[Out of Entrance - Blue Dot Sessions]

Stella (00:11) Hi there and welcome back to Carry the One Radio. Today we're talking about something we probably couldn't freely discuss, maybe 10 years ago?

Seesha (00:19) That's right! we're talking about psychedelics and the natural medicine space.

Stella (00:23) And to help shine a light on this, we're joined by scientist-slash-social entrepreneur Dr. Victoria Hale.

Seesha (00:30) Since completing her PhD in Pharmaceutical Chemistry at UCSF, Dr. Hale has worked to develop and increase accessibility to medicines.

Stella(00:38)Dr. Hale has gained expertise in all levels of drug development working in the US Food and<br/>Drug Administration and Genentech.

Seesha (00:46) Beyond these experiences, Dr. Hale created her own path in the area of public health to reduce health inequity.

Stella (00:52) She sure did! She founded the first ever non-profit pharmaceutical company. In fact, she founded two, One World Health, which focuses on parasitic infections and cholera, and Medicines360, which focuses on womens' reproductive health.

Seesha (01:08) In the realm of psychedelics and natural remedies, Dr. Hale serves as a board member on Multidisciplinary Association for Psychedelic Studies or MAPS, a nonprofit drug policy reform organization with the goal of raising awareness and understanding of psychedelics.

Stella (1:24) And, she recently co-founded an ayahuasca tea company called Sacred Medicines, which she's going to tell us all about.

Seesha (01:32)

To learn more about how psychedelics are making a comeback and being used in the mental health space, what it's like to found a health innovation company with a psychedelic compound, and the societal and political changes surrounding the psychedelics and natural medicine space, Stay Tuned!

[CTOR Tag]

Stella (02:02) Hi everyone, I'm Stella.

Seesha (02:04) And I'm Seesha. Today we're going to be talking about research in psychedelics. Let's introduce you to our guest, Dr. Hale.

Dr. Victoria Hale (02:10) My name is Victoria Hale. I live in San Francisco. Pronouns are she and her.

Stella (02:18) Dr. Hale's work has an important mission: medical accessibility.

#### Dr. Hale (02:22)

I'm a social entrepreneur and a scientist. It's not only the medicines that I develop, but also the business models that are really important to me. One of the underlying currents in my work is making sure that these medicines are accessible and that generally means affordable, right, for people around the world. I've worked in infectious disease and reproductive health, and now focusing primarily on mental health, but also some diseases of aging.

The numbers of people impacted by the work that I do, I want to be very large. It's not about the profit or the returns or the blockbuster nature, if it's not a blockbuster in terms of numbers of people for me. So what truly are unmet needs, and what needs are other people addressing, and then I just walk away from those because those will be taken care of.

Seesha (03:25) But, as we'll see, Dr. Hale has held many different positions before landing in her current career!

# Dr. Hale (03:30)

I always knew that I wanted to make medicines, let's say from ... I was less than 10 when I knew how important medicines were. But how I would do that exactly has changed and shifted and it still does. So, I have a PhD from UCSF in pharmaceutical chemistry, and instead of the traditional postdoc route, I went to FDA for five years, and it's a great place to see how all kinds of companies develop medicine.

Seesha (04:02) A post-doc is short for post-doctoral. This is generally a 3-5 year position that's completed after a PhD, usually in a lab at a university, but also sometimes at a company, like Genentech. After completing a post-doc, people can take a variety of different career paths. Let's hear where Dr. Hale ended up.

# Dr. Hale (04:20)

I had an opportunity to move into management and I knew that working in the government was not, let's just say, aligned with my spirit, okay? So, I came back to California, spent three years at Genentech.

So, I have an executive role in a couple of different companies. I've co-founded and I'm co-CEO of an ayahuasca tea company, which we can talk about and then there'll be one or two others that I will serve an executive role in.

Stella (04:46) Quite the journey, am I right?

Seesha (04:48) Totally, I'm excited to hear more!

[Kid Kodi - Blue Dot Sessions]

Stella (05:00) I gotta say, I am SO stoked to get started! Dr Hale was so much fun to interview and boy, did we cover a lot of ground.

Seesha (05:08) I hear you! But before we jump in, I think we should take some time up front to lay down some definitions.

Stella (05:14) Yeah, okay, that's fair. Where should we start?

Seesha (05:16) Well, why don't we start with what ayahuasca is and why Dr Hale wants to work with it in the first place? That seems like an important context to have.

Stella (05:25) So, ayahuasca is a psychoactive brew used by indigenous peoples in South America as a traditional, spiritual medicine. It's made of 2 plants, the Banisteriopsis caapi vine and Psychotria viridis shrub, and we'll get into the biology of the plants in a little bit. But, as far as how she got started...

Dr. Hale (05:45) Well, I met an amazing woman, Dr. Leanna Standish. She's a naturopathic physician and a PhD neuroscientist. She's in Seattle. She had sampled ayahuasca in a sacred ceremony in South America a few years before and knew that she wanted to bring this medicine forward. So, meeting her - she had already submitted her investigational new drug (IND) application to the FDA - and was looking to build a team and fundraise and expand, and it - these are majestic plants, um...

And I had learned a bit about ayahuasca. I actually had traveled to Costa Rica to a center that was partnered with the Ministry of Health of Costa Rica to, to study ayahuasca and administer ayahuasca - mostly to tourists and visitors. And I was just, um, so impressed by the ayahuasca ceremony. It is a sacred medicine. The fact that it is natural, I've spoken here about how natural medicines, right, are so important.

#### Seesha (06:50)

No wonder Dr Hale is so interested in ayahuasca! I have to say, though...I feel a little uneasy about "bringing" ayahuasca, this traditional, culturally important plant and ritual, into the pharmaceutical-based medicine that we're used to. And for that matter, I'm not sure that "modern", "Western", or "traditional" are appropriate terms. I feel like those words can imply that traditional medicines and practices are inferior to what most of us are probably used to - even though, like, ayahuasca is clearly an example of where traditional healing is incredibly powerful.

#### Stella: (07:23)

Those are definitely valid concerns to have, and I get what you mean. They're easy classifications that we use all the time without thinking about the implications as often as we should. And, "natural" sounds great, but let's not forget or downplay how incredible pharmaceutical medicines are! I think we can acknowledge and celebrate the variety of medicines and therapies that are available today. So back to Dr. Hale: we did ask her about "western" and "natural" medicines, and how she would describe ayahuasca tea.

# Dr. Hale (07:51)

Yeah, good point. Um, natural products, I think, are a big umbrella that would include botanical products. So there can be natural products that are, um, let's, let's just say vitamin C powder is a natural product as opposed to allopathic medicine or Western medicine, right? But not all natural products are botanicals - and, strictly speaking, mushrooms are not botanicals, right? They are fungi. They're fungal medicines. Um, so that would also be under the 'natural medicine' umbrella. I think we all understand what Western medicine is and allopathic medicine, certainly all prescriptions are in that category. Um, we would see curcumin - even though it's encapsulated, perhaps it still would be viewed in the natural category.

So where will ayahuasca land? It will not appear to be a classic pharmaceutical. It's not going to be encapsulated, it's going to have a taste, it's going to be a tea. Is it a natural product? Yes. And is it a Western medicine? Well, I feel one of the definitions of a Western medicine is something that's approved by the FDA. So I hadn't thought about this before. Thank you for the question.

We really are producing that middle way, that middle ground, right, by bringing something like ayahuasca through the FDA. It is a natural product, but validating its science and efficacy with

various clinical indications through FDA development and hopefully approval would then make it a Western medicine.

Seesha (09:23) Okay, so we'll use "Western" to mean FDA-approved, and "traditional" to mean plant-derived medicines and therapies that weren't developed in a lab or synthesized by manufacturers.

Stella (09:34) And to your other point about making ayahuasca tea more "mainstream", if you will...

Seesha (09:39) Like, I have to question whether it's appropriate to bring ayahuasca and the tea ceremony out of its native culture. And it's not necessarily the case here, but you can imagine that some people will do so without considering or respecting the context in which it's used.

Stella (09:54) Yeah, it's an important question to ask. I think it depends on the intent, what the end goal is, and what's being done to preserve the cultural relevance.

Dr. Hale (10:02) ...About the conserving the ceremony or preserving, right? Yes, we are going to try to keep as much of it as we can.

Stella (10:08) And we'll get more into the details of what Dr. Hale is planning later in this episode, but suffice it to say that it's complicated.

Seesha (10:17) Right, let's get back on track. So, ayahuasca's a psychedelic substance - hallucinogen. Doesn't that make it illegal in the US? How do you work with that in the first place?

Stella (10:27) Yeah, that's right. So, ayahuasca is a psychedelic drug, or hallucinogen, which are Schedule I drugs - which the Drug Enforcement Agency, the DEA, classifies as having no accepted medical use and a high potential for abuse. And, as you mentioned, is illegal to use or distribute in any capacity at the federal level. But, there are obviously ways around that for research and drug development.

Dr. Hale (10:51) Yes. So, most pharmaceutical companies just need to deal with the FDA. When you're dealing with Schedule I substances, the Drug Enforcement Agency, the DEA, has to be involved as well, and you have to apply, and be licensed, and have permission to do various things. You can have a DEA license to do research and you can have a DEA license to manufacture and other things. And some psychedelics are just Schedule I as they are. Others, like ayahuasca, it's not the vine or the leaf, the two plans that are scheduled, they are unscheduled. What is scheduled is the cooked vine and leaf together, which would then make dimethyltryptamine orally bioavailable because of monoamine oxidase inhibitors present in the vine. It's ayahuasca tea that's Schedule 1, but anyone can work with the vine or the leaf alone.

Seesha (11:47) Wait, the plants are unscheduled? So theoretically, you could just grow them, and I don't know, make a salad? Asking for a friend, of course.

Stella (11:56) Yeah, the DEA won't bat an eye - unless you start brewing the leaves and vine together.

Seesha (12:00) Okay, so explain to me why that makes such a big difference. Monoamine oxidase inhibitor? Bioavailable?

Stella (12:07) So, you have these enzymes called monoamine oxidases (MAOs) in your gut. These break down the monoamines, a class of molecules that includes serotonin (the happy juice). That means that a monoamine oxidase inhibitor prevents serotonin from being broken down - this is actually the basis of some antidepressant drugs - so if you can't break down the serotonin, then it hangs around in your system longer.

Seesha (12:31) Okay, that makes sense. And by "bioavailability", Dr. Hale means...?

Stella (12:36) Bioavailability is basically referring to the amount of a drug that survives metabolism or breakdown in your GI tract or gut after being orally ingested. So the percentage that is absorbed and reaches systemic circulation.

Seesha (12:51) Gotcha! So, how does all this relate to ayahuasca?

Stella (12:55) Well, Psychotria viridis leaves contain dimethyltryptamine, or DMT, which is a monoamine. If you ate the plant raw, the MAOs in your gut would just break it down and you wouldn't get any psychoactive effects. But the Banisteriopsis caapi vine has MAO inhibitors...

Seesha (13:14) Oh, and that keeps the DMT from being digested and broken down, which creates the high from ayahuasca. You basically need to prepare both plants together, so it makes sense that the vine and leaf combo is Scheduled.

Stella (13:26) Exactly! So now, back to Dr Hale - basically, you need to work with the DEA and keep them involved in every step of the way, which makes sense. And one of the key components of passing new therapies is the clinical trial, and this is where Dr Hale says that most of the time and money is spent.

# Dr. Hale (13:43)

The cost is really clinical development. Yeah, and the time from the first, let's say, toxicology studies - that would be real development work - and you create some formulations and products for animals...it can take 10 years. Companies have really, and FDA has worked together with industry to figure out where they could save time, but not compromise public health and safety...um, I would say it's closer to seven years. If you are studying, let's say, you have death trials, so death due to cancer or whatever, those are longer trials which could take 10, 12, 15 years. Yeah. But these psychiatry trials are fairly short. Follow up for maybe six months?

Seesha (14:22) What does it take to get to the clinical trial stage? Dr Hale mentioned that her co-founder, Dr. Leanna Standish, had submitted an investigational new drug, IND, application to the FDA. What

Leanna Standish, had submitted an investigational new drug, IND, application is that, and what does it mean for ayahuasca?

# Dr. Hale (14:37)

But at a certain point with an investigational new drug application, you need to carve a few things in stone: what is your formulation? How do you make it? You identify the cultivars - we're doing genomic analysis of the plans to be sure that we have the same cultivars that are being used. That would be a dimension of, if it was recommended that we use plants from the Amazon Basin - boy, that would require a big pause to identify the different plants that exist. How many variants are there? We know that there are a few variants of ayahuasca vine - banisteriopsis - um, there's yellow, red, black, I'm sure there's more under each of those color names than just that.

So, um, working with FDA is a serious commitment, right? And there are some factors that are very constrained - including, um, how do we define standardized ayahuasca how much DMT does it have, how many of the harmala alkaloids do we measure? What are their concentrations? We have to come up with a shelf life... Stability of most medicines in liquids is a challenge. It's something that the pharmaceutical industry has worked with. There's a reason most of our dosage forms are not wet in this country.

Seesha (15:52)

You know, that's a good point. I can't remember the last time I took medicine in liquid form...cough syrup, maybe?

Stella (15:59)

Now I'm imagining pouring out ayahuasca tea into those mini-cups like for Robitussin or something.

Seesha (16:05) But, it wasn't so long ago that psychedelics were incredibly taboo and seen as dangerous. So, what's behind the sudden surge of support for psychedelics as medicine?

#### Dr. Hale (16:16)

So, timing is very important as well, particularly when you're working with Schedule I substances. And our country - and Canada's leading actually in the opening towards psychedelic substances, but I would say the US is second - and quarterly, you can see real evolution and change. We saw that in the 2020 ballot measures, right, in various states and cities in terms of decriminalization or legalization.

Stella (16:41) Right, so psilocybin - mushrooms - were legalized in Colorado. Cannabis has been legal in many countries since 1939 in Burma. And while ayahuasca hasn't been on any ballots (yet), Dr Hale has worked to legalize another Schedule 1 substance - MDMA, or ecstasy.

Seesha (17:00) Yeah, she's on the board of MAPS, the Multidisciplinary Association for Psychedelic Studies, whose current mission is to legalize MDMA for its therapeutic uses. This is what they've done:

Dr. Hale (17:11) What needed to be done is to actually synthesize pharmaceutical grade MDMA, which is what MAPS has done, and actually study it in animals first, healthy volunteers first, single dose, low dose, medium dose, and then, okay, how about a dose a month later, a month later, and slowly unravel those beliefs and convince people that they really were myths or fears, put in society with the intention of protecting people from harm.

Um, but in reality, some of them may have been overstated, and in reality, the science shows at certain doses with high purity, with - as you opened up with this conversation - set and setting and having someone with you, right, shows that these products can be quite safe. Once that safety bar was cleared, okay, what's the efficacy? And how long does that efficacy last? Could you take one dose of LSD in a beautiful, maybe a sacred setting with intention work first and integration after, and heal, let's say, from sexual trauma as a teenager or a child, and cure your anxiety and panic disorder? And would it last after that one dose for years, right? I think that one belief - I'm not promoting this - one belief in the sector is that comparatively, let's say to the SSRIs or the benzodiazepines that you often have to take for weeks, months, or years, it is a few treatments of these psychedelic medicines done as labeled. These will be labeled by FDA.

Seesha (18:50) Okay, back up. Dr Hale talks about "intention setting", which honestly sounds more like a yoga class than taking, like, SSRIs, or selective serotonin reuptake inhibitors, or benzodiazepines (benzos for short), which are classes of psychoactive drugs used to treat mental illnesses.

Stella (19:09) Yeah, but that's kind of the point with psychedelics. With ayahuasca, it's not just about the molecule, DMT; it's about the setting of the experience and the way you prepare for it. So, by "intention", she's referring to the steps you take pre-dose to guide yourself to achieve whatever you're seeking from taking the tea.

# Seesha (19:28)

And integration will be more of a post-dose debrief. I guess that makes sense. For psychedelics - really, any psychoactive drug - you do need to be very mindful of your surroundings and how you feel going into the experience. Otherwise, you will end up with a bad trip.

Stella (19:43) Yeah and even so, there's no guarantee that everyone will get the benefits from psychedelics. Just like how certain medications may work for, do nothing, or even harm different sets of people, those experiences can still happen with psychedelics. So, obviously a lot more research needs to be done in order to figure out more about what makes a particular psychedelic effective for some people over others.

Seesha (20:06) Good point. It's definitely not one-size-fits-all, but it looks like there are some ways to increase the likelihood of having a decent experience from it.

Stella (20:14) Right, so, with ayahuasca, Dr Hale wants to make sure that future patients actually get the full experience of an ayahuasca ceremony in the healing journey.

Dr. Hale (20:24)

Do therapy first, have a therapist with you, do therapy [claps] after. And done in that way, after one, two, or three doses spread apart in time, you will know if it works for you or not. And that is not "take a medicine every day for the rest of your life", right? So, people are hoping that there is a real efficiency as well, and a lasting and enduring efficacy. But we have a little ways to go on that yet.

FDA doesn't require that you demonstrate, "what does a cure for depression mean, right? What would the timeline be?", but that you resolve the symptoms of depression, or you no longer qualify as meeting the criteria for moderate to severe PTSD, for instance.

Seesha (21:08)

Ah, that brings up an interesting point. How does Dr Hale plan to get the FDA to approve the spiritual side of ayahuasca tea?

# Dr. Hale (21:17)

We will have group administration of medicine; FDA has said yes to that. Um, we haven't clarified with FDA who will serve the medicine. All of the psychedelics, to my knowledge, that are in development, and there are many, are being administered by therapists who are your guide for your medicine period. We do not want ayahuasca to be served by therapist. You'll work with a therapist for that intention prior and for the integration after, and a good amount of therapy. But we really do want an ayahuasca healer, someone who is quite experienced...ideally, um, a shaman from South America would be great, but we expect this medicine to be quite popular, and these shaman lead their communities. So to ask them to move here would be a no-go and it would be rude, right, just ridiculous. So, just like we can't use the word "shaman", because FDA will say, "What does that mean?" Right? "Ceremony" isn't appropriate, either; nor is "spiritual healing", right, which we don't know how to measure.

Seesha (22:21) And that's a major problem that Dr. Hale is working on now. How do you quantify spiritual healing?

#### Stella (22:27)

Right, so that kind of brings us back to this whole question of legalization. It's really great to have increased awareness and support of potential therapies, especially those like psilocybin and cannabis, and hopefully ayahuasca, that can help treatment-resistant patients. But Dr Hale, despite supporting decriminalization and legalization, wonders if the whole movement is maybe moving too fast and we're all missing potential dangers because of it - including how to communicate the benefits of psychedelic medicines to different communities.

#### Dr. Hale (22:59)

Well the decriminalized nature movement or decriminalization in general, um, is doing a great job of informing people who want to know, but perhaps your question, Stella, is what about people who don't know, who don't know much about psychedelics and, you know, need to be informed. Um, reaching out to particular communities is, um, is something that is being done. I've sat on the MAPS board. And that is one...that is an issue. People of color, particularly African Americans, um, have had an incredibly harsh burden, right, of dealing with, the War on Drugs, right?

And I've had African-American leaders, um, say to me, "drugs are bad. Our people are in prison, particularly our young men. And now you want to say 'drugs are medicine'? Whoa. You know, we have to talk about this." So what does that look like? Um, and how do we get there? I don't believe that ayahuasca is unique in the world of psychedelic medicines, and others are going before us, but let's see how the decrim nature or decriminalization movement reaches out to people and, and who it's able to access.

What we ask though is that those decriminalization movements for ayahuasca also strongly recommend and maybe even provide resources for people to find therapists who are

experienced in working with ayahuasca, and can point people to harm reduction initiatives. We are trying to come together here because what everyone really does want is - let's ease people's suffering with medicines that actually may really be effective. But the point is we're going to be doing experiments. The public is going to be doing experiments, right? They're not just experiments approved and taken through the FDA.

I think psychedelics work, a decade ago, was also equally hard. Now it's really opened up quite a bit. I would say it is the non-scientific, non-technical, non-legal aspects of society that bring very strong beliefs and adamant passionate arguments against new medicines. I just see medicines as neutral, and not all people do. That's really hard, yeah.

[KeoKeo - Blue Dot Sessions]

Seesha (25:28)

Okay, so now we've learned about the complications of working with psychedelics because of their classification as Schedule I substances.

Stella(25:35)Yeah, and there has been a lot of progress recently to make working with psychedelics possible.

Seesha (25:40) Although, just because you can study ayahuasca, that doesn't mean you can bring them into quote-unquote "Western" medical practices, right?

Stella (25:48) Right, those are two separate things. Being able to conduct psychedelic research has had its issues though.

Dr. Hale (25:55)

In psychiatry research and development, and even discovery, there's some going on, but it's not keeping pace with the level of the global health crisis that we're in, and - oh, and even before coronavirus, right, COVID-19, one could say that we had a pretty high level of mental illness and opiate use, right? What else was out there and what came up really quickly was the psychedelics. Now, my skepticism, and I grew up in an era where they said, "This is your brain," which was an egg, and they showed a frying pan with hot oil in it, "And this is your brain on drugs," and they dropped the egg in and it fried, right? So, I drank that Kool-Aid, and drugs are not good, so what could this be about? But I can step away as an objective scientist and say, "Let me look at the data. Let me look at the science and the research. Has there been any?" Which for many years there wasn't, right?

Stella (26:50)

Yeah there was a halt in psychedelic research starting in the 70s, over concerns of adverse experiences that were being reported, which, understandably, is pretty scary to think about.

# Seesha (27:01)

It is...but let's remember that those concerns really only became prevalent after the shady research practices of Harvard psychologists Timothy Leary and Richard Alpert came out. They studied and advocated for psychedelic substances, but there were concerns about the legitimacy and safety of their experiments - for example, that students taking a required class taught by Leary and Alpert felt pressured to take LSD with the professors.

# Stella (27:26)

Sheesh, talk about a different time, right? But yeah, there were concerns about the increasing use of psychedelics among young people overall, and though Leary argued for the benefits of LSD, well, he wasn't exactly the kind of advocate that inspired confidence in the public. And so, LSD and other psychedelic drugs were Scheduled under President Nixon's Controlled Substances Act, and all psychedelic research - even the legitimate stuff - went underground.... But things have changed since then.

# Dr. Hale (27:56)

So, in the mental health space, working with a couple of different organizations who are developing psychedelic medicines, also focused on natural products...and I really realized that nature does have quite a few potential solutions, right, and healing modalities. And in fact, the source, the original source of a lot of our current medicines, are from nature. Looking at how complicated the chemical system with intellectual property was, and also just listening to society speaking of wanting more natural products: what exactly was there in nature? So, spending a lot of time learning about those opportunities, and for true healing modalities.

Seesha (28:45) After learning and thinking critically about psychiatric procedures, Dr. Hale began to envision that psychedelics may prove effective.

# Dr. Hale (28:52)

Yes, I wouldn't have predicted 10 years ago that I would be working in the psychedelic medicine space. But when you step back and look at mental health, about treating symptoms versus what is the true cause, right, of an illness? And can you heal that in any way, and therefore lessen the disease and then have fewer symptoms that are bothersome or cause suffering or need treatment?

I've learned a lot about psychiatry in particular, and how we treat, let's say, depression and anxiety now, and in many ways that is treating symptoms. One of my questions has always been, well, are we limited to treating symptoms or can we go at the core? In mental health and mental illness, there is often trauma at the core. So, are there modalities or pathways - they don't have to be medicines. It doesn't have to be anything you swallow or inject. It could be digital health, it could be being in nature, it could be, you know, um...meditation and spiritual practice - but what are the ways to go at the core and essence of disorders and suffering? Right? Something that has also been important to me is I've looked at, over the years of my career, how medicalized our health has become.

# Stella (30:12)

When talking about medicines, researchers, doctors, prescribers - people in this field - often use the word "indications", which means, what health conditions a medicine may be used for. Dr. Hale has an idea of what sorts of "indications" psychedelics may be used for, with a lot of evidence coming from indigenous practices in South America.

# Dr. Hale (30:30)

Mark my words, each of the psychedelics will be developed in each of the indications, right? Because they probably have efficacy, right? So, each company is going to have multiple. It's just which one do you start with first?

So, depression definitely is near the top of the list, anxiety, OCD, eating disorders, PTSD like MAPS's MDMA. But also - I sit down and have conversations through translators whenever I can - you ask the shaman, "What do you use this medicine for when you're actually treating a formal psychiatric disorder?" They say two in South America. One is alcohol abuse; that there is something about ayahuasca and it's been published for other psychedelics as well, with a shaman and a sacred ceremony, that has led to good effects, right, with alcohol abuse and Western tobacco cigarette smoking.

That's very interesting and that is something that they see in either indigenous people or people who are non-indigenous, but live in South America and come for ceremonies. Lots of indications, right? And, you can as well count on, in the future, there being some neurologic indications that will be pursued. Psychiatric first, but the science, because we can now with permission study these substances - um, there are lots of signs pointing toward mechanisms of action that suggest potential efficacy.

# Seesha (32:01)

That all sounds amazing, but I have to ask - how do you even measure the effect of a psychedelic trip? Like, I trust the reports of the ayahuasca tea ceremony being life-changing, but I also want to know by how much, if that's even possible to quantify.

Stella (32:15) Yeah, it's a problem that still needs to be worked out for psychedelic, spiritual, or "mystical", experiences.

# Dr. Hale (32:21)

So, mystical experiences are something that, for instance, psilocybin researchers at Johns Hopkins, have begun to measure, and there are scales - questionnaires, basically, surveys. I don't know if those are validated or how you would validate them, but they are publishing their work on that and exploring that. Do you need to get to the level of a mystical experience before you can have this transformative experience that potentially leads to deeper healing? And many people do believe that that's necessary, but what does that require? How is it defined? How would you measure it? What can you do to facilitate it? Um, that's not really known.

We will also use similar scales. If Hopkins hadn't gone forward first with psilocybin, we wouldn't. We wouldn't want to be the first to do that while we're taking ayahuasca through the FDA. But now that they have, we'll ask the FDA about that.

Seesha (33:15) Okay, that's a start! So, there's a way to evaluate the psychedelic experience, and there's evidence for a number of ayahuasca indications...that seems like Dr Hale is good to go, right?

Stella (33:27) Kind of, though there are still challenges left in the way of incorporating psychedelics into pharmaceutical-centred health practices.

# Dr. Hale (33:35)

What is the truth? Not just, what are we being told from a public health perspective to protect us from, as you say, right, things can go wrong in an inappropriate set or setting, or let's say, the drug you take isn't pure. So it's really an appreciation that right now the psychedelics are what I feel is our best shot at having true interventions that do more than treat symptoms - potentially. I have to be careful because none of these have been approved yet, right? They're all still hypothesis-testing stage with clinical trials, a lot of investment, a lot of funding. It's a super hot area.

Stella (34:15) Dr. Hale believes there's a path forward.

I don't know that most Western health professionals, if they accept this until they're maybe older where they see that people with traumas or psychiatric disorders begin to feel the effects of that trauma in their physical body, right? It's beyond the mental aspects of our existence. Yes, I have met people, and their stories written and films made about healing physical disorders that go beyond psychiatry and neurology. So yes, I do believe it's possible.

[Kid Kodi]

Stella (35:01) From our interview, it was clear Dr. Hale had taken a big interest in the healing potential of psychedelics, and wanted to really apply it to her latest venture, an ayahuasca tea company she co-founded called Sacred Medicines.

Seesha (35:14) Ayahuasca is not something to easily stumble upon, as it has indigenous origins in South America and is usually administered in sacred ceremonies by a shaman. We were curious why she chose to focus her efforts on ayahuasca.

Dr. Hale (35:27)

Um, not everyone believes this, but everyone on our team does - and that is how superior plant medicines are to synthetic chemicals...it's just a different experience. Is it softer, is it rougher, is it deeper, how many molecules are acting pharmacologically, you know...it's difficult to express the words. But let's just say we really believe that carrying forward ayahuasca tea as two decocted plants and as a liquid is very important to us. And it's something that we're committed to.

#### Stella (36:02) When adopting elements of anot

When adopting elements of another culture, it's important to be respectful and mindful about how it is used and interpreted. In this case, where ayahuasca originates from South American tradition, we wanted to know how this would come into play in Sacred Medicines.

# Seesha (36:16)

Ayahuasca administration is typically performed at night and accompanied by a ceremony led by a Shaman, so we asked Dr. Hale if any of these elements would be conserved and if so, in what capacity. And she explained..

# Dr. Hale (36:28)

So there are what are called shamanic practitioners who are Westerners who are trained by shaman. And we are exploring now what a certification of shamanic practitioners for ayahuasca ceremonies could be for our medicine. And ayahuasca is quite powerful; and people in the psychedelic medicine sector would agree that that's the case; starting with more gentle medicines, like MDMA, or even lower dose psilocybin is a good way to go. So all the more reason to have experienced ayahuasca healers, right?

So, we are working on, um, translating, right? We see ourselves as translators, and which parts of the ceremonies or group medicine experiences can we keep. For instance, shaman almost universally administer the medicines at night, and this would be maybe 6, 7, 8 o'clock at night and you finish at dawn. Is that something that Americans are going to want to do? And there are reasons for that. But is that something ... Maybe we'll have some night ceremonies available and some just daytime. Yeah, we shall see. Good question about conserving. How much will we be able to conserve?

# Stella (37:41)

Interesting...Shamanic practitioners? That's a first. So, going back to what you said when we started the episode...is it insensitive to the origin and traditional relevance of ayahuasca tea ceremonies?

# Seesha (37:54)

I'm kind of torn - again, I think it depends on intent. I bet there are shamanic practitioners who call themselves that without respecting the culture. On the other hand, not everyone has the resources to drop everything to fly down to South America and spend days? Weeks? To seek enlightenment. And even so, ayahuasca tourism is something problematic of its own, where the medicine is not only commercialized, but it loses authenticity and is catered to the tourists. So

for shamanic practitioners, maybe it's insensitive, but it makes the ceremony more accessible and hopefully educates a wide audience, too.

# Stella (38:30)

That's a good point, and Dr Hale does say that they're looking at the kind of certification that shamanic practitioners have, and whether that works with the overall mission of staying true to the origins of the ayahuasca tea ceremony. So, with these trained individuals, thinking back to what Dr. Hale described as "setting and intention" and "integrating after", they plan to uphold the ceremony and intended use of ayahuasca while introducing it to a totally new population. But, let's get more information from Dr. Hale about what it means to be a shamanic practitioner.

# Dr. Hale (39:02)

The term "shamanic practitioner" is one that we chose to try to honor shaman and say, you know, people with American citizenship who were not born into indigenous communities and those lineages, are different and we've gotten some pushback that says we should not use that, those terms. So we may call these ayahuasca "guides", or ayahuasca "healers"...so the term may change.

Our perspective on this right now is that individuals who we propose would be qualified to serve our medicine in clinical trials under FDA guidance would be, um, individuals who have trained not just visited, trained - in indigenous communities with ayahuasca for years, right, and that's really what it takes, and that they have been given some sort of nod or told that you, you know, you meet a certain criteria, which I - we don't understand, right. And some of these individuals come back and start churches, some of them are here serving medicine. So, we don't know exactly how to do this, um, but we are seeking individuals to help guide us.

Seesha (40:11)

So, I gathered that shamanic practitioners are people who are not from indiginous communities but have trained with them on all things ayahuasca, in this case.

Stella (40:21) Yeah, I wonder what recruitment would look like or even certification? This is something Dr. Hale is still trying to work out.

Dr. Hale (40:28) Yeah, this is word of mouth, as is the case in this sector, right? And actually, if it's possible, you know, to legally do so to work with them, that would be in a church or in South America and see what their ceremonies are like.

We should probably change the word "certified". Maybe it's more like "qualified" right now, um, for the people who serve the medicine, and these are people who are already qualified - we just have to decide what that is. We will develop a training program for therapists - that is not a de novo program. It's one that we want to add to MDMA psychotherapist training or psilocybin

psychotherapist training. And that would be an add on, and that, that would be then, uh, a certification.

Stella (41:14)

Okay, so what we do know now is that there will be experienced guides to aid in this spiritual journey with ayahuasca.

Seesha (41:22)

Yeah - and speaking of journeys, in our quest to uncover more tea on Dr. Hale's newest venture, we asked about her ayahuasca production pipeline.

Stella (41:31) We asked Dr. Hale about how she's sourcing ayahuasca for Sacred Medicines and if she has ever considered distilling the chemical compounds. She said:

#### Dr. Hale (41:39)

So, pharmahuasca would be DMT, dimethyltryptamine, with harmine or harmaline, which are the harmala alkaloids that are the MAO inhibitors. And our understanding is that there's been a little bit of work that's been done there, and comparing that - pharmahuasca to ayahuasca and the decision was made to really develop that further.

Um, Dr. Leanna Standish, my business partner is a naturopathic physician, and they're all about plant medicines, you know, and supplements and natural healing, and I am too. That's really where my orientation is. So, we will stay with plants. We'd like to develop other plant medicines as well, maybe not all psychedelics.

Your question as to where we're growing the medicines: we're growing them in Hawaii, So we're growing a Psychotria viridis, which is a bush or a shrub, and the leaves have dimethyltryptamine, DMT. That's the Schedule I substance. Then there is a vine that needs to grow for many years called Banisteriopsis caapi, or BC vine, and that has the harmala alkaloids in it. All sustainable farming. We're not certified organic, but there has been nothing added that's not natural.

Seesha (42:51) Who doesn't love sustainable farming, and in Hawaii? Why Hawaii?

Dr. Hale (42:56)

Culturally, Hawaii is pro-farming and pro-agriculture. Um, so it is a, you know, a place that's open to growing various plants and plant medicines or foods, whatever.

Hawaiian land being volcanic in origin is very fertile. And these particular plants are in a tropical rainforest. They're up at a pretty high elevation, as well, in order to maintain that rainforest. And the vine needs to grow on trees. So, neither of the plants that Dr. Standish is growing in this ethnobotanical preserve are in rows, right, they're in the forest; shade is important. And

particularly for a banisteriopsis to have, um, healthy trees to climb. Yeah, so Hawaii sort of brought all that together. But I have been urged - we have been urged - to think about Louisiana or other parts of the Southeastern United States for that.

Stella (43:53) Okay, it seems that it's more about the climate there that helps the plants thrive. And since the plants are technically unscheduled, it was fine to just go ahead and grow it there.

Seesha (44:02) Oh, that checks out. How was she able to get access to the plants?

Dr. Hale (44:06)

Well, the plants were given to Terence McKenna, Dennis McKenna and Kat Harrison 45 years ago. So my partner, Dr. Leanna Standish, bought property in Hawaii from - these are famous names - Terence McKenna, who has now passed, Dennis McKenna, his brother, and Kat Harrison, who was the botanist on the land. She was married to Terrence. And when Terrence passed, the land was carved up and Leanna bought that property.

Stella (44:38) For some of you, the name "McKenna" might ring a bell. You see, Terence McKenna was a very important figure in the psychedelic movement. He was an author, practicing shaman, and ethnobotanist, which is someone who intensely studies plants used by other societies in different regions around the world). Fun fact - he and his brother, Dennis, actually discovered a method for growing psilocybin mushrooms at home.

Seesha (45:00) He was also a huge advocate for naturally occurring psychedelics. Not surprisingly, he was known as the "Timothy Leary of the 90s" and was considered a central figure in rave culture. So in a way it's like things came full circle.

[Kid Kodi]

Stella (45:27) Now that we've learned about how Dr. Hale sources ayahuasca, we asked her about how the tea will be prepared and administered.

Dr. Hale (45:35) So you cook the vine and the leaf in water for many hours. Shaman bless it and pray over it, put their intentions in it the whole time they're making it. We don't know exactly how to translate that part yet, but we're working on it. So a tea that will be a 50 milliliter amber vial..

Stella (45:55) As a comparison, a shot is about 1.5 ounces or 44 milliliters, so a single dose of the ayahuasca tea is a little over one shot.

#### Seesha (46:06)

Gotta say, I guess in this case you can pick your poison, since you'll end up puking all night, but with one option you reach enlightenment.

Stella (46:13)

For real! Okay, while we're discussing administration, how does Sacred Medicines plan to raise awareness and increase accessibility to ayahuasca?

Seesha (46:23)

Yeah exactly, from what I've seen online it is pretty expensive to go on an ayahuasca journey, ranging from 900 to 1500 dollars. What will Sacred Medicines do to make it accessible?

#### Dr. Hale (46:35)

Cost, particularly in this country, in the United States, is often the biggest barrier, right? We're sort of watching the rest of the psychedelic medicine sector, who does, let's say there, there are not warm fuzzies between the psychedelic medicine sector and in the large pharmaceutical companies right now, but I'd like to, you know, see that move. So we set for instance, with the intrauterine device that I developed at Medicines360 with my team, we had a commercial insurance price that was X dollars that was set by our commercial partner.

And we gained a certain percent of royalties, a small portion, but, but with decent enough sales, it was a good amount, right, to support a nonprofit afterwards. Um, then there is the, um, Medicaid price, right, that we talked with the commercial partner about and try not to go over this particular level. We want Medicaid to be able to afford this IUD. And then thirdly, we had for this IUD, a \$50 flat price for US public sector, uninsured, underinsured, non citizens, there were a few other cases, and that was fixed with no cap on the volume of sales in that particular group. So as many, you know, women who wanted it would be able to have access to it. So I see something similar. That was beautifully received by pharmaceutical executives, right? And these huge contracts that took months to put together.

We also outsource, um, manufacturing as well. We're going to retain ayahuasca manufacturing, but commercialization - I'm pretty confident that, you know, everyone understands that ayahuasca is a sacred medicine and it's plant-based, and we're bringing it forward to help people. Sacred Medicines is a public benefit corporation and we will have firm control over the prices. And if we cannot get a pharmaceutical company to move forward, as we did with the IUD, then we will retain it and commercialize it ourselves, or work with other companies in the psychedelic medicine space and perhaps co-commercialize or co-market.

So we are confident that we can, uh, make this medicine affordable and a big part of that is, um, having group administration, right, versus one person at a time; that does go to affordability. We are not proceeding with group medicine administration because of cost - that is a secondary benefit. The primary reason is that's the way ayahuasca is given,

# Stella (48:59)

It's been super interesting to learn about the components of ayahuasca and how Sacred Medicine plans to administer it. It's also soo different from the typical "take as prescribed" medications most of us are used to.

# Seesha (49:11) Yeah, totally different. In fact, while we're on the topic of dosing, there's this adage in the realm of toxicology that states, "the dose makes the poison," which essentially means that every drug is dangerous, it just depends on the dose - even for ayahuasca which is naturally sourced. So, we asked about what possible negative reactions might happen and contraindications - or conditions where one should avoid taking the ayahuasca tea

# Dr. Hale (49:37)

So what you're worried about with ayahuasca is serotonin syndrome, and that would be...probably death. There have been a couple of those cases reported. You really need to stay away from SSRIs. Um, at this point, we're not capable of enrolling people who have psychosis, right, or psychotic events, or even a history and an immediate relative in a family, nor is bipolar diagnosis in yourself or in an immediate family member good. The ability to manage that, at least in the West, is just not available yet...I think it will, it will come.

Stella (50:15) So, Dr Hale mentioned that it's not just ayahuasca that's been seen to have effects with treating addiction. But, what makes ayahuasca stand out from other psychedelic compounds?

# Dr. Hale (50:27)

People say, just in general, it's a little bit laughable, but LSD will take you on a wild trip. But it's a chemical and shaman say chemicals are not the same as plants or molecules derived in plants. Um, psilocybin is derived from the mushroom, right, but if you use the whole mushrooms as well, ayahuasca shaman will say psilocybin is significant, from a natural source, but it's not like ayahuasca in that it will show you lots of colors, is what the ayahuasca shaman say. Um, MDMA, also a chemical, and it is an amphetamine, right? And it probably has something to do with release of oxytocin, and the others don't, to my knowledge.

Uh, there is ibogaine, right? Which comes from the root of the iboga plant originally from Africa. And that one is one that people, the most hope for opiate and stimulant addiction - cocaine, methamphetamine, right, then obviously heroin, et cetera, but different as well. That one has lots of potential cardiovascular events because MDMA is an amphetamine, there are some contraindications for people with some, you know, cardiovascular disease, hypertension, arrhythmias, because you're taken to a different place and state where you can be frightened, right? And then your responses could, you know, lead you to a place where if you're not healthy or maintained - cannot maintain stability, you could potentially get into trouble.

Yeah. Then ayahuasca has two plants. There are currently ... I think LSD and MDMA will be combined now. But ayahuasca was the first to combine two medicines. And it's best to study

medicine singly first so that you understand them each before you combine them. That's what FDA wants as well.

[KeoKeo]

Stella (52:38)

In our discussion of ayahuasca, we have alluded to concerns about making ayahuasca tea more "mainstream".

Seesha (52:45) We discussed the importance of respecting cultures when adopting them, and Dr. Hale shared with us her plans to conserve the South American ceremony tradition through what she calls shamanic practitioners.

Stella (52:55)

Along these lines, we thought it would be very important to discuss potential issues with adopting ayahuasca and working to push it through the FDA for therapeutic use. We asked Dr. Hale about her thoughts as it relates to exploitation of indiginous cultures and cultural appropriation.

Dr. Hale (53:11)

So, cultural appropriation of ayahuasca tea...one could even say the plants because they're sacred. And the ceremony, even the music - the ikaros\* - that you could have is, um, potentially very problematic. We have had cultural appropriation discussions, um, that have been quite heated with indigenous communities. Um, and I cannot say we are at a peaceful place.

\*<u>Ikaro</u> (icaro in English) refers to the medicine songs performed in healing ceremonies, ayahuasca included, by shamans.

The plants are grown in Hawaii. Um, we thought that conserving the plants and not harvesting and the Amazon from wild or even cultivated plants would be a good thing; that isn't always viewed as good by indigenous people. Um, our desire to engage shamanic practitioners or ayahuasca guides or healers, or - we don't use the word Shaman because that we really believe Shaman only come from South America and they're studying most of their lives and they're part of lineages and we just will never, never get there.

And even the concept of whose land is ayahuasca served on has come up in discussions with indigenous communities. Some communities believe that ayahuasca, which is grown in, um, South America is what should be served and it should be served on the land and in the Amazonian Basin.

Stella (54:54)

Wow, I must say I'm relieved that there has been some discussion about these issues. I also find it interesting that issues can arise not only from this...adopting the ceremony, but also from where the plants are cultivated and served.

# Seesha (54:57)

Yeah, exactly. I can see how removing ayahuasca farther from the culture where it was developed could lead to heated discussions with these indigenous communities. I'm curious about how Sacred Medicines plans to address this.

#### Dr. Hale (55:09)

The topic of cultural appropriation - uh, those two words, cultural appropriation is sort of a kind way to say what could be a very bad thing. One could say that we're stealing it, right? And that it is violent to move forward with what we're doing. Um, so engaging to say that this is about the science and validation of the medicine that we want, the science that we do in this project to be bi-directional. So we want to begin to understand, because we're also naive in the West or the North.

And we would love to engage with indigenous shamanic practitioners to, um, to understand what it is we should be measuring or exploring, and really work hard to bring their input into our protocol designs. It's going to take a while. We need to get to real trust and understanding, right, for that, for that to happen.

Um, so we have met with some individuals who are leaders of their communities, um, Amazonian medicine-practicing communities, medicine-honoring communities, and some of them are quite negative. And they say, we don't know you, and they speak of five centuries of violence and abuse and bio-piracy, right, and theft of their medicines. We learned in a recent conversation about the history of rubber and taking it to Indonesia. And one of those individuals who was explaining this asked us how - how is stealing rubber from the Amazon and taking it to Indonesia different from taking ayahuasca plants, either the vine or the leaf from the Amazon to Hawaii, where a lot of it is grown right now? And boy, my co-founder and co CEO, Leanna Standish, yeah, and I were, um, silenced by that question.

Stella (57:15) Since these cultures have a history of exploitation, addressing these hard questions seems really necessary in bringing ayahuasca to the US, without erasing the indigenous culture from where it came.

Seesha (57:26) I completely agree. And it's compounded by the fact that ayahuasca has religious significance, and so requires even greater respect.

Stella (57:34) I also have the question of, who will profit from this business - will anything be funneled back to the communities where ayahuasca originated?

Dr. Hale (57:42)

We need to be able to discuss it. How, how is it different? How are we different or will it be the same? We speak of reciprocity programs and - and what is reciprocity? And one thing that we

know for sure about reciprocity is it's all about relationship and relationship takes time. And there is extraordinary justification for zero trust, right, Indigenous people of us in our work. Period. So, um, we are asking a couple of questions and then we, we listen, we listen to, historically what has happened to these communities, what white people have done to these communities.

Are we medicalizing ayahuasca? That is more of a challenge or question we get from advocates of indigenous rights of people who live here. Um, what has been communicated by indigenous people, um, is, "this is our intellectual property. How are you not stealing it?"

# Seesha (58:56)

By the way, this is one aspect of the cultural appropriation issue around ayahuasca tea ceremonies. Another major one is the idea of ayahuasca tourism, where you can pay thousands of dollars to travel to these communities and experience a ceremony in situ...kind of.

Stella (59:11) As you might imagine, that kind of attention has changed the ways some communities perform the ceremonies; one of them is by catering to foreign expectations and giving tourists an inauthentic version of the ceremony. So, by default, what you and I would experience might not be a true ayahuasca tea ceremony, even if we were physically in the right location.

Dr. Hale (59:33)

Absolutely. And I will say I've worked with different shaman from South America, from different countries, and the ceremonies are different even between them. And then I agree Stella, um, indigenous community-only ceremonies would be different. I haven't participated in any obviously by definition, but it would be different from those for tourists. And then, I think as well, do tourists come occasionally? Or is it really a tourism business that has been set up and it's a regular thing, is a question as well.

So yeah, it's challenging, but that doesn't mean it shouldn't be done... how to do it really well really well. And what is good and well, can't be defined by us, right, it's a joint definition and discussion and agreement.

Stella (1:00:21) So, Sacred Medicines hopes to have a bidirectional aspect to their work, where they can do research on ayahuasca, relay back this information, and also use the community's input while studying ayahuasca. But, trust is a huge factor in accomplishing this sort of reciprocity agreement.

# Seesha (1:00:40)

Yeah, and conducting this work in a way that doesn't put any additional burden on the indigenous community. Like Dr. Hale said, there's backlash from a lot of these communities who

have gone through moments in history of violence, abuse, and theft of their medicines and natural resources, among other things.

Stella (1:00:56) And this brings up the big question of what makes ayahuasca different. Now with ayahuasca, it's expected for these communities to be heavily cautious and proactively working to prevent history from repeating itself. We asked Dr. Hale about what actions she may take if the trust relationship never builds.

# Dr Hale (1:01:15)

We will consider stopping or pausing. Um, what's possible as well as a middle ground, not to proceed as planned, not to stop forever, but to slow down or pause and get this right, and figure out how to do it. There's also an international treaty, the Conference on Biodiversity, which was initiated in 1992 and then the Nagoya protocol followed, um, and, uh, adhering to those, um, means that we can't do this by ourselves.

One challenge is, um, there is no single unified voice for ayahuasca. We know that there are more than 100 communities in the Amazon basin that use this medicine in six countries. How - when we speak of proceeding with a ceremony, we have learned, uh, and of course we should have perhaps appreciated this more, um, that the ceremony is their intellectual property. It belongs to them. And that is not something we had thought about. Um, so we are becoming more wise and that is correct. We have to modify the ceremony to move through and work with FDA.

# Stella (1:02:31)

Yes, there definitely has to be full cooperation from these indigenous communities before moving further, and it's good to see that Dr. Hale and colleagues are at least recognizing things to rectify, like the way Sacred Medicines intends to adopt the ceremony.

Seesha (1:02:46) Dr. Hale also brings up a great point that there is no unified voice of ayahuasca, which adds a bit more complexity to the situation. But, consulting a wide array of people from the origin cultures seems like a good start.

# Dr. Hale (1:02:09)

Is there a middle way, a middle path, a Buddhist concept, right?. Um, we have met with now a handful of individuals who we would call bridge builders, who are mostly, uh, from South America. Um, they are not of indigenous origin, but they live in the countries where ayahuasca is served ceremonially and they are familiar with it. And they have used the medicine there, and now they are here. Some of them have been educated here, some of them work with churches, um, some of them are engaged in human rights work, some just health and healing. Um, so I think our immediate path forward would be to engage with those bridge builders who are in direct communication. It's gone so slowly for us. So for those who have already established trusting relationships, I think, is a way to go.

One path that I would then consider if we decided that taking this medicine through the FDA is not the right thing to do for a variety of reasons, is to consider partnering with academics to study the medicine. There has been no published ayahuasca clinical research trials done in the United States. There are quite a few publications. Many are from churches, a couple have been done in the, in Europe with dehydrated ayahuasca in capsules...but to use the tea that's freshly prepared as per these original recipes and do studies with academics, you know, that's how the psilocybin work started, right, at Johns Hopkins. Yeah. So maybe we would think of something similar and I live in the Bay area and I'm a UCSF alum. So you can guess which university I have in mind.

# [Kid Kodi]

Stella (1:05:04) Throughout Dr. Hale's career, she's undertaken numerous ventures. She was classically trained in pharmaceutical chemistry, and she worked in the FDA and Genentech.

Seesha (1:05:15) She also started multiple businesses, like the two non-profit companies: One World Health, which focuses on parasitic infections and cholera, and Medicines360, which focuses on womens' reproductive health

Stella (1:05:28) Given her involvement in public health service work, social entrepreneurship, and her quest to redefine healing around the world, we asked about what parts had been the most difficult and meaningful in her experience thus far.

Dr. Hale (1:05:34)

I'll tell you, reproductive health was the most challenging because you think if you do good science and follow all the regulations and laws and work with people who want to move medicines forward - contraceptives - that you can just do it. But reproductive health has religion and politics deeply involved. You see it in this country and it's in many countries of the world. It's really about power and control. That one was really hard.

Um, most meaningful. So many learnings from people in other cultures, and now from indigenous people, mostly in South America, right, with ayahuasca. So just opening my horizons as to what does healing mean? What is suffering? Right? Who are healers and how should they show up? Um, what are medicines, uh, what should medicines cost? What does access to medicines mean? How do we define impact? I have a question that I have not been able to answer - by the end of my career, I'll have a better idea - and that is, how much of disease and suffering is due to spiritual wounds?

That question is not one that lands very well on a scientist's ears or even a physician's ear. It would land well in a minister's ears, right? Or some others, perhaps a parent or a therapist or

counselor. But I do believe there is a big aspect of healing that involves soul and spirit. I would love to come to touch that and know that and open that up for we Westerners who don't know so much about that.

Stella (1:07:29) Wow, she definitely gave us a lot to think about.

Seesha (1:07:26) As for her final thoughts, she shared...

Dr. Hale (1:07:28)

May I say, Sacred Medicines is open to volunteers, really bright people who are passionate about these medicines, whether or not these volunteers have ever used ayahuasca it would be good if they'd heard about ayahuasca and read a little bit and were a little bit informed. It isn't so easy to find on our website, but we are inviting some volunteers and in One World Health and Medicines360, my two nonprofits, we had lots of volunteers, which was great. They really make a difference.

I encourage your listeners to go inside and ask what really calls them? What aspect or application of science and life sciences and applications to healing draw them? There is so much out there. To take that and partner with people around the world who are doing other kinds of healing, and science can be ... I mean, it's mutual learning just for the benefit of all, and go for it.

[Order of Entrance]

Stella (1:08:37) If you've liked what we've discussed today, and want to learn more about or follow-up with the progression of Dr. Hale's ayahuasca tea company, be sure to check out <u>SacredMedicines.Earth</u>.

Seesha (1:08:48) Don't worry, we'll have this along with some other resources relevant to what we've talked about today in our show notes.

Stella (1:08:04) This episode was produced by Stella Belonwu, Cindy Liu, and Seesha Takagishi with help from the rest of the team at Carry the One Radio. I want to give a big thank you to Dr. Victoria Hale for taking the time to speak with us, and of course, you for listening!

Seesha (1:09:08)

So, this episode really wouldn't have been possible without the enormous, generous support of our Patreon supporters. This in mind, I'd like to thank this episode's Science Producers: Sama Ahmed, Carly Van Orsdel, Jeannine Cuevas, Samantha Ancona Esselmann, and David Cabral. Big thanks to them for supporting us financially through our Patreon.

Stella (1:09:28)

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Stella & Seesha (1:09:01) Stay curious!