



## **Ep. 17: CBD, THC, FDA – What You Need to Know About Cannabis and Its Regulation**

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**Jose Garriga:**

Hello, and welcome to *OnAir with Akin Gump*. I'm your host, Jose Garriga.

With the advent in a variety of states around the U.S. of medical marijuana programs, of marijuana decriminalization initiatives and of legal marijuana, cannabis is, in the public eye, traveling from forbidden narcotic to mainstream recreational and medicinal substance.

Running on a parallel track and outdistancing the psychoactive variety of cannabis in popularity and use is CBD. Many people who would refrain from smoking a joint at a concert are readily turning to CBD products that range from balms and ointments to tinctures to sprays, teas, candies, shampoos, soaps and sparkling water. Despite its popularity, however, questions remain as to the legality of CBD's sale, use, and transport as well as to how CBD is being regarded by the federal government's regulatory agencies.

We have with us today Akin Gump health care and life sciences partner Howard Sklamberg. Prior to joining the firm, Howard served in a series of high-level positions at the U.S. Food and Drug Administration culminating in his role as Deputy Commissioner for Global Regulatory Operations and Policy at that agency.

We'll be discussing the legal landscape for marijuana and hemp in the U.S., FDA's regulation of CBD products and where state law regarding the use and sale of CBD fits into the equation.

Welcome to the podcast.

Howard, thank you for appearing on the show today.

**Howard Sklamberg:**

Thank you for having me.

**Jose Garriga:**

Let me start by sharing a story I saw last month on national evening news. Two women, one in Texas, one in Florida, both identified as “grandmothers,” were arrested as they tried to board domestic flights. As it turns out, in both cases they were arrested for possession of CBD oil. Although both were eventually released, this points to a real disconnect, I think, between what the public views as legal, acceptable behavior and how the laws and regulations actually read on the books.

So, let's start by giving listeners some background. What is CBD? How does it differ from THC, and how is it produced?

**Howard Sklamberg:**

The vocabulary in this area is a bit complicated, so I'm going to talk a little bit about the botany first, which is hardly my expertise. We start with the cannabis plant, and the cannabis plant or *Cannabis sativa*, you can divide that into two categories. One category is marijuana, which has concentrations of THC of generally 5 to 30 percent, and another you can put in the category of hemp, which is THC concentration of 0.3 percent or less. THC is tetrahydrocannabinol, which is, if someone were smoking a joint, it's the stuff in the joint that makes you high. THC is, if you are in states that have legal recreational marijuana, for example, and you had a marijuana brownie, it would have THC in it. Cannabidiol, or CBD, can come from either the marijuana plant or the hemp plant. Cannabidiol itself is not psychoactive. It's a chemical, a cannabinoid, a class of chemicals that are in those plants. They do not have the psychoactive effect, so they're not going to make you high, but they have certain other effects.

And one of the effects is, it's in an approved drug called Epidiolex, went through the FDA approval process which is a drug that treats epileptic seizures, particularly severe type of seizure that some children have. But CBD can be either from the marijuana or the hemp plant, which ends up being legally important because the hemp plant itself and hemp are no longer controlled substances as of the end of 2018, no longer a **federal** controlled substance. CBD that is derived from the marijuana plant and, thus, is from a plant that has more THC in it, still is a federal controlled substance, which makes it per se illegal.

And I can add in one other category, hemp. So, people think of CBD, and it's often sold as CBD oil. So, you can have CBD oil from marijuana, which could be a controlled substance; you can have CBD oil from hemp; and you can also have hemp oil, which does not have CBD in it, but comes from the hemp plant. And hemp oil, you can find in many specialty supermarkets and the like as just an oil.

**Jose Garriga:**

A cooking oil.

**Howard Sklamberg:**

Yeah, without the properties of CBD.

**Jose Garriga:**

Okay. So, is that the primary difference in the way CBD is treated under the law, particularly I'm thinking of the federal Controlled Substances Act, or are there other ways in which it's considered differently?

**Howard Sklamberg:**

When you talk about the legal status of CBD, the classic legal answer: it depends, and it's complicated. So, two legal answers. First, I will say that there are a wide variety of state regulations and laws governing CBD. So, in some states, CBD, wherever it's derived, is still a controlled substance. Some states

follow more like the federal rule—I'm not going to go through all 50 states here—but, federally, if CBD is marijuana-derived and has a concentration of THC of more than 0.3 percent, it remains a federal controlled substance. Marijuana-derived CBD is what you will find in state medical marijuana programs and that sort of thing.

So, what is the federal legal status of that type of product? And again, I'm speaking generally, I'm not offering a legal opinion without looking at the specific product. Well, controlled substances, the possession and distribution of controlled substances is illegal and, in fact, a serious crime, generally speaking. The enforcement posture of the federal government has been, really since the second Obama administration, abstaining from using federal enforcement under the Controlled Substances Act if CBD or marijuana is dispensed pursuant to a state medical marijuana program. So, if a state has CBD that's a controlled substance, and doctors are dispensing it pursuant to that program and in compliance with the rules of that program, it is technically federally illegal, but the policy is not to enforce federally, and policy is in a couple of categories.

In the Obama administration, there had been a formal memorandum called the Cole memorandum, which said it is DOJ policy not to. Attorney General Sessions revoked that memorandum. But Attorney General Barr said, at his confirmation hearing, this is not really a priority of ours. There has not been enforcement in this area with one exception I'll get to.

The other is, there is language in the DOJ appropriations bill each year since 2014 or 2015, it used to be called the Rohrabacher-Farr Amendment—Rohrabacher's no longer in Congress—but it prohibits DOJ from using funds to take enforcement action that would interfere with the state medical marijuana program, which would make it hard for DOJ, in fact. The exception in enforcement in this area is when there are CBD products, whether they're marijuana- or hemp-derived, that are making outlandish claims of curing diseases. So, FDA has taken some enforcement action: They've issued warning letters—and they're on FDA's website—for various CBD products that claim to cure cancer or Alzheimer's. The idea there is that there's no evidence of that, and those are fraudulent products. And FDA has continued to say that's a priority.

With hemp-derived CBD, the status is even more complicated. Hemp-derived CBD is no longer a controlled substance, so you don't have to worry about the federal Controlled Substances Act, but you may have to worry about state ones depending upon what state you're in. But hemp-derived CBD, a lot of folks—and you can find it on the Internet—are selling it as a food additive or dietary supplement, and you can walk through the streets of lots of cities that have a lot of CBD products. You'll see it in coffee; you'll see it in gummy bears. And the legal status of that is, it's not a federal controlled substance. However, FDA's position is that, under the Food, Drug, and Cosmetic Act, CBD is an illegal food additive and, without getting too much in the weeds, so to speak—and that was not an intentional joke—without getting too much in the weeds, CBD is not “generally recognized as safe” or GRAS, which is also not intended as a joke. Also there's a provision of the Food, Drug, and Cosmetic Act that makes it illegal to have a food additive that contains an ingredient in an approved drug. And, as I mentioned before, CBD is an ingredient in an approved drug.

Now, some in the industry have legal arguments and disagree with FDA on those positions, but, broadly speaking, FDA's view—and they've announced this on their website, and their commissioners announced it—is: CBD is an illegal food additive. Getting back to your initial question from a long time ago, and forgive the monologue, it's illegal, but again, CBD in foods, there has been very, very little enforcement in the domestic industry. So, FDA's position is it's illegal, but it's not been an enforcement priority. For importing CBD, which you go back to the example you were talking about, it's a little different because, when something is in domestic commerce, FDA has the ability to just say, "We have limited resources, and what are we going to concentrate on, and we can't do everything." And they make these types of decisions all the time. Products in some way, shape or form are often in violation of some regulation or another, and [FDA] look[s] at what the public health significance is of the particular violation and what it means for FDA's regulatory systems and stuff like that.

When it's an import, and FDA comes across the product, sometimes they're in a position, whether it's FDA or it's Customs or it's some other enforcement agency at the border, to make an affirmative decision to allow it to enter the country, which, from the perspective of a regulator, is a bit different, so it's a little complicated. Sometimes people will ask a question, is something illegal? If someone said to me, "Is the possession of cocaine illegal?" Well, that's easy. Yes, for a million reasons, and there are not many loopholes one can come up with for that. If you asked the question about hemp-based CBD, I would have to ask you, how is it being used? How is it being labeled? How is it being marketed? What's its intended use? and a whole bunch of other details. And the answer might be, FDA thinks it's illegal, but it also doesn't think it's an enforcement priority. It may be, in some instances, like cosmetics, that it may not be illegal, or FDA has not asserted that hemp-based CBD used in cosmetics is illegal; double negative there. They've not said it's legal, but they've not asserted that it's illegal. And, so, it's quite complicated depending upon how it's marketed.

**Jose Garriga:**

So, the question then is, you mentioned that they look at it as something that is illegal as a food supplement. If you're taking it, for example, as some people do as a balm or an ointment, you rub it on if you have muscle aches, or if you're taking it as a tincture as an anti-inflammatory, at that point does it cease to be a food additive and become more of a supplement or a drug?

**Howard Sklamberg:**

This would be wonderful for a law school exam question for food and drug law. The question as to what something is under food and drug law goes to its intended use and considers how it's marketed. So, if you are selling—an easy question—you're selling a food product that has CBD in it, obviously the CBD in there is a food additive, right?, whether it's a drink or something else. If you're selling CBD in some other way, maybe just as the oil, it would depend what its intended use is. If it is, less of a chance, let's put it that way, that FDA would consider that illegal. If you're talking about something you're going to apply to your skin, you have a bunch of other questions that are asked. So, how is it marketed?

If it is marketed in a way that the application of it to your skin, the claim is going to be that it is going to cure some condition or disease—psoriasis or something like that—that would make it a drug, and it would be illegal as a drug because if you claim to cure disease, you have to be an approved drug. If it is making

merely cosmetic claims—and I don't know the exact words for cosmetic claims; basically makes you look better—then it would not be a drug, it'd probably be a cosmetic, and you'd have a strong argument for it being legal. So, a lot depends if someone goes in this market, there's different amounts of legal risk here depending upon how the product's marketed, what exactly the product is, how it's derived.

**Jose Garriga:**

That's interesting, and it certainly sounds like there's just so many different ways in which the cat can be skinned, so to speak. I'll remind our listeners that we're here today with...

**Howard Sklamberg:**

It's in pet food, too. That's a whole other issue. *[laughter]*

**Jose Garriga:**

We're here today with Akin Gump partner and former FDA official Howard Sklamberg discussing CBD, its legality and its regulation.

As we discussed, you can find CBD in everything from chocolate to soap, and it's also being sold by some of the largest retailers in the U.S. You can certainly find it online; you can find it in stores. So the question is, then: Is CBD's widespread popularity outdistancing federal regulators' attempts to control it?

**Howard Sklamberg:**

It's always challenging as a regulator when you have a situation where there is widespread use of a product. You believe that the sale of a product is violating some rule, but it doesn't present too high of a public health risk. Because, for an agency like FDA, there's a question of resources. You know, FDA's budget is incredibly complicated. FDA's budget has user fees for drug applications, device applications. In the food area, though, it has very few, and it's congressional appropriations. And it's used to keep seafood safe and spinach and melons and processed food. And does FDA want to divert resources from those endeavors to CBD foods?

The *[CBD]* industry grew in steps, I would say. I was Deputy Commissioner from 2014 to '17. And it grew, basically, with some of the recreational marijuana legalization programs: Colorado, Washington state being the first two recent ones. And then it was steadily growing in that period along with the medical marijuana programs where you had marijuana-derived CBD being used in some states; Colorado would be one of them.

And then as hemp was no longer a controlled substance because of the farm bill that got passed in late 2018, that's caused this whole thing to just escalate dramatically. The agency has indicated that it is wanting to take steps to regularize this. What I mean by "regularize" is FDA can adopt a regulation if it wants to, that would allow CBD to be a food additive even though it's an active pharmaceutical ingredient. That can be, depending upon exactly how they do it, it can be quite a lengthy process. But if they were to do this—and they had a public meeting at the end of May where they talked about this—they've indicated we have to know a whole bunch of other questions. We have to know, how can it be marketed? Should there be limits on concentration levels? What about children? What kind of manufacturing standards should there be? And, ultimately, if it is regularized, and there are standards that are set, FDA is then going to have to come up with an enforcement program for it, inspections and all that. So, it's a complicated process.

**Jose Garriga:**

Stepping back a bit, what should listeners take away, then, regarding legal risk and CBD production or distribution?

**Howard Sklamberg:**

The first question I would ask, and we get questions like this from people, from the investor community sometimes, from people just saying, "We're not doing this now, but other companies are, so why shouldn't we do it?" And everything in between, all kinds of variations of this.

And I would say that the way I've been answering this is, first of all, I can't give you a 30-second answer that this is illegal or this isn't. Now, you may get an answer that it is, like in the case of food containing CBD, it is a situation in which the regulator believes you are violating the law. At the same time, the regulator has not given you a green light to do so, but the regulator has not taken a lot of enforcement action in that area, particularly if you're not making outlandish claims or if you're not endangering the public, the product isn't contaminated or something like that.

So, I think it depends on a bunch of things. One is the particulars of the product, where it comes from, how it's marketed. The other is who you are. If you are a big institutional player in your industry, and you don't want to be in a position of violating the law or, at least, taking steps that the regulator thinks are violation of law, you might not want to do that.

If somebody has a food truck, and they have CBD in it, or a gas station, those folks take more risks. And I think it depends what posture people are in, and, obviously, we are never counseling people to not follow the law. But sometimes—we don't have food truck clients and the like who are doing this—but sometimes you have situations where it's somebody connected to one of these clients, or they're thinking of investing in an entity that may think of doing this in the future. So, they have to weigh all these questions, and sometimes it involves lots of different areas of expertise. It involves someone like me in our food and drug practice. It might involve people who have investor clients who know those areas and know what the various rules are for this sort of thing.

**Jose Garriga:**

Thank you. Listeners, you've been listening to Akin Gump partner Howard Sklamberg. Thank you, Howard, for sharing your knowledge and insights into this very hot, very relevant topic.

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