Dr. Bruno Chaves speaks at MAPS' 2017 Psychedelic Science Conference in Oakland, California

Good afternoon. First of all, I want to thank MAPS for the invitation. Today I will talk about what we are doing in Brazil about bringing ibogaine to be, let's say, [an] above ground treatment to people. So, that's why we ask if finally in Brazil, is ibogaine stepping out from the underground? I am a medical provider of ibogaine since 1994. I am the first medical provider in Brazil, and I think I am the first provider in Brazil, medical or non-medical. I've done more than 1000 treatments.

In Brazil, we don't have too much heroin addiction, we have more stimulent addiction, like cocaine and crack cocaine. So everything that I will talk about our work there, I will be talking about stimulant addiction. We've published some works on ibogaine, a retrospective study, in 2014. I helped to write the clinical guidelines published by GITA, and we've recently published a politative study on treatment, on ibogaine. I'm a former GITA board member.

Brazil has the most rigorous laws about prescription medicines in the world, and this happens because some time ago there were a lot of women who got pregnant after consuming birth control pills containing wheat flour. That was a big scandal in the country, and after that, ANVISA, which is our FDA equivalent, it changed all the regulations about prescription medicines. So it's easier in Brazil for you to get a drug like cocaine or crack than to buy a medicine if you don't have a prescription. This was the birth control pills that were contaminated with wheat flour...it happened in 1998. And after that, they published this law that we call article 273, that says that it's forbidden to sell, or to administer, to use or prescribe or take with you any kind of medicines that are unregistered in the ANVISA, or are from unknown origin. And it is so rigorous that in some situations you get more time in jail for prescribing a non-registered medicine than for a registered one. It's very, very rigorous.

What is a registered medicine in Brazil? It's a medicine that was previously evaluated by the ANVISA, who will analyze the documentation, the clinical trials, the scientific advances. They are more prone to approve a medicine if it's already approved in another country, but there are some medicines that are only approved in Brazil. They see the package, and they see the labels, and if all the requirements are fitted, ANVISA declares that this is a registered medicine. After that, the doctors can prescribe it, and it can be sold, and there are various levels of control on that. Some medicines only need a simple prescription, and others need to be prescribed in special forms that are provided to the clinicians under request.

So it's possible to do the ibogaine legal treatment in Brazil because it's not forbidden, it's not controlled, it's not banned, but it's not registered until now as a prescription medicine. But ANVISA allows people to use non-registered medicines if we meet some requirements that they ask. Basically, we have these two laws that state that non-registered medicines can be used since they are bought in the name of the patient - the medicine must be imported in the name of the patient - in the exact amount of medicine that patient will use, and this importation must be for a single use or for a limited time of use, and the maximum time of 6 months.

This situation doesn't apply to ibogaine because ibogaine normally we use only once, so it fits the law. In Brazil, people are using this law to import a lot of unregistered medicines - medicines for appetite, ibogaine, and medical marijuana preparations. So we import ibogaine to Brazil legally. It arrives in a box that goes through the customs and through ANVISA, and every time they ask a lot of questions, but they allow us to use it. As you can see in the stamp, it's a national agency on sanitary vigilence, "ANVISA liberated" without opening. The first times we imported it 20 years ago, people used the ANVISA at the airport, they used it to open the package and look at the bottle of the medicine, but now they are used to that - they know that we do it - so they are releasing it without opening the box.

But this kind of situation, this kind of importation, has some disadvantages. It takes a lot of time for the medicine to arrive in Brazil and to be released in the airport. The patient must wait all this time. The average time is 30 days, but sometimes it took around 3 months for the medicine to be released. There are costs because you must hire brokers and people to help release the medicine in the airport. If you use an amount that is less than what you bought, you must discard what you didn't use, which makes the patient pay for more than they really need. And ANVISA asks for a medical prescription to accept the importation. So this makes the cost higher than we would like it to be, but at this moment, it's the only way to import it legally.

In 2014 we published a retrospective study on ibogaine, showing a good affect on maintaining a distance from cocaine and crack cocaine. During that year, around 62% of the patients remained clean. And after that, helped by people - activists, psychologists, psychiatrists - people who understand the need for a shift in the treatment of addiction in Brazil - they helped us to talk with the government. We went to the State Council on Drugs Policy, and we went to the National Secretary on Drugs Policy and the Ministry of Justice, and we explained it for the people how ibogaine works, we showed them the study, we asked for more funds for research, and we asked for some kind of facilitation in this regulation - we wanted for regulation not to be so hard for us to try to lower the costs. We showed them that ibogaine really changes the QTc interval and EKG, so the State Council on Drugs Policy - they published some resolutions. It works only for the Sao Paulo state, but anyway, they said :

1. The use of hallucinogenic substances for treatment of problematic use of psychoactive substances should be considered an option that requires scientific research.

2. Scientific research with the use of hallucinogenic substances, including the development of options for treatment of substance abuse, should be encouraged financially by development institutions in order to ensure the realization of quantitative research, qualitative and randomized controlled clinical trials.

3. The semi-synthetic or synthetic compounds based on active principles of Tabernanthe iboga and other species of the genus Tabernaemontana (Aponynaceae family) must have their therapeutic potential in the treatment of problematic psychoactive substance use investigated through scientific research.

4. The semi-synthetic or synthetic compounds based on the active principles of Tabernanthe iboga and other species of the genus Tabernaemontana (Aponynaceae family), particularly ibogaine formulations, can only be administered for the treatment of the abuse of psychoactive substances in a hospital environment, with doctor's supervision and control, given the and good practice of the profession and good recommendations to clinical practice, including rigorous clinical, psychiatric and psychological assessment and psychotherapeutic monitoring.

It was interesting that this decision of the State Council had more repercussion in the U.S. than in Brazil, and in Brazil few people were aware of it, but in the U.S., we saw on the internet some posts talking about this situation, that it opens the door for ibogaine treatment. After that, at the end of 2016, we published a retrospective study - a qualitative study. We saw that the patients improved their quality of life. Even if they relapsed after ibogaine, their relapses were different, and the patients, most of the time, even after relapsing, they said that they felt different, and they felt that this relapse after taking ibogaine was different - that it was easier to get off again and to be clean again. So we measured in a quantitative study the percent, the amount of people that were clean. And in this politative study, we measured how people felt after ibogaine, even if relapsing. Most of the patients relayed that it was different, and even [if] relapsing, they thought that ibogaine had helped them.

So we are at this moment taking the next steps. We are trying to extend this regulation from Sao Paulo to other states. We are trying to somehow register the medicine. It's not easy to because it costs a lot of money - we think about 2 million dollars to register the medicine in ANVISA, because we need to show a lot of documents. We had a signal from ANVISA that maybe they could allow us to have what they said a fast track, which is maybe they will not ask for so many documents that they normally ask because they understand that it's an emergency. We have a lot of people in Brazil dealing with this problem. So it's possible - it's in negotiation at this moment - but it's possible that ANVISA will allow us to register the medicine and give us around 3 or 4 years to use it, and they could wait for this time for us to provide them the documentation. And we are trying to copy the MAPS's model on MDMA - we are trying to negotiate with ANVISA, that ibogaine treatment should be done in a controlled environment, with all the equipment necessary, and all the conditions necessary in the case of emergency.

I need to comment that all these years working with ibogaine, and more that a thousand treatments that I've done, I never saw a real emergency, I never saw a patient die. The worst thing I saw during a treatment was the patient vomiting a little more than the usual, but no problem. I think that this happens because we really [carefully] selected the patients who were going to do the treatment. We do a lot of clinical examinations, we do psychological evaluations, and we only allow people to take ibogaine if they are really in good health. We think that ibogaine treatment works like a minor surgery, so we do some pre-op operating examinations - like in a surgery of the stomach, or of the bladder, or anything in traditional medicine: If the patient is not ok, with blood pressure or with diabetes, for example, the surgery is postponed.

So we do the same thing. We only give ibogaine to the patient if he is really ok, if he is in good shape, in good health. So I think that this explains partially the reason why we never saw complications. We know that other places in Brazil, underground treatments, there was at least one death in Brazil, but it was not in our hospital. The patients that we treated, nothing really important happened. But we really need to convince the government that this is important, that this medicine really works. But what we feel is that the government agencies, they are open to hear us, and they are open to try to make some regulations.

In an ideal world it will be not necessary to be regulated, and people would have their responsibility to give or to take ibogaine, only in a proper situation. But as we see there are a lot of people who are looking more for profits than really worried about the health of the patients. We think that from the first moment, it would be good if we really follow the ANVISA regulations, and we show that it works, and that in the proper conditions, it's safe. And I think that after that, maybe the regulations could be loosened, and it will be more accessible for people.

The fact is that we need to bring ibogaine to the people, with not [such a] high cost, and easier for people to achieve it. It's important for people that they know that there is an option in the end that's a light in the end of the tunnel, and they must seek for a treatment that could be done in a good place, being cared [for] with responsible people, and in a place that they can feel that if anything different or dangerous happens, they will be cared [for]. What we see in some underground treatments in Brazil is that when people start to have some major reactions, normally the people 'put the patient away,' [or] dismiss the patient and say 'go home', like saying 'go and die at home.' And this is exactly what we don't want to happen. We want ibogaine to be seen like a normal treatment, like a lot of other medicines that are hard on the body.

I remember when I was studying medicine we used to treat pulmonary infection with a medicine that was highly cardiotoxic medicine, and the professors used to ask the internists to stay sitting by the patient during all the time that this medicine was dropping into the system of the patient, because we could have some kind of cardiac arrythmias. We want to do ibogaine like that. We want to have the authorization to do ibogaine since there's a person [there] to care for the patient, to be around. If anything different happens, the patient will be protected. And I think from all the treatments that I saw, I think that it's worth the risk. I think it's much more dangerous to take crack in the streets than to take ibogaine in a hospital.