[00:02] HUSEIN: This is Episode 89 of Lawyered. I'm Husein Panju. And on this week's episode, we're chatting all about the changing rules involving psychedelics and other controlled substances featuring lawyer and leading expert David Wood. First step, we'll chat about a landmark new decision, as Alberta has become the first Canadian province to regulate the use of psychedelics for psychotherapy. We'll break down the mechanics of how this regulatory framework operates, as well as how federalism issues and psychiatric wait times may impact the overall accessibility.

[00:38] We'll also speak about a new federal court ruling about the ability of healthcare practitioners to obtain psychedelics through an exemption for their own professional use. And this ruling is prompting new questions about whether clinical trials are practical alternative for the real thing. Later, we'll also discuss new amendments to Canada's Special Access Program that will allow practitioners to request psychedelics and other previously restricted substances under certain conditions.

[01:05] And finally, in our Ask-Me-Anything segment, we will relay the questions submitted by our listeners, about a range of topics including mushroom retail shops, psychedelic guides, and alternative approaches to a Western medicalized structure. All that and lots more is coming up in just a bit. This is Lawyered.

[Music Break]

[01:33] HUSEIN: Hey, everybody, welcome to lawyer. Thanks for joining us for another installment of our podcasts. I know I say this every year, but I'm still finding it hard to believe that we are now nearly done this season for the year. We're about to wrap up Season 9 in two weeks-time. So, I'll be doing another roundup as I normally do on that episode. But I didn't want to say for now. Thanks so much to everyone who stuck around for this season. I'm very happy with how it's has gone far, I think we've got a great range of guests, both in terms of geography and ideology, and subject matter.

[02:08] I got a lot of great feedback, not just from the guests themselves, but from a lot of listeners, I got a lot of new listeners as well. So, thanks to everyone who's made the season so special. We will be starting up next season, of course, in just a couple of months-time for season 10. A suggestion I got which I will be implementing is we're going to be having a forum on our website for people to submit suggestions for guests, who they want to hear, whether that's yourself if you want to be a guest. Or if you know if someone or a particular topic they think can be a good fodder for the episode or the upcoming season. I'd love to hear it.

[02:44] I will try to get input from as many sources as possible. And I figured that having a forum that's really handy on the website might be a good fit. So, keep an eye out for that. And of course, if you ever want to reach me, LinkedIn, Twitter, email, I make myself as available as I can on as many platforms as

I can as well. Our last episode was really fantastic, it was about the area of crypto law. Our guests, there was a lawyer named Sohaib Mohammad who is based out of Ottawa. He spoke about a number of topics there. We talked about Mareeba Injunctions, which is a fancy way of saying asset freezing orders. And we were talking specifically about how that applies to cryptocurrency.

[03:24] We also talked about enhancing investor protection for websites or platforms that actually allow for the sale of cryptocurrency, talking about how those mechanisms can be improved, there's more strict guidelines that are being introduced as well. My favourite topic in the episode was talking about a recent or ongoing case and that case involved the alleged theft of certain cryptocurrency tokens. And the defendant in that case will be arguing a Defense known as Code is Law that is essentially saying that the program code in a system is considered the law. And that if there's a breach of that code, or the ability to undermine the code that is considered lawful.

[04:10] A really fascinating topic and one that I don't think a lot of lawyers would have predicted a couple of decades ago, or even a couple of years ago. And we'll see how viable that defense is. But it was really interesting to break that defense down, in terms of first principles, as well as what it means, at a practical level for lawyers, whether you're practicing in this area or otherwise. Also, you can expect a lot of insightful comments in the Ask-Me-Anything segment, one of them I really came across, which was interesting, is that our guest was actually involved – and we talked about this in the episode.

[04:44] He was actually involved as representative of a plaintiff to initiate and secure what was then the first judgment that found that an NFT AirDrop can be affected as a form of service. So, it's really cool to chat with a lawyer who was very instrumental in this very new and niche growing field and I encourage you to check it out whether or not you know about this era because cryptocurrency is largely becoming part of our day-to-day vernacular. That's Episode 88—you can find that in our archive.

[05:19] On today's episode is about a topic that was triggered largely by popper demand, we're going to be talking about Psychedelics Law. And if you haven't looked around online or elsewhere, this is largely becoming very much a popular topic of discussion. And we talked about this at the beginning of the interview, that it's very much having a moment in terms of a revolution, similar to how popular psychedelics was in the 60s and 70s.

[05:49] This was a topic that was suggested by a number of our listeners. And so I found a guest who is very well versed in this topic, and you'll hear that he not only has a PhD in biochemistry, but he's also very much ingrained in the industry and the space as a lawyer. He's got a real passion for advancing and progressing the maturation of the Canadian global law in particular area and then this comes across in the dialogue that we have. So, it's really interesting topic, I'm really excited to share this

episode with you. And so without further ado, here is our psychedelic episode featuring our guests, David Wood.

[Music Break]

[06:30] HUSEIN: David is a lawyer and Patent Agent who divides his time between an in-house position as General Counsel and Chief Legal Officer at Psygen Industries Ltd., and his private legal practice, R-Group Legal. Psygen is a contract development and manufacturing organization focused on GMP manufacture. And he's also a licensed dealer authorized to manufacture LSD, MDMA, psilocybin, psilocybin, psilocin, DMT, 2-CB and mescaline.

[07:00] And in both his in-house role and R-Group Legal, David provides intellectual property, regulatory and commercial advice. And in addition to other clients in psychedelics and cannabis, R-Group Legal provides pro bono support to Psygen Industries Ltd., which is a nonprofit supporting patients and physicians in accessing psilocybin and advocating for psilocybin access. And David also holds a PhD in biochemistry, and a bachelor's degree from the University of Saskatchewan. So, David, thanks for joining us on the show today.

[07:27] DAVID: Yeah, thank you very much for having me, Husein. I'm happy to be here.

[07:32] HUSEIN: Before we get to the questions, I wanted to get your take on where we're at right now, in the psychedelic landscape. When I think about psychedelics, like a lot of people I think of the culture of the 60s and 70s, where arts and music were heavily influenced by psychedelics, as they're typically known. But now, in 2023, and even very recently before, and we've been seeing a lot in psychedelics in the mainstream discussion as well. So, tell us more about where we're at right now and what this resurgence on psychedelic revolution is.

[08:05] DAVID: I'd be happy to. So, a big departure from what was happening in the 1960s was that until the late 60s, psychedelics were prohibited in most US states and Canada, and were prohibited federally in the US till the 70s — till 1971. So, that being the case that they were viewed in a very different way, culturally, and so from a cultural perspective, just very, very different. Whereas now, I mean, I grew up with the idea that LSD was bad, and the people that used it were bad, and everything about it was dangerous, that that was a very different perception than someone back in that time would have had.

[08:45] So, that said, with respect to commercial activity, I think where we're at now is that in the face of mounting evidence, primarily driven by one nonprofit, and one nonprofit turn profit, the work that those two companies, Maps Public Benefit Corp and Compass, have demonstrated respectively with

MDMA, and psilocybin shows a lot of evidence for efficacy. And there are many, many groups that are right now working with Classical Psychedelics, as well as New Chemical Entity Psychedelics that are patentable, to bring these products to market and use them in supportive psychotherapy for mental health conditions. Because you don't have to try very hard online to understand that mental health is a bit of an issue right now.

[09:30] HUSEIN: And is this something... I don't know if there is an official timeframe of when the current revolution started. Is this something you could have predicted years ago that would be in this particular period in terms of psychedelic use and discussion?

[09:44] DAVID: Well, I'll never know if I could have predicted it. It was so outside of what I considered possible, let's say a decade ago, that I didn't even give it enough time to reflect on and be able to predict or not. It just seemed over the horizon wherever it was. And then I started working in cannabis a lot in 2016. Once I started working in cannabis a lot, this topic came up pretty quickly. And I became alive to psychedelics as well. So, I've had a pretty focused view on this for the last five, six years. So, it's very hard for me to say what I would have predicted back then, but likely answer no,

[10:30] HUSEIN: It makes sense. So, we got a number of topics to speak about in this area of psychedelics, which I think are all through reflection of the changing attitudes and also changing positions on regulation as well. So, the first topic we're going to speak about is Alberta's regulation of psychedelics. Last fall in October of 2022, Alberta became the first Canadian province to regulate the use of psychedelics for therapy. And these regulations are aimed to ensure the safety and medical oversight of patients seeking treatment with substances like psilocybin, also known as magic mushrooms, LSD and ketamine.

[11:03] However, these regulations are drawing mixed reactions from those in the space with some question whether this will meaningfully improve access for those who need the most support. So, David, before we get into this new regulation itself, can you just provide a brief context about what we mean when we talk about psychedelic-assisted psychotherapy?

[11:23] DAVID: Sure. So, psychedelics, as most people understand induce profound changes in consciousness, temporarily. And there's increasing evidence that with psychotherapy, some of those changes are not the acute changes where people experienced visual phenomenon, or what we'd say, as directly under the effects of a drug, not that but the change in perspective that can accompany it might be sustainable and permanent with psychotherapy, or at least faster than it would be without the psychedelics. That's kind of the evidence.

[12:00] But LSD was first discovered in 1943, on April 19th, by Albert Hoffman. And it was not long before in the early 50s, it was being used by psychiatrists in experiments. And then later in the 50s and 60s at length by psychiatrists and psychologists in support of their psychotherapy. And essentially what it means is, psychotherapy is a process very rarely is psychotherapy, a one-time affair, for most people, it goes on for periods of time to accomplish a goal.

[12:32] And the way psychedelics are used in psychotherapy is in the middle of, say, a six-week program, you might use a psychedelic one or two times, maybe a week or two apart. And I think the really important part of the therapy is what precedes and follows the use of a psychedelic.

[12:58] HUSEIN: Is part of the benefit to help increase awareness of the patient in the process?

[13:05] DAVID: I think that's part of it. Yes. Now, I'm not a psychotherapist. But that said my educated understanding of it is essentially psychotherapy is generally about getting past something trauma related, or making some habit disappear, or a new habit up here like effecting some sort of lasting change in yourself. That's generally the goal of psychotherapy. And psychedelics, which generally and here's where... this is a general trend, there seems to be some sort of link between neuroplasticity and a lot of psychedelics.

[13:42] But the point is that for one reason or another, it seems it use of psychedelics in the context of psychotherapy, which will mean a day of using psychedelics at high dose, with psychotherapy, the following day being especially important for integration seems to accelerate the change we're trying to achieve.

[14:00] HUSEIN: So, as I mentioned, the Alberta has been making these headlines about becoming the first province to regulate psychedelics for therapy. And this took the form of a new regulation. So, can you just give us a very short summary of what this regulation says?

[14:15] DAVID: The MHSPR, the Mental Health Services Protection Regulation is an it's a regulation that's been around for a long time, but Part Four was just added, which is psychedelic-assisted psychotherapy services. And what that part does, is it defines psychedelic drug services. And it defines activities in relation to psychedelic drugs that are regulated in a specific way. And the broad way of describing regulated in a specific way would be to say, if you're a service provider, like a clinic, that includes professionals who practice medicine and practice psychology, then you need a license if you're going to use psychedelic drugs in the provision of those services or otherwise.

[15:20] And there's some very specific rules around ketamine. Those differences are a result of the fact that ketamine already is used for anesthesia. But generally speaking, if psychedelic assisted

psychotherapy, which is called out specifically as a subset of psychedelic drug treatment services is provided in the clinic, or other psychedelic drug treatment services are provided, then the clinic needs a license, a special psychedelics license.

[15:51] In order to have that license, the clinic needs to have a psychiatrist as medical director. And every physician who prescribes has to be a psychiatrist, or has to work in close association with a psychiatrist. And it's not just the psychiatrist. It's the psychiatrist who's passed criteria relevant psychedelic assisted psychotherapy training, and using psychedelic drugs in therapeutic settings.

[16:18] HUSEIN: Can you tell us more about the role of psychiatrists specifically? I know this is an issue that should attract a lot of debate or discussion about the need or specific requirements for psychiatrists in this context.

[16:29] DAVID: Yes, we have regulated health care professionals in this country and in this province. And we put the highest level of faith on the depth of understanding the working knowledge, and the full appreciation of the complex factors at play when you're treating someone's healthcare. In physicians, they're at the top of the expertise scale in health care, delivering health care day-to-day with patients, using psychedelics, clinically, is an interesting phenomenon. It's got an interrupted history. So, we don't really have a modern body of practice. But I say don't really because we do have a modern body of practice. It is just unusual. And I'm really referring only to physicians that use psychedelics in their practice, in compliance with the law.

[17:25] HUSEIN: This issue about having these psychiatrists being specifically called out in the regulation is also flagging some concerns about how this ultimately may limit access to therapy. What do you think about that?

[17:37] DAVID: Yes, it will. It will limit access, and perhaps that's a design and perhaps that's a flaw. The physicians in Canada that have experienced working in compliance with the law with psychedelics are not all psychiatrists. However, outside of exceptions, I would say that if you took the average doctor who has zero real focus on or interest in psychedelics, the ones best equipped to understand it, probably psychiatrists. I mean, they think about the human mind, psychedelics affect the human mind. And in a perfect world with infinite access to physicians, probably everyone would talk to a psychiatrist for psychotherapy.

Now, there is one thing that mitigates this today, psilocybin, MDMA are the ones that are the furthest advanced in clinical trials, but neither of them is approved. So, the amount of people who be accessing it with or without this additional regulation in Alberta, it's going to be small either way. So, this bottleneck, it might be more of a federal bottleneck right now, because drug products are regulated

federally, drug products, including MDMA, as well as drug products, including psilocybin, neither of those is approved for sale. So, at the federal level, there are no products to prescribe.

[18:51] HUSEIN: So, this is partly like a federalism issue, in terms of what regulations can take meaningful effect?

[19:57] DAVID: To the extent that what you mean is there are federal as well as provincial issues? Yes, products federal, practice of medicine, provincial. In Alberta, a physician, a psychiatrist because he or she has a license at a clinic to practice psychiatry, and they have an Alberta MHS PR license so that they can work with psychedelic drugs therapeutically. And let's say they decide their patient would benefit from psilocybin. They would file an application with Health Canada—a federal entity—for authorization to receive and use psilocybin in accordance with criteria that they establish.

[19:39] When I say they establish, I mean, the physician establishes in their application to Health Canada, saying why their patient is a good choice for psilocybin or MDMA. And I'm saying those two because again, there's the most data for them. If Health Canada says yes, then the practitioner who would have named manufacturer, when the doctor receives authorization, then the manufacturer will send it to the physician. And then the physician will be able to administer it to their patient or hand it to their patient for their patient to administer to themselves, however you look at it.

[20:15] And that last part is also federal, because you need permission to possess controlled substances. And there's an automatic permission given, it's called a Subsection 56(1) Exemption for MDMA or psilocybin used in patient. Any other restricted drugs would need their own exemption. That's the federal part. Anything that happens once it reaches the physician, that would be provincially regulated. So, the way psychedelics are treated in Alberta is with the most detail, you need a specific license, but I'm sure every college will have something to say about it in the next 12 to 24 months.

[Music Break]

[21:00] HUSEIN: A recent federal court case is shaking the psychedelic community. And as promised some new questions that engage regarding the standard of review, as well as policy matters regarding care. This decision relates to a specific exemption that's available under the Controlled Drugs and Substances Act under Subsection 56(1), and may influence upcoming case are in the same area. So, David, before we get into this decision, can you give a description on what we talked about when we mean Section 561 Exemption?

[21:30] DAVID: Yeah. Subsection 56(1) Exemption under the Control Drugs and Substances Act is an authorization that the minister can provide on application to a person who wants to engage in

activities with controlled substances. So, a default use case for this would be a university, or a private entity wants to do an experiment on animals, let's say or on tissue culture of cells with a psychedelic drug, they ask for permission. Health Canada says yes, they receive the psychedelic drug, they put it on their tissue culture, they get their data, they dispose of the rest of the drug, they document everything, everyone is happy. That's a normal Subsection 56(1) Exemption. As we'll talk about in the case, an unusual one was under review here.

[22:20] HUSEIN: So, the case we're talking about here, the case name is *Toth v. Canada (Health and Addictions)*. And the citation is 2023, FC 1283. And we'll put the hyperlink on our website, as always. And so as you mentioned, David, this case involved healthcare practitioners who applied for the same exemption. Can you give us a summary or short summary of the underlying facts here?

[22:44] DAVID: Absolutely. So, I advise the group TheraPsil on a pro bono basis, I was not retained specifically for this, and I'm not counsel of record on this decision. So, I'm obviously respecting my client's confidentiality, but I'm not counsel of record on this decision. Toth essentially was a group of health care practitioners who asked the Office of Controlled Substances—the DEA version of Health Canada, to use American jargon – for permission to possess psilocybin, and to consume it for training purposes.

[23:20] In the past, in late 2021, Health Canada did give authorization to 19 health care practitioners to do so. So, that a reasonable basis to expect some success, they were unsuccessful in their application for an exemption – the health care practitioners. So, they brought the decision for judicial review to the federal court. Essentially, they believe the decision was inappropriate, the decision to say no health care practitioners, I the Office of Controlled Substances declined, giving you permission to possess psilocybin and to consume it for training purposes.

[23:55] HUSEIN: And then how did the federal court decide on this issue?

[23:57] DAVID: Yeah. So, court decision was these physicians could get what they're looking for through a clinical trial. Therefore, there's no reason to review this administrative decision.

[24:10] HUSEIN: So, there's another remedy that's available for them outside of this exemption, is that right?

[24:13] DAVID: Correct.

[24:15] HUSEIN: I know that this decision has been getting a lot of attention. And so what do you think? What are some of the impacts that psychedelics lawyers are thinking about coming out of this court decision?

[24:26] DAVID: The way I see it, it makes sense for the Minister to follow a checklist. And it makes sense for the Crown or for the federal court say, well... and I mean, the trial division because they look at the facts, they look at the laws as it is and they apply that law. And unless the law can be proven to be wrong, and that's is its own bar to get there. Then they apply it as it is. And in this case, I mean, the judgment is correct. The judgment says that there is an alternative. That alternative is called a clinical trial.

[25:07] Now, that judgment ignores the practicalities and the cost of a clinical trial. It's also to me in a real live discussion point as to how appropriate clinical trials are to train doctors, or other healthcare practitioners. Clinical trials that answer medical questions. The exemptions were not requested so that a medical question could be answered. The exemptions were requested so that physicians and other healthcare practitioners would understand without the social baggage of having to confess contravening the CDSA so that they could understand what they're about to recommend other patients.

[25:54] HUSEIN: This exemption, Subsection 56(1) exists for a purpose. But I'm curious that how do you think this decision might impact future applicants who are requesting the use of this exemption to get access to these drugs?

[26:09] DAVID: I believe it would only impact future applications for access to psilocybin, specifically for training purposes. I don't think it would have any impact whatsoever on someone requesting access for a university project on cell cultures.

[26:30] HUSEIN: Okay. And is there like a specific test that the government does to warrant that exemption?

[26:35] DAVID: Well, yeah, the whether it would cause a public health hazard or diversion of a controlled substance, that kind of thing. But generally, they just say, the evidence, the argument you've made isn't enough? There's better ways, there's better ways might be the answer a lot of the time.

[26:55] HUSEIN: So, based on what you're saying, I imagine if there is an alternative, regardless of how practical it is, that will supersede that exemption, is that is that right?

[27:05] DAVID: I think so, especially where the goal is human consumption, because I'll be clear, what was being proposed would be that the health care practitioners would source the psilocybin from I believe the term used is "trusted source". So, to be clear, that's someone who's contravening the law by possessing and distributing psilocybin, that's their trusted source. Now, I think we all know that that person could be very trustworthy and reasonable of course they could.

[27:32] But it's interesting that these health care practitioners are willing to put their reputation out there saying, "Look, I believe in this so much, that I'm willing to go talk to someone who's distributing this illicitly and source it there. Because I trust that enough to do this for my patients to do this, so that when an 80-year-old, who's traumatized and is dying, wants to make the most of their last nine months on Earth, I can tell them, truthfully, I've done this before. I know what you're going to experience. I don't want to color your conception of it. But if things get difficult, trust me, I know what you're going through. Please talk to me. I can relate. Because I I've actually taken twice as much as I'm giving you before". Isn't that better than the physician saying, "Well, I've never done this. But my iPad says".

[28:32] HUSEIN: Like "I've read about this in books"?

[28:34] DAVID: Yeah, this is not like taking an SSRI. This is not like taking an antibiotic. This is an experience people describe as mystical or religious. And there's evidence behind that. This is special. And everyone who uses these see what's special. I don't mean it's clinically special. I mean, the experience is special to most people that have it. The patients deserve that this be done thoughtfully. And it's important that we get it right and that we get the correct number of people access to it.

[29:05] HUSEIN: This case may be appealed higher. But assuming that this is the definitive law in this area, how do you think this might impact those practices in this area?

[29:16] DAVID: It will slow down the full training of healthcare practitioners who are going to be good at using psychedelics therapeutically. If these drugs are as efficacious, as the data suggests they are and being a rational person with a PhD in biochemistry, I believe the data, then there's going to be demand. Now, most physicians are pretty risk averse. Most physicians probably aren't just going to waltz into having people show up at their office, traumatized people doing high doses of psilocybin and hang out on their couch for eight hours, and then come back the next day for psychotherapy.

[30:05] That takes different types of infrastructure, different types of skill sets, different types of teamwork, everything about that's going to be different than a lot of other types of medical practice. So, for it to go out at scale, we need trained people. And it is an issue and I've worked with clients who

have a strong interest in seeing more people trained in this. And it would be great if there were an easier way to get MDMA and psilocybin, specifically to physicians who want to train them.

[Music Break]

[30:44] HUSEIN: One of the most consequential changes in the healthcare space in 2022 was the revival of Canada's Special Access Program, also known as SAP for restricted drugs, including psychedelics. Now, previously, these restricted drugs can only be authorized for patient treatment, through clinical trials or through narrow exemptions. However, healthcare practitioners can now request access to these drugs on a case-by-case basis for patients with serious or life-threatening conditions, when conventional treatments are either ineffective, unsuitable or unavailable. So, David can you start by telling us a little bit about the mechanics of the Special Access Program, in light of these recent amendments to the Special Access Program.

[31:24] DAVID: The Special Access Program never went anywhere, but in 2013, the Food and Drug Regulations were amended to exclude restricted drugs from the Special Access Program. Restricted drugs is what we use to refer to drugs with no medical use that are controlled substances in Canada. It's what in the US is called schedule one.

[31:43] HUSEIN: Can you give us some examples of what those might be?

[31:45] DAVID: Sure. The ones we're primarily focused on here would be LSD and psilocybin. Psilocybin is the active ingredient in magic mushrooms, along with its less stable counterparts, psilocin, DMT, which is in the plant ayahuasca and I'm including, M-pathogens or however you want to describe MDMA.

[32:10] HUSEIN: Okay, so let's get back to the SAP. What are the mechanics of that?

[32:12] DAVID: Yeah, so through the SAP, when a physician believes that their patient would benefit from access to a drug, the physician can apply to Health Canada for permission to receive that drug, even if it's not approved. SAP is designed for things like rare cancers that affect very few people that are approved in larger markets like Japan, the United States, UK, etc. So, in those cases, a physician will request the drug for on-label use in treatment of said rare cancer, rare genetic disorder. And Health Canada will usually respond within 24 hours saying, "Oh, this drug is approved in Japan and is used 500 times a year, they're no problem. Here you go".

[33:55] However, with the change, to allow restricted drugs to the system psychedelics are eligible for access through the SAP. That said, there are no approved psychedelic drugs for clinical use. If someone

applies for a psychedelic drug through the SAP, Health Canada will look at it and apply the usual criteria, which are: Is there a demonstrated need? Have other treatments been ruled out or had been tried and failed? And then lastly, is there evidence that this is safe? And also same criteria: Is there evidence that there is efficacy?

[33:32] And if those three are good answers, then Health Canada will give access to a product, which is their jurisdiction, so that the physician can execute on the medical choice that they've already made. Which is more under provincial jurisdiction.

[33:45] HUSEIN: What do you think as someone who worked in this area about those being the criteria that are considered?

[33:51] DAVID: I do think they're perfect criteria. This is special access. That's what the program is for. It's not the Psychedelic Drugs Access Program. The Special Access Program was made for drugs, where there is strong evidence that they have safety and efficacy for a condition, such as existing regulatory approval in another country. I mean, that's really as strong as it gets. So, I think it's a great program. I don't think it was custom built for accessing psychedelics, and I don't think anyone should expect it to be.

[34:25] HUSEIN: And do you think that these amendments will have a meaningful impact for patients with life-threatening conditions?

[34:33] DAVID: Yeah, I think they have meaningful impacts for people who have conditions where there's evidence psychedelics might help. And Health Canada – and when I say Health Canada, I'm now talking about the Office of Controlled Substances, have given automatic permission to physicians, not patients, and that makes sense because it's for inpatient use to possess psilocybin or MDMA as long as it's approved through the SAP. To me, it is just an interesting regulatory point because for anyone to possess a controlled substance, the Office of Controlled Substances needs to be okay with it. But for a physician to receive it to give to a patient, the therapeutic products, people have to be okay with it. So, under SAP, you have to get both, because these are controlled substances.

[35:22] HUSEIN: So, we've got these new amendments to the regulation. Do you think that this recent round of amendments will signal something? Whether that's new amendment of the regulation itself? Or do you think this may open the door for new changes on this space?

[35:36] DAVID: Yeah, of course, I mean, the more it's used, the more people are it, the more anything is used therapeutically, the more comfortable people will be with that thing. Psilocybin and MDMA, or other psychedelics are no exception. The more use there is, my prediction is, the more positive

outcomes there'll be, I believe there will be more good than harm. So, that being the case, it'll become popular. And of some of the things about psilocybin or MDMA therapy that evidence suggests are true, bear out to be true and bear to be clinically proven, we're going to see people stop using other medications, we're going to see people back to work sooner, we're going to see people enjoy life more.

[36:20] Which means they might make other decisions that will keep them out of the hospital for other reasons. And I mean, most of the evidence is focused on conditions where trauma is the underlying cause. Perhaps there's people in sub pathological effects of trauma, that aren't diagnosed with anything who can benefit from this. And that's where I think a very interesting future lies is in elective psychedelic assisted psychotherapy. That's not going to be a 2024 thing. But I think if things follow the progression they ought to, it will be something people in the near future can benefit from.

[36:58] HUSEIN: Are there any other legal issues that you think are triggered as a result of these amendments?

[37:03] DAVID: I think the main point here is that there is a way to get your hands on these, that it's limited. There are all kinds of reasons why it's sub optimal for the demand that's out there all kinds of reasons. And that's why there's motivation to bring these things to market. But it's very unusual compared to other drugs for a few reasons, including you have promising evidence with MDMA and psilocybin patenting, each of those is complicated, because they've been around for a long time. So, you got to get more specific than just MDMA or psilocybin.

[37:38] And the more specific you get, the more different ways there are to circumvent your monopoly. So, it's unusual to have an emerging area of pharmaceuticals where the two leading like furthest along trials are for drugs that can't be patented, as unqualified compositions of matter. Beyond that, you also have an area of medicine, where you're going to see out of the pile of money spent on every patient, it makes sense in this case, to get well with MDMA therapy, probably more money should go to the practitioner than to the drug company.

[38:15] Well, I just think the way people use the fact that the SAP exists will change and that gets very creative. It's just the way people use it. I mean, that's kind of with anything with law, right? The opportunity can lie in the creative.

[Music Break]

[38:40] HUSEIN: All right. And to wrap up this episode, we're going to do our Ask-Me-Anything segment with David, on questions submitted about psychedelic law. As our listeners will note, one of

the bonus rewards for members of our Lawyered patreon community is the opportunity to submit questions that they want to hear answered on the show. These can be questions about anything within reason in our guest's area of expertise, so long as they're not asking for legal advice specifically.

[39:04] We always do a call for this questions about a week or so before each recording. So, if you want to learn how you can submit your own questions, and become a patron and get other rewards as well, you can check out our crowd funding website, which is <u>www.lawyeredpodcast.com/patron</u>, for more information. Okay, so David, we had a lot of great questions for this episode. The first question is, "What exactly is legal regarding psychedelics? I've heard that psychedelics can be a tool for therapy, but what's legal considerations are there for waging that and other different considerations across provinces?"

[39:37] DAVID: Yeah, it's a great question. So, second question is easy. Yes, they there are different requirements province to province. Those requirements would depend on the professional college regulating the professional you're talking about here, the physician or registered psychologist or other health care practitioner. The federal level, to access psychedelics, you need authorization from two parties, The Health Canada, Therapeutic Products Directorate and the Office of Controlled Substances.

[40:08] A physician gets permission to receive and use the psychedelic therapeutically with their inpatient for MDMA or psilocybin, merely by applying through the Special Access Program. For use of any other psychedelic that is not already available for prescription. So, anything except ketamine really, any other psychedelic that the physician wants to access or if they want to access psilocybin or MDMA for outpatient use, then they need to apply to both parts of Health Canada; Therapeutic Products and Office of Controlled Substances.

[40:44] HUSEIN: Okay, but for like recreational use, is that something that's legal as of now?

[40:50] DAVID: Well, I don't like the word legal or not. It depends what the Constitution says. But the Controlled Drugs and Substances Act consistent with Canada's UN convention obligations, prohibits possession of scheduled substances. So, if a substance is scheduled like LSD or psilocybin or DMT, than its use outside of authorization to use is prohibited.

[41:17] HUSEIN: Do you foresee that there will be a legalization of psilocybin?

[41:22] DAVID: Neither outcome would surprise me. It would not surprise me if psilocybin become saleable, just like cannabis in the stores. But it's also true that nothing might happen and psilocybin may be only a prescription drug, and never anything more. Neither of those outcomes would surprise me. If I had to bet on one, I'd bet on the former, I bet that at some point, if you're an adult in a country

where you can walk into a cannabis store and buy a product with 1000 milligrams of THC in it, nothing really stops you from reading the whole thing when you get outside.

[41:56] So, that's not going to be less impactful than a normal amount of psilocybin that you'd get from three and a half grams or less Psilocybin Cubensis Mushrooms. So, I guess my thinking on it, is that a sensible policy would be to do it. So, I really hope we do because it's hard to buy psilocybin right now, I do not acquire psilocybin illicitly. But when I went to Vancouver, last I walked into a store that been operating for four years where they were openly selling it. And there are a lot of young people lined up in there. And I got to say, I wasn't worried about any of them. That said, what was happening was clearly a contravention of the Controlled Drugs and Substances Act.

[42:42] HUSEIN: This actually gets to the next question that's been submitted. So, the next question we have on our list is, what do you make of the mushroom commercial retail shops that have been popping up across Canada? And how does this compare to the rise of cannabis retail shops that occurred pre-legalization?

[43:00] DAVID: Any comparison of psychedelics to cannabis on a regulatory level, is playing with fire, you're almost certain to be misunderstood on this topic. Here's my take on it. When there were a lot of cannabis stores in Vancouver, let's say, post 2012, that was when there was a regulated medical way to access cannabis with tens of thousands, hundreds at its end of thousands of Canadians enrolled. That system, sort of if you really twist your mind around, it had a role for these dispensaries in Vancouver, sort of, the MMPR. That doesn't exist for psilocybin, there is no set of regulations through which some people can access psilocybin and that where the stores sort of make sense, it doesn't exist. So, it's really just people contravening the CDSA, and law enforcement choosing not to enforce.

[43:56] HUSEIN: So, what do you think about the decision not to enforce some of these rules?

[44:00] DAVID: I think it's a pragmatic allocation of resources. Because, as a taxpayer, I am not stressed about an insufficient budget going in to controlling rampant use of psilocybin. I don't care when we have far bigger problem. And I think if it was regulated it being psilocybin and psilocin, so that the products could be sold. I believe that there would be less impact on societal harms. The UN conventions are there to prevent social and economic harms of drug abuse. I don't see how prohibition is doing that with psilocybin. And we already have a functional system that sells cannabis products, getting psilocybin products into that system, or into a very similar system would be something Canada's administratively and infrastructure wise and government well equipped to do.

[45:58] HUSEIN: Well, is there a risk though of the authorities cracking down on some of these mushroom shops rather than others, if they're being more selective about which rules they're

enforcing. I imagine there was a risk that they might be also applying them to some players rather than others.

[45:22] DAVID: But of course, it's a risk. That's the thing with prohibiting something, and then not really enforcing, there's selective enforcement. And that can lead into a whole bunch of other problems. That aside, though, I think there's a broader consequence. When you have a country that made cannabis a federally regulated consumer packaged goods, and then you have psilocybin stores online, and in some cities in brick and mortar that just seemed to operate with impunity, and advertise on YouTube and stuff. It's easy as an average person to be confused about what's legal and what's not.

[46:02] Because after all, psilocybin, culturally, gets as much of a pass as cannabis, maybe more. It kind of feels like it's no longer a controlled substance, but it is. And that itself is a bit of a problem, the fact that it can feel that way. If there's a change in policy, are we just going to arrest everyone who talks about this and look on Instagram with AI and take down everyone? What happens when you just tolerate contravening the CDSA for a while, then you don't?

[46:34] HUSEIN: The next question we have is in a very different area. Do you think that psychedelic guides should be subject to professional regulation, analogous to other health professionals? Unfortunately, there's been numerous reported instances of a psychedelic guides abusing practitioners, including in clinical trial.

[46:54] DAVID: A psychedelic guide seems to be whoever believes they're qualified to guide people who are using psychedelics, there don't seem to be any rules. First off, I'm not a qualified as a therapeutic practitioner of any kind. A fair answer to this, you should ask a self-professed unqualified psychedelic guide, and you should ask psychiatrists, and you should ask the psychotherapist. But from a legal regulatory perspective, if you're giving a prescribed service, and in Alberta, at least, this would be to be with someone who is using psychedelics and giving them psychotherapy, like talking to them, you need to be a professional to do that.

[47:37] You could just check on them and get someone. If someone qualified is needed, like a paramedic, or a psychologist, that person who just plays that role, they don't need specific qualification. So, in Alberta, at least there could be a role for a psychedelic guide that way, but they're not guiding anything. They're getting a doctor if they have to. I think the idea of a self-professed psychedelic guide is very dangerous, because if you don't have qualification, then bad actors can just waltz right in and they will and they have and there are examples.

[48:18] If it were a regulated thing, fine. I mean, why would I object to the idea of a regulated psychedelic guide? Do I think it's a huge priority? No. I think when MDMA and psilocybin are available

as prescription drugs, imminently or if psilocybin became available through a separate system, I think we're fine with psychologists, physicians, nurses, people that already exist, who want to do this. They'll get trained up, and they'll work in it like Alberta has sort of positioned itself and built the administrative infrastructure for it.

[48:47] HUSEIN: The last question that we have is, some commentators have suggested that requiring psychedelics to be administered only by psychiatrists follows a Western medicalized structure. Other valid approaches; indigenous, religious or others that could be left behind.

[49:05] DAVID: Yes. And now this might seem to conflict with what I just said about guides. I don't think it does. But in Canada, you have a right to your religious practices. And I think, as a First Nations person, there's evidence that peyote made its way all the way up here to be used. There's evidence that there's psilocybin mushroom use in British Columbia. To the extent that there's traditional use of either of those drugs, I think they should be allowed to use 100% of psychedelic drugs, anything, even two, four or five substituted amphetamines doesn't matter what it is.

[49:49] Because when a First Nation person... I'm not going to use the word in the legislation. But when a First Nations person exercises their right to hunt, they don't use a bow and arrow, like their ancestors did. They use a rifle, maybe with a scope, maybe with a night scope, maybe in their truck. That being the case, if there's any traditional right at all to use psilocybin, then that right to me exists for LSD, MDMA, anything, so long as it's used in that way.

[50:15] Now, I don't think that's therapeutic work. It might be good for the people involved. But I don't think it's therapeutic per se. And that's a good thing. I'm supporting a First Nations practitioner when I say that, because as soon as it becomes therapeutic, it's one of two things, Western medicine that's regulated, like, in a very specific way, or at some sort of First Nations, non-cultural, therapeutic traditional practice, which I think under the eyes of the law would probably be looked at similar to the generally traditional one. Now, that's not my area, that's consistent with my understanding. Anyone who hears what I've said and disagrees, I'd love to talk to you about it.

[51:00] But that's kind of how I see it, as just these three layers, strictly, Westernized use, as you referred to, and then traditional use in a non-therapeutic setting for cultural reasons, which I think should be completely allowed. And then use traditionally in non-western therapeutic ways, because of on my understanding, these substances were used intentionally to heal in those cultures. If I'm wrong, I apologize. But that's the way I understand it with peyote use in the southern US. I don't know how it was used up in Canada. But there's evidence it was moved through trade.

[51:42] HUSEIN: Do you think that there's room for these parallel approaches?

[51:44] DAVID: I think they should both exist, for sure. Yes. Because, if you're going to allow people to hunt and fish outside of season, because of their traditional values, why would you not allow them to interact with nature and their cultural and religious beliefs in the way their ancestors did?

[52:04] HUSEIN: So David, I want to thank you for joining us for this very interesting episode. As you mentioned, at the very beginning, we are witnessing the psychedelic revolution that's happening in real time, so, it is very timely to have this important chat about how these issues are changing in real time. We appreciate your insights and position. We look forward to stay in touch in the future.

[52:25] DAVID: Yeah, likewise, Husein. I think I learned a thing or two talking these topics through with you. You're great at interviewing, and I really appreciated the opportunity. And I'd encourage anyone listening who's interested to reach out to me on LinkedIn. That's definitely the easiest way to get in touch with me.

[Music Break]

[52:52] HUSEIN: And that's going to be a wrap on this week's episode of Lawyered. Thank you so much for listening. Our guest for today's episode was David Wood. You can learn more about him and his practice on his LinkedIn page, as well as on his firm's website, which is located at <u>www.rgrouplegal.com</u>. And for more about today's show, and links for all cases that we spoke about today, as well the new regulations, you can find those on our website, which is www.lawyeredpodcast.com.

[53:18] And our next episode, we're going to be shifting gears to speak about the topic of Workplace Investigations Law. And we'll be speaking with our guests, Christine Tomlinson, who is one of the leading experts in this field and has recently written a book on this exact topic. There are major new decisions in this era, and we're going to be speaking about some new guidance related to workplace culture, the duty of care that's owed to complainants in the context of an investigation, and other factors that may deem investigation to be improper. So keep an eye out for that for sure.

[53:48] And also, if you want help to improve our show, and get some neat and affordable Legal awards, including the opportunity to get early access to our episodes, and the ability to submit questions for our show like you heard today, the very best thing you could do would be to check out our crowd funding website, which is located at <u>www.lawyeredpodcast.com/patron</u>. And if you're not doing so, already, I encourage you to search for the podcast for free on iTunes, from which most people get it or anywhere else you get podcasts as well.

[54:20] You can also follow the show on Facebook, LinkedIn or on Twitter/X. And our handle is @LawyeredPodcast. Our sound editing work is managed by Solomon Krause-Imlach. Our theme music is provided by Ben Swirsky, and our website is maintained by Steve DeMello. And finally, please be advised that while the show always aim to be helpful and informative, that it is not legal advice. However, if you do want legal advice, please reach out to a lawyer directly to help you with your particular situation. And with that, we'll see you back here in two weeks' time for our season finale. And till then, keep it legal.