Controlled Substances Advisory Committee

AGENDA 10/20/2020

I. Attendance & Review/approval of minutes.
II. Follow up discussions regarding Kratom, spice, and Gabapentin.
III. Presentation from Dr. Von Hafften on Gabapentin.
IV. New discussion regarding current scheduling and definitions of marijuana (specifically CBD products).
V. Next steps / Next meeting date(s)

I. Attendance & Review/approval of minutes.

Members - Katholyn Runnels; Tammy Lindemuth; Dr. Alex Von Hafften; Chief Timothy Putney; Leon Morgan; Donna Phillips

Guests – Derek Walton

Review of Minutes: Dr. Von Hafften suggested that under the first paragraph of roles and responsibilities, right after introductions, the meetings should be held no less frequently than twice a year. There was a correction made in that same paragraph to the word discussed from discusses, grammatical error. No other suggestions or corrections.

Motion made by Dr. Von Hafften to accept the Corrections to the minutes; seconded by Katholyn Runnels. Approved by all.

II. Follow-up Discussion on Kratom, Spice, and Gabapentin

KR – Kratom – need to come up with the language for scheduling Kratom. The best practice is to schedule the chemicals within Kratom rather than Kratom itself. We need to discuss what schedule we would recommend it be.

Derek Walton gave a brief overview of what we discussed about Kratom previously. The Alaska State Crime lab is very good at identifying chemicals – individual chemicals. Not botanical plant chemicals. Except cannabis. There is no botanical identification for the Kratom plant itself. The labs recommendation would be to schedule the component chemicals – mytragynine and 7-hydroxy-mitragynine – rather than scheduling Kratom itself, or perhaps in addition to Kratom itself, if that was the recommendation of the committee.

KR – there are 5 factors to look for in recommending scheduling, and the guidelines state; The committee shall address the probable danger; the actual or probable abuse of the substance including the history and current pattern of abuse, both in this state and other states; the scope, duration and significance of abuse; the degree of actual or probable detriment, which may result from abuse of the substance; the probable physical and social impact of widespread abuse of the substance; to the biomedical hazard of the substance including its pharmacology; and the effects and modifiers of the effects of the substance; it's toxicology; the acute and chronic toxicity interaction with other substances, whether controlled or not, and to the degree with which it may cause psychological and physiological dependence; the risk to public health and the

particular susceptibility of segments of the population. 3) whether the substance is an immediate precursor of a substance already controlled; 4) the current state of scientific knowledge regarding the substance including whether there is any acceptable means to safely use the substance under medical supervision. 5) The relationship between the use of the substance and other criminal activity including: a) whether people engaged in illicit trafficking of the substance or other criminal activities, whether the nature and relative profitability of manufacturing or delivering the substance encourages illicit trafficking of the substance; whether the commission of other crimes is one of the effects of abuse of the substance, and whether addiction of the substance relates to the commission of crimes to support the continued use of the substance.

In following up on Kratom, 7 other states currently have Kratom controlled. Most of the states list is to the same level as cocaine, ecstasy, etc. Labeled as a Schedule I. One other state listed it as a synthetic drug, but it is not. But all had it scheduled fairly high.

Leon Morgan from DPS – they would like Kratom as a schedule III substance so that it would be make it a felony for distribution, but just a misdemeanor on possession so that we are not overcharging those with it only in possession. This way we are concentrating our efforts on those who are profiting from the distribution of Kratom.

KR – under Alaska statute we need to look at where that would be under. For instance, opioids are a schedule I. Mainly what I consider our big drugs – meth, cocaine, ecstasy, LSD, PCP; those are all schedule II's. The only schedule III's that we really see are anabolic steroids, and there is a special exception for hydrocodone. Pure hydrocodone would be a schedule I, but hydrocodone is always cut with acetaminophen which under the statutes moves it down to a schedule III. Our schedule IV's are typically most of your prescription drugs, so Xanax, all the pams, tramadol. There are not a lot of schedule V's, and then schedule VI is marijuana.

Katholyn went over current schedules and how law enforcement categorizes first offense, second offense, etc. This information can be found in Alaska Statute, Article 1. Offenses Relating to Controlled Substances. Chapter 71. Controlled Substances.

In agreement with the recommendation of a schedule III since it doesn't seem to rise to the level of needing a schedule II level.

Dr. Von Hafften: from his POV there is no upside to kratom or therapeutic benefits. See only downside risk. So would look to the DOL and DPS as to how to most effectively schedule the components for the best possible way for DOL and DPS.

Leon Morgan: if we have a substance that is a misdemeanor even for distribution, we must triage what cases we are going to take and what impact it is going to make. We will focus on the higher scheduled drugs. They have a greater effect on the community when they get through our firewalls. The best enforcement of it will be if it is a schedule III.

KR: Is there a chance of fatality/overdose risk with Kratom.

VH: Not known. But behavior related in general can lead to this situation and would lead to the intervention at this point.

TL: Sgt. Blanchett talked about the difficulties with kratom usage leading to the medivac situations necessary from bush Alaska. We should go on the recommendation of DPS and DOL, especially when looking at the pros and cons of scheduling is as a schedule III.

KR: The schedules are already difficult because of the chemical compounds. It's a matter of remembering which drug/substance is on what schedule.

TL: If we do the recommendation for schedule III, then we would have public comment regarding this recommendation held for the February 2021 meeting.

Katholyn Runnels moved that we make a recommendation the chemical compounds within Kratom – mitragynine and 7-hydroxy-mitragynine – that they be scheduled as a IIIA controlled substance. Seconded by Leon Morgan. All in favor.

VH: Commented about DEA information on Kratom.

- At low doses, increased alertness, physical energy, and talkativeness
- At high doses, sedation
- Addictive: causes hallucinations, delusion, and confusion
- Nausea, itching, sweating, dry mouth, constipation, increased urination, and loss of appetite
- Long-term use can cause anorexia, weight loss, and insomnia.

But it doesn't say anything with respect to fatalities. The addictive issues have led to other harmful actions with other substances.

Follow-up discussion on Spice:

Derek – summarized previous discussion: the lab has challenges with synthetic drugs. There are many, many variations of those substances. We have an existing statute regarding the bath salts substances, different types of modifications that could result in something controlled. Thus far we are just listing specific names. The Clandestine Laboratory Investigating Chemists recommended we look at the Texas Statute. Section 481. My impression is that we don't need to reinvent the wheel and we consider using similar language. The risk would be overcontrolling a substance, but with the specific requirements the risk of overcontrolling a substance would be low.

Specifically, From Derek Walton to Everyone:

Here is the current Sec. 11.71.150. Schedule IIA. (e) for comparison. This covers the "bath salt" substances (15) substituted cathinones, including any compound, except bupropion or a compound listed in another schedule, structurally derived from 2-amino-1-phenyl-1-propanone by modification in any of the following ways:

(A) by substitution in the phenyl ring to any extent with alkyl, alkoxy, alkylenedioxy, haloalkyl, hydroxyl, or halide substituents, whether or not further substituted in the phenyl ring by one or more other univalent substituents.

(B) by substitution at the 3-position with an alkyl substituent.

(C) by substitution at the nitrogen atom with alkyl or dialkyl groups or by inclusion of the nitrogen atom in a cyclic structure.

Leon Morgan – the difficult with Spice is that there isn't a specific field test for it. There is of course for other controlled substances, but not for synthetic cannabinoids /designer drugs.

KR – the best way to solve that problem, and in having a discussion with Derek, we need to specifically have the chemical substance scheduled and helps us get in front of the issue.

Leon Morgan – I would like to have a medical analysis of any other substances that are needed medically so we don't run the risk of overcontrolling/scheduling a substance. Thus, allow us time to be better educated on synthetic cannabinoids/designer drugs. We don't want to criminalize behavior that doesn't need to be criminalize.

TL- we can look at getting a presentation more on Spice so we can have a better understanding of it. And we can look at wording and see what would be beneficial.

WE NEED TO HAVE A PRESENTATOIN/BETTER PERSPECTIVE ON HOW THE TEXAS STATUTE HAS HAD A BENEFICIAL EFFECT ON THE COMMUNITY

VH – what would be the downside of using the Texas Statute as a model and making sure there are no known clinical uses for any version of compounds within the way the statues can be interpreted.

Derek – cannabinoid receptors can be activated by a much broader variety of substances.

TL – Will do some research on the Texas Statute and see what the upside/downside of the law has been.

KH – who would we be able to get to explain the chemicals, a chemist and medical professional?

TL – let's query Dr. Zink as to who could help us with that information.

KH – Has some contacts in Texas and will query them.

VH – recalls Dr. Butler possibly doing a presentation regarding Spice, K2 and "bath salts."

Chief Putney – Doesn't recall specifically a presentation, but there may have been.

TL – moving on to Gabapentin. But first follow-up about gabapentin – it isn't required to be tracked in the PDMP. There is an increased trend in it showing up since 2016. As of recently the number of RX's for gabapentin reported in the PDMP did peak in the first quarter of 2020 with almost 5500 prescriptions compared to 4,600 prescriptions in the same quarter in 2019. But we can't really say how reliable that data is since it is not required to be reported. Of note, if Alaska schedules gabapentin as a controlled substance, it still doesn't mean that it becomes mandatory to report to the PMDP because the PDMP is based on federal classification, not state.

III. Presentation from Dr. Von Hafften on Gabapentin.

Dr. Von Hafften – presentation on Gabapentin, via power point presentation.

Brand names include Neurontin, Gralise, Fanatrex, FusePaq, Horizant, others. The FDA in 1993 approved it for epilepsy, adjuvant anticonvulsant; in 2004 approved for post-herpetic neuralgia; and in 2004 generic. FDA Warnings – 2019 respiratory risk. DEA Scheduling – unscheduled; unlike pregabalin (Lyrica) which is a Schedule V.

Off-label Use: 80-95% of all gabapentin use is off-label; 90% of sales. Used for Bipolar Affective Disorder, Anxiety, Insomnia, Alcohol Use Disorder, Drug Use Disorders, Migraine, Restless Leg Syndrome, Vertigo, Pruritic Disorders, and Others.

Assumptions: Overdose – no fatalities; Long-term Use – Safe; Misuse/abuse/dependence – No; Easy to obtain a Prescription – Yes; Not on most drug screens – yes.

Misuse Data: 40-65% of persons with gabapentin prescription (2016); Correctional settings (Scotland, Florida) - 80% of prescriptions in hands of people not actually prescribed drug; 1.0% of general population (2016); 1.6% of non-opioid users (2016); 15-22% of opioid users (2016).

Why: reduce pain; control mood and/or anxiety; recreational misuse; Enhance/prolong effects of other drugs, i.e. cannabis, SSRI's, LSD, amphetamines, GHB, others; potentiate effects of substance use disorder treatment medications, i.e. buprenorphine/naloxone, methadone; Reduce craving for/manage withdrawal from other drugs; Reducing reinforcing effects of cocaine, reduce symptoms of alcohol withdrawal; Substitute for other drugs; Intentional self-harm.

Fatalities: When ingested with opioids, benzodiazepine, alcohol (all CNS suppressants); 93% included benzodiazepines, antidepressants, other CNS depressants, antiepileptics, cannabinoids, stimulants, ethanol; 0.6% of impaired driving cases (USA); 1% all drug-related deaths (Scotland); 0.3% of postmortem impaired driving (Finland).

State Actions: Schedule V – Kentucky (2017) – 1 in 4 overdoses, 1 in 3 overdose deaths; West Virginia (2018); Tennessee (2018); Michigan (2019); Virginia (2019). Considering/pending: Alabama, North Dakota, and Ohio. PDMP Monitoring – Ohio, Minnesota, Illinois, Wyoming, Massachusetts, others

Possible Recommendations or Interventions that the CSAC can do: Increased Prescriber education; Increased Patient education; do we make it a Schedule V; Prescription Drug Monitoring Program (PDMP) – Information, Monitoring; can we obtain additional information/monitoring.

Also provided Summary from Canadian Medical Association Journal on Gabapentin misuse; CMAJ 2019 January 14;191:E47.doi:10.1503/cmaj.180599

Discussion post presentation:

Leon Morgan - noted that people aren't going to their doctors for a prescription. People are getting it from a foreign source. It takes the border patrol and others more time to stop them from coming in. It is out there. About $10-$20 per pill. They are getting smuggled (thousands of pills), added on to any bypass shipment. We are currently just observing this activity. Haven't seen anyone die from gabapentin. Are we seeing it as a source of person-related crime as we do alcohol? Is gabapentin leading to that, I don't know. It is certainly out there. You can cut one source off and another one pops up.

Donna Phillips – we see it in the hospital as a multi-modal approach to pain therapy instead of using narcotics. It is frequently used for nerve pain. You must fail on gabapentin before using Lyrica and others. There is an increased use of it because people are getting it shipped from a foreign source. If it is scheduled it will be more work as we will have to count it.

KR– without them being controlled it is not illegal even when they are shipped from a foreign source and they have to let them go through. Thus, the pills make it to their final destination. If it is controlled, then they can interdict those and get them pulled from going out in the population into the stream of commerce.

LM – it does need to be controlled so we can interdict the distribution of it, seize and dispose of it.

KR – the most common schedule VA is buprenorphine. Distribution is a Class C felony; possession is a misdemeanor.

TL – recommend that we do advise it being scheduled as a VA.

VH – let's see where the level of opposition might be from the legislature with gabapentin. This specific step is trying to give the framework for DPS to intercede when clearly people are moving this substance in for no clinical benefit. The Board of Pharmacy should think about this – are there steps the DHSS or the BOP can do to help education folks about the advantages as well as the risks/benefits?, as the general population is unaware of this information. We want to balance the most amount of benefit for the last amount of risk.

Dr. Alex Von Hafften made a motion that we recommend gabapentin be classified as a Schedule VA. Leon Morgan from DPS seconded the motion. All approved.

*Would like to have Dr. Ann Zink's input on the scheduling of gabapentin, as well as Spice and potential scheduling of it (Texas has scheduled it).

IV. New Discussion – Marijuana/CBD products

KH – this is about the decriminalization of CBD products. Currently the definition for marijuana includes botanical products and oils specifically, and currently the lab doesn't have a way to quantify how much THC is in a product. But when they legalized marijuana, they didn't change those definitions. So, it didn't account for the different types of products that CBD products come in, the forms – edibles, lotions, powders, etc. So, what the Crime Lab is seeing when coming across these products it is just testing for THC or not and there is no real exception for the CBD products, so technically they potentially might be criminalized. So, we wanted to talk about changing the definitions or making exceptions that would allow for people to use CBD products.

Derek – the two places in the statutes where we kind of have a provision for THC content would be with plant material, and then also something with what is termed cannabidiol oil. The definition of cannabidiol oil under Section 11.71.900 is the liquid viscous concentrate of cannabidiol extracted from the plant or genus cannabis containing not more than 0.3% delta-9-tetrahydrol cannabinoid which is just the commonly used term THC. So, this presents a couple of challenges for the interpretation by the laboratory. Throughout the labs contribution to this with this particular committee there is a common theme which is just having a sufficiently clear statute that we can interpret and then also pass along this information to the criminal justice community so that we can all be on the same page basically with regards to that communication. Currently, the lab does not have a way of determining how much THC is in a particular product. This is something we are working on. However, this won't be available until sometime mid-2021. Thus, the current question is what happens to something that is not a viscous liquid concentrate or a plant material? A corollary to that is, most cannabis plants contain some THC, that's the psychoactive ingredient common to marijuana, so even if your cultivating a plant that is a hemp product and you're saying this is a cannabidiol or for some other purpose besides "getting high", there still is a detectable amount of psychoactive chemical present in that product and that's what the laboratory is seeing when we are doing that analysis. When we do have something that does meet the definition of a viscous liquid concentrate, if it contains a little bit of THC then we might suspect that that is a cannabidiol product because there is a provision for that. But if it is anything other than a viscous liquid concentrate, if we see any THC in there whatsoever, that means that's a Schedule III product with regards to the way we are interpreting the statutes. I don't think that's really the intent of the law. Some examples of this could be a cannabidiol hand cream that's designed for topical relief of arthritis, or you can get cannabidiol in your coffee if you're in the Palmer/Wasilla area, so there are all these other types of products out there that don't meet this definition of viscous liquid concentrate, so if we detect any THC in that product whatsoever that means that's a Schedule III product which might include your cup of CBD coffee in the morning which doesn't seem to fit the intent of the law. Thus, the first question is: what is the intent of that?, and is it intended to cover other types of things that are designed to be cannabidiol products other than just viscous liquid concentrate. How do we handle that situation? Perhaps a modification to the current language? Example – gummy bears that had CBD in it and thought to be legal, but when tested there was traces of THC in it. Is this still a Schedule III product when clearly that was not the intent of its production?

KR – this is a two-step project. First, identifying the language and make it broader. Possibly change the definition to cannabidiol product away from the viscous liquid concentrate.

Derek – the portion that stays the same is the percentage of THC found in the product which is the distinguishing factor for something that is intended to be a drug type product and more of therapeutic type product, but anything under that amount would be okay. There are a variety of materials that could be classified under the cannabidiol product.

KR – not sure how to fix this without being able to quantify which is the second part of this. Maybe it's more of a reporting rather than correcting.

Derek – This is what the Crime lab is doing now - prior to the 2018 Pharm bill that added the 0.3% delta-9-tetrahydrol cannabinoid requirement to the federal statutes, that is something that Alaska basically adopted, the 0.3% number, to specifically differentiate industrial hemp from marijuana or drug type cannabis. So, for those of you that don't know, the cannabis sativa plant is the same plant that is used for marijuana and is used for industrial hemp. The only differentiation between those two is that the industrial hemp plant has been bred in such a way that it has a very low THC content to begin with where a marijuana type product would have a much higher THC content in most cases. That has been an issue for the lab for quite a while now and our plan, which we are sort of executing right now, is to get the equipment to be able to make that determination in the future, but we just want to try to kind of cover all of our bases at one. So if it is difficult for us to interpret the statutes for plant material and for the derived products as a result of the language that is in there, it would seem like it makes sense to try to handle those things at the same time. Right now we have wiggle words that are helping us to handle it and to use on our reports, at least for plants, we can say for sure that this is cannabis but we can't say for sure it is marijuana because of the need to make that distinction in THC content. The reports that the lab are sending out right now are in some ways not very useful to the criminal justice system because they don't really answer that question of "is this a drug type product or is this a hemp type product or a cannabidiol type product." It is in our plan to be able to address this issue in the future. Revising this language would be helpful for everyone in terms of interpreting the statutes and bringing clarity.

KR – the next step would be to advise the governor with laying out and addressing the problem with our proposed fix. Question to Derek – say we are a year in the future where we can quantify it and we expanded the definition; would that ultimately solve the problem?

Derek – Yes. I think that the best possible situation would be that everybody is on the same page. What that would mean is that the portion of the statute that talks about plant material would basically say that the cannabis sativa plant if it has more than 0.3% THC then it is considered drug-type, if it has less than 0.3% THC then it is considered hemp, or not marijuana basically. Then there would be corresponding language for these cannabinoid type products. So, a cannabinoid product means a product containing cannabinoids, if it has above 0.3% delta-9-tetrahydrol cannabinoid, then it is considered controlled. And if it contains less than 0.3% delta-9-tetrahydrol cannabinoid then it is not considered controlled. That would synchronize all of the language across all of the statutes, make it easy for the laboratory to interpret, make it easy for us to report, and then make it easy for the local community to understand what we mean when we provide a particular result.

TL – I think we should move forward with making this recommendation to the governor.

VH – Two questions for Derek with respect to the HPLC. Is that going to be quantifying or is there a minimal threshold? So, either above what the minimal threshold is, i.e. if I get a drug screen on somebody, I can sometimes request that it be quantified, or it's either present or not present, depending on what the threshold?

Derek – Yes, it would be a fully quantitative method. Certainly, there would be a lower limit where we would have to say that it is below this number or it's undetected, but our intention would be to have a numerical result in most cases.

VH – second question, if I remember the CSAC as the marijuana process was unfolding a few years ago, I think there was a marijuana control board of some sort, and so I guess my question is there a marijuana board such that if we put the forth language we are trying to modify, and is there a marijuana control board that we would need to be including in supporting whatever recommendations we are making?

KR – I think it is all one now. The Alcohol and Marijuana Control Board. I want to say mostly my dealings with them have dealt mostly with the legal requirements for permits and dealing on the business side of that, but we could easily reach out to them. My understanding, however, is that they are more regulatory than dealing with the statutory language.

Derek – it would be helpful from the Crime Lab's stance if we had their agreement and to just be able to make sure that whatever we are proposing syncs up with the requirements they already have in place.

V. Next Steps

Overall, for next steps, we are recommending scheduling of mitragynine and 7-hydroxy-mitragynine as a Schedule IIIA. We are also recommending scheduling gabapentin as a schedule VA. In addition, we are moving forward with conferring with the Alcohol and Marijuana Control Board letting them know that we are looking at the definitions of marijuana in products and expanding the language so as to give clarification with respect to quantifying and use of the HPLC device in the Crime Lab.

Katholyn and Derek with do a comparison of the statutes so we can have proposed language for the clarification.

Katholyn suggested we invite someone from the Alcohol and Marijuana Control Board for the next meeting to share from their perspective.

Next Meeting: Tuesday, February 16th, 2021, 1:00-4:00 p.m.

Donna Phillips moved to adjourn the meeting. Chief Putney seconded. All in favor.

Minutes completed by tjl