



Podcast Transcript

Left to Our Own Devices

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Rubenking: Thank you for joining us for another episode of BakerHosts AD Nauseam, a podcast series focusing on new and trending advertising issues with an emphasis on the FTC and the NAD. I'm Randall Rubenking, and you're listening to BakerHosts.

We are once again joined by Amy Mudge and Daniel Kauffman, two partners from BakerHostetler's Advertising, Marketing and Digital Media team. Together, they have decades of advertising experience and approach advertising issues from multiple perspectives. On today's episode of AD Nauseam, Amy and Daniel are back to discuss health cases involving medical devices and FTC rulings. With that, welcome to AD Nauseum, and let's turn it over to Amy and Daniel.

Kaufman: Welcome back to AD Nauseam, your first stop, we hope, for all things advertising law related. And today, we're going to talk about some of those health cases that don't quite involve pills and creams, but fall into that category of devices or things

similar to devices. There are, of course, very specific definitions of what is considered to be a device, but we're not going to get too worked up over that definition for today. And we have seen many an FTC device case or device-adjacent case over the years, and some of them are really quite interesting.

Mudge: Daniel, you're chill today. Not getting worked up over definition, I love this new Daniel. I'm usually the one that is like, oh, you know it is, we can squint and get there. Alright. I mean, we are going to dive into the FTC. We're not going to dive into the FDA particularities of what is a medical device. But I do like to see you calm, cool, and collected there.

I did, I will tell you, I did pooh-pooh this topic when Daniel brought it up. But then, of course, he reminded me that we could discuss QRay bracelets, and I was all in. In honor, of course, of one of our favorite 80s bands, maybe Daniel's favorite favorite, the Pet Shop Boys, we're going to call this podcast Left to Our Own Devices. Which is the title, of course, of a particularly wonderful Pet Shop Boys song. But they're all really wonderful. That one was from 1988, and it was on their Introspective CD. Kind of sure Daniel wasn't thinking about QRay. He was just excited to do this podcast on devices when he came up with that awesome name. And I do got to give credit where credit is due, sir.

Kaufman: The name comes first, totally agree with you on that, Amy. So, look, I know we have both seen the Pet Shop Boys many times live. I remember my first time seeing them. I was living in Boston in 1991. It was a few years after I graduated college, at the Orpheum Theater. It was amazing. So, Amy, let's talk Pet Shop Boys a little bit.

Mudge: I don't remember if I saw them in the 80s or the 90s. A lot of those decades are kind of a blur to me. I also will say, I did not have as much disposable income back then. So I did not see as many concerts when those bands were in their heydays. I'm a big concert goer now, as you know, and seeing a lot of the retro tours. But I did see the Pet Shop Boys in DC in 2016 at a great local small theater. And then they did this awesome show with New Order that was supposed to happen over the pandemic, and it actually did come to town in 2022.

Kaufman: So, I didn't see the New Order show, but I saw that one in 2016. We weren't working together then, but I totally remember going to that specific concert. It was pretty amazing, but...

Mudge: You were there? Where were you sitting?

Kaufman: Yeah. Oh, way up front. I don't go to that many concerts, but when I go, I go well.

Mudge: Oh, I was in the back. I was in the back.

Kaufman: Okay.

Mudge: I was loud and having a good time. That was one where you could buy your drinks and bring them in with you and goodness knows I was.

Kaufman: Favorite Pet Shop Boys song?

Mudge: So, I do, this is kind of lame. But I'm going to go, I think the cover of the Willie Nelson song Always On My Mind is, I mean, it is really good. I would put it up there as one of, if not the best, covers of all time. Probably the popular songs if we want to go, I really love Love Comes Quickly. I like the self-loathing, what have I done to deserve this? But, you know, since I just adopted two wonderful dogs, I've also always loved their I Want a Dog song.

Kaufman: All good ones. Yeah, I've got so many favorites. Look, I love the Opportunities (Let's Make Lots of Money) song. I remember singing that lot.

Mudge: Let's make lots of money. Sorry, I won't sing.

Kaufman: And then, this is probably one of my favorite songs with the best title that I think any group has ever come up with, but You Only Tell Me You Love Me When You're Drunk. And I just think it is such an evocative title, and it is such a great song. Not a cheerful song, to be clear. But one of my favorites.

Mudge: I think you could listen to that song followed by I Want a Dog...

Kaufman: Yes.

Mudge: ...and then together they have, well, yes. I really love that we, or you, brilliantly designated this the Pet Shop Boys episode. Please, to all of our loyal listeners, download, if you do not know this band or if it has been a while since you've heard them, download their greatest hits album and listen to it after you finish this podcast.

But, ad law calls, and let's get back to those device cases. And let's get back to that bracelet that was all the rage about two decades ago, the QRay bracelet. It was featured in program-length commercial, 30 minute infomercial. Those were all the rage, ubiquitous back then. And ads then had touted this C-shaped metal bracelet as ionized. And it was ionized through a secret process that gave it pain-relieving abilities. And the infomercials, of course, featured a lot of consumer testimonials. I'll do a few dramatic readings for you. Such as, I wore it last night and in 24 hours all of my pain disappeared from my arm, my hip, and my shoulder. We also had someone who'd actually had knee replacement surgery, I believe it was both knees.

Kaufman: This is my favorite testimony, I have to...

Mudge: And you know, which is, I think Daniel, you and I have not been there yet. But I'm sure it is coming for us, and I've heard this is not a fun surgery. But apparently, this person put on the QRay bracelet. And they literally said, after I put on the QRay bracelet, everything changed, it was as if a miracle of sorts happened. So, pretty strong claims and also claims that the pain relief qualities were substantiated with scientific testing. And, for starters, because of the intended uses for this bracelet, it was of course considered a medical device. And the FTC has, of course, jurisdiction over such devices.

Kaufman: And this was back in the days we saw a lot of FTC cases focus on infomercials and this one did not go unnoticed. Huge sales. The FTC kicked off the litigation in 2003 by seeking and successfully obtaining a temporary restraining order with an asset freeze and eventually the case gets to the Seventh Circuit.

Mudge: Asset freezes were, I mean, that is the Big Mac Daddy of...

Kaufman: That is serious stuff.

Mudge: Very, very serious. But before the appeal, which we'll talk about, there is a very strong District Court decision, with the FTC having a complete win on all counts. And the Court entered judgment for \$87,000,000. Okay, that is more than 20 years ago, \$87,000,000. If the identical case was filed now, directly in federal court, money would not be an option. But the FTC would more likely go the administrative and then the federal route to allow for money. But I digress. This case actually went to trial. And after a seven-day bench trial, the Court found that the defendants made the challenge claims and establishment claims. And perhaps not too surprisingly, found that the pain claims, like ones that QRay made, were not adequately substantiated.

Kaufman: And notably, the Court points out there was a placebo-controlled study that was conducted by a really well-known clinic that showed that the bracelet and the control bracelet both did improve pain symptoms.

Mudge: The bracelet actually improved pain.

Kaufman: As did the control bracelet, exactly. They both improved it and there were no differences observed between the groups. I will say, I've done pain cases in the past and pain is susceptible to a placebo effect. The court also does go through all of the substantiation that was produced and really, this serves as a reminder that when it comes to substantiation, quality is a lot more important than quantity. And there is a lot of studies that the court goes through and quickly discounts, really based on a lot of expert testimony proffered by the FTC and contrary testimony that was not persuasive.

Mudge: Right. And ultimately, the court ruled here that the claims made here, pain relief claims, for those, you need competent and reliable scientific evidence. And here, there should have been a well-conducted, placebo-controlled, randomized, double-blind study. But the Court does note that if the defendants had not made such strong claims, they wouldn't have had to achieve such a gold standard study. They said, look, the Court, that you know, you can say the QRay bracelet will look cool on your wrist. But I'm sure they wouldn't do that because their sales wouldn't have been through the roof with claims like that.

Kaufman: Yeah. And, of course, the court also finds that any placebo effect that might be attributed to the bracelet, as we were talking about, doesn't cut it as substantiation. And this is a principle that comes from an earlier litigated FTC case called *Pantron*, which involved a baldness cure and the placebo effect there.

Mudge: There was a placebo effect shown in a baldness case?

Kaufman: Kind of fascinating. The strength of rubbing something on your head, I guess, will cause your body to produce a little bit of hair. I don't know, something like that.

Mudge: Alright, Daniel, go find a song from a band we love about baldness, and we're going to come back and we're going to have that. We're going to have that podcast.

But look, in fairness, I actually did think that that advertiser in that case had a great run at really saying, come on, there is pain relief here, and shouldn't I get credit for the placebo effect? And I, again, I thought those were good arguments to try. I think they pushed them as far as they could go. But the answer was a resoundingly no, you are not going to get credit for a placebo effect.

But what makes this case even more significant is the appeal to the Seventh Circuit and the infamous decision from Judge Easterbrook upholding the lower court's decision. The defendants complain of the gold star standard that they were held to, and the Seventh Circuit compares QRay's strong claims to claims for an adhesive bandage with a disinfectant. There, the seller doesn't generally have to conduct tests because the bandage keeps out foreign materials and the disinfectant helps prevent infection. Although, of course, you start making some strong claims there, be careful there too. But those kinds of claims are based on well-known scientific principles. For the bracelet, however, the court describes the statements about how it works as, yes, quote-unquote blather, and notes that proof is what separates an effect new to science from the swindle. And they call on the test on which they relied, called it bunk.

Kaufman: It is such an entertaining decision. And they also, of course, discount the testimonials as not adequate. And note that, another quote here, that is why the testimonial of someone who keeps elephants off the streets of a large city by snapping his fingers is the basis of a joke rather than proof of cause and effect. It is such a great decision, really colorful.

Mudge: Always worth a read if you want to read an ad law case and you need a giggle. But another thing that is quite interesting, really, I come back to it, is that discussion of the placebo effect. And the Seventh Circuit actually was a little bit more reserved than the District Court, and some might say surprisingly. I'm going to read a pretty long quote here, but it is a good one.

We appreciate the possibility that a vague claim along the lines of, this bracelet will reduce your pain without the side effect of drugs, could be rendered true by the placebo effect. To the extent that we were skeptical of language in that other FTC baldness case, suggesting that placebo effects always are worthless to consumers. But our defendants advanced claims beyond those that could be supported by a placebo effect. They made statements about QRays, ionization, and bioenergy that they knew to be poppycock. They stated that the bracelet remembers its first owner and won't work for anyone else. The list is extensive.

Kaufman: Amy, we got to use the word poppycock more often. I feel like we are at that age where we can start using the word poppycock.

Mudge: With a British accent is even better, Daniel. You start practicing that. But I guess, I will say that I think that, so I get, I love the discussion of placebo. But I've never seen this endorsed. I think we can be very clear. If you cannot separate your medical device's efficacy from a placebo, you cannot make claims.

Kaufman: Could not agree more. But let's talk about a different kind of bracelet. It is one that purports to get rid of pesky bugs. And although this is technically not a device because of the claims at issue, who would have thought we would get to talk about two bracelet cases?

Mudge: You know I love jewelry, Daniel. We could talk all day long.

Kaufman: And this is really good jewelry. The case, it is from 2015, *ViaTek*, and the product was a mosquito shield band.

Mudge: Well, very different claims here. I guess slightly related to the pain would be the annoyance of mosquito bites. And the company stated that consumers could place the band on their wrist, their ankle, on their belt, their stroller, their walker, and keep those pesky mosquitoes away. And that it was, ready, scientifically proven to repel mosquitoes. And in blogs, it was noted that the West Nile virus is spread by mosquitoes.

Kaufman: Certainly encouraging people to make the purchase for that reason. And the complaint specifically challenges the notion that the bracelets would, create a vapor barrier that protects or prevents any person within five feet from being bitten by mosquitoes. But Amy, something else about the case is particularly interesting administratively.

Mudge: Yes, indeed. This was an order enforcement case. The complaint notes that 10 years before the FTC had entered an order against some of the same parties. And the conduct at issue here, in the more recent case, allegedly violated, not just the FTC Act, but also the old order. So, the FTC could have sought penalties. Something as we know, post-*AMG*, that is particularly important because the FTC now really needs to rely on things like older orders to get money. But ultimately, that case settled about a year later and the company paid I think a couple hundred thousand dollars in redress.

Kaufman: Okay. Well, let's move on away from bracelets for today and get back to another definite device, hearing aids.

Mudge: What? Huh?

Kaufman: Not falling for that, I'm not falling for it. Okay. So, we have a company marketing the MSA 30X Sound Amplifier through ads that the FTC in 2018 alleges that the company claimed that independent testing showed that you can hear up to 30 times better with their device.

Mudge: 2018, was this when you were running the place over there? Close to it?

Kaufman: I was Deputy Director, definitely helping a lot to run the place, put it that way. I had a Bureau Director, I was his deputy.

Mudge: Alright, okay. Okay, alright. So, this device itself though wasn't, I don't know all the ins and outs of this. I'm sure I'll learn soon. It wasn't technically a hearing aid. It was marketed as a rechargeable wearable sound amplifier product, alright? And this predated the introduction of over-the-counter hearing aids. And there was a footnote in the complaint that notes that the ads had a pretty inconspicuous disclaimer that stated, MSA 30X device is not a substitute for a hearing aid or intended for use by hearing-impaired people.

Kaufman: Which is certainly inconsistent with what the ads were showing, needless to say. And the FTC challenged not just the 30-times claim, but again, also that claim that independent studies proved that it would help users hear up to 30 times better. The case did settle, very large judgement that was ultimately suspended, based upon the ability to pay, to about half a million dollars.

Mudge: Alright. And our final case for the day involved an app. Now, an interesting thing about medical devices, and this really comes from how the FDA defines them, which, as Daniel promised, we're not going to get into too much of those particulars. But you can have a thing that is a medical device based on how it is advertised, and that same thing can also not be a medical device, depending on how it is advertised. So, this is one of these kind of neat cases that the words you choose and the claims that you make really go to defining what you're selling. So of course, not all apps are medical devices. But when you promise an app will cure, treat, or prevent a disease or a condition, boom, becomes a medical device.

So, there have been lots of times when apps have been considered to be devices, and this one was an app that purported to measure blood pressure. Not a bad idea, and quite helpful if you don't have to have one of those bulky devices with you. The company, however, marketed a downloadable app where you could input information about yourself, then you can place your finger on the device and against your chest, and this would purport to provide you with accurate blood pressure results.

Kaufman: And the ads showed people using their phones to test their blood pressure. And of course, no cuff was required here. But because this is an FTC case, I think we all know where this is heading, with the complaint noting that studies demonstrate clinically and statistically significant deviations between the app's measurements and those from a traditional blood pressure cuff.

Mudge: Also worth noting, there were some allegations about review shenanigans. I understand that the CEO purportedly left a great review on the app store but failed to disclose his connection to the company. That, of course, today would violate the consumer review rule. And the great Jessica Rich, who was Bureau Director at the time, noted in the press release, while the Commission

encourages the development of new technologies, health-related claims should not go beyond the scientific evidence available to support them.

And suffice to say, the NAD gets its share of medical device cases as well. There have been a few years where there were tons of cases involving claims for braces. Over the years, there have been lots of cases involving air purifiers. And this is another idea where depending on how you market the products, can or can't be medical devices. We've seen bandage cases, hearing aid cases, thermometer cases. All of these cases very closely follow the same requirements that the FTC has laid out, competent and reliable scientific evidence. And we know this is going to continue as what I call the FTC takeover of NAD continues with the new director, Phyllis Marcus, who spent a lot of time at the FTC, who will be joining us on our next podcast.

Kaufman: I am so excited to have Phyllis on our next podcast, totally looking forward to that. So, Amy, we've got four very different cases, lots of health and health-adjacent claims, but some other related issues as well. What should be our takeaway today?

Mudge: Alright, let's go for three takeaways. First, just because you aren't ingesting it doesn't mean you can be lax with your substantiation. Health claims come in all forms, and the FTC's health claims guidance document applies to all of them. Second, also good to remember that the FTC will also expect even better substantiation when you claim that a product is scientifically proven, clinically tested, or anything like that. Alright? General health claims also require good substantiation. But those establishment claims, where you set the bar for what you have, are even more so. And finally, innovation and creativity is awesome, but you've got to make sure that your claims are ahead of the science.

Kaufman: And get ready for a podcast with Phyllis Marcus coming up soon, too.

Mudge: Don't forget to go listen to the Pet Shop Boys now.

Kaufman: Thank you for joining us at AD Nauseum, really appreciate it.

Mudge: See you next time.

Rubenking: Thank you, Amy and Daniel. If you have any questions for Amy or Daniel, their contact information is in the show notes. For more information on the latest developments in ad law, visit our ADventures in Law Blog at www.adventures-in-law.com. And check out all AD Nauseum episodes by subscribing to BakerHosts wherever you get your podcasts. As always, thanks for listening to BakerHosts.

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