there was a huge increase both in attention and ... I was talking with someone before, there are lots of people out there who are willing to pay just as much and maybe more than their human participants at home. So certainly COVID, obviously a terrible thing, but definitely there are some industries where just by the nature and circumstances of what happened it caused huge increases in things. And I can see just pets in general, but the pet industry also suffered a big boom right after that.

Bill Bookout (48:24):

It did. So I think the growth in the pet industry, as you alluded to, I think people will cut down on things for themselves before they'll cut down on things for their pets, for their dogs and cats. Horse industry, it's not true. The horse industry is more susceptible to economic downturns -

Justin Prochnow (48:40):

Sure.

Bill Bookout (48:41):

- than the dog and cat side. Bigger animal, more expensive overall, farriers and things. But I think growth and the outlook for the industry is pretty solid on the dog and cat side. I think the economic stresses can affect the equine side more so than the dog and cat side. But I don't see any big landmines. Something's going to happen with hemp and CBD in the future. It just can't go on as it exists today. So what's that going to look like? Nobody knows exactly, but I'm confident that there's more and more data, at least on the animal side that shows that CBD within certain limits is not a high risk substance for dogs and cats. That won't be true on the livestock side. And hemp, and I don't think CBD will ever make it on the production animal side, meaning human food consumption, but hemp will certainly go through the processes and eventually be approved there. So I think those are some things that'll break in the foreseeable future.

Justin Prochnow (49:48):

Bill, if people want to learn more about NASC or even potentially join, how do they get in contact with you and the NASC?

Bill Bookout (49:58):

Sure. My email address is B.Bookout@NASC.cc, or our website is animalsupplements.org. So either one of those two work, or you can call. Telephone number is (760) 751-3360. My extension is 101.

Justin Prochnow (50:25):

And all that information I assume is on the website as well.

Bill Bookout (50:28):

It is.

Justin Prochnow (50:29):

Well, Bill, can't thank you enough for joining me. As we said, we've been on a lot of panels. You've moderated a lot of panels I've been on, so kind of fun to be on the other side of things here and to really hear some great information. We appreciate the efforts you've made to keep "animal supplements" as a thing to be available. And the real efforts you've made to do that I think have been a big plus for the industry. So we thank you for that. And we thank you for participating today.

Bill Bookout (51:06):

I really appreciate the opportunity, Justin. Always a pleasure.

Justin Prochnow (51:09):

Thanks for joining us today. If you enjoyed the episode, please like it on your various social medias. And if you didn't, as my mom used to say, if you don't have something nice to say, don't say anything at all. Thanks, everyone.