Controlled Substances Advisory Committee

Date:	Tuesday, December 20, 2016 from 1:00-4:00 PM
Location:	Attorney General's Office, 1031 W 4th Ave Conference Room 502, Anchorage, AK 99501
Chairperson:	Robert Henderson (LAW)
Member in Attendance:	Leonard (Skip) Coile (public member) Lana Bell (Board of Pharmacy) Dr. Alexander Von Hafften (public member) Sandra Aspen (public member - telephonic) Major Jeff Laughlin (DPS) Dr. Jay Butler (DHSS)
Public in Attendance:	Staci Kraly Jim Cantor, Deputy AG C.J. Kim Katie Bell
Secretary:	Shiloh Werner

Handouts

- Synthetic Opiate Bulletin
- GW Pharmaceuticals Letter to Attorney General Richards dated May 3, 2016
- Alaska Pharmacists Association Letter to CSAC dated September 12, 2016
- GW Pharmaceuticals Letter to Attorney General Richards dated December 2, 2016
- House Bill No. 51
- AS 11.71.120, Authority to Schedule Controlled Substances

Agenda

- Approval of Minutes from January 27, 2016
- Tramadol – The Alaska Pharmacists Association's request to schedule tramadol
- U-47700 – aka "pink" – general discussion regarding substance and need for inclusion in Alaska Statute
- GW Pharmaceuticals' request to de-schedule CBD
- Update regarding the Alaska Opioid Task Force (http://dhss.alaska.gov/AKOpioidTaskForce/Pages/default.aspx)
- On-going discussion regarding the Controlled Substance Revision Project
- General Discussion
- Next Steps / Next Meeting

APPROVAL OF MINUTES

Minutes from the meeting held on January 27, 2016 approved unanimously by the Committee.

TRAMADOL – THE ALASKA PHARMACISTS ASSOCIATION'S REQUEST TO SCHEDULE TRAMADOL

Mr. Henderson offers the letter from the Alaska Pharmacists Association up for discussion. Does the committee want to take a position on Tramadol; do they want to become involved? Major Laughlin, former statewide drug enforcement commander, mentions that tramadol has been a topic for a long time. Tramadol is not a controlled substance in Alaska and thus remote communities possess the ability to order it. Lots of calls have come in from the public regarding "cold calls" received from outside sources offering these drugs for sale to remote communities, causing a lot of concern. The federal government has since scheduled it. Mr. Henderson wonders what the Department of Public Safety does if a drug Alaska has not scheduled is scheduled by the Feds. Major Laughlin responds that they work with their postal partners and try to have them monitor and refer information of incoming shipments to federal law enforcement. To his knowledge, DPS does not currently have cases in which they have seized these unscheduled drugs. These types of cases are passed on to federal agencies.

Deputy AG Cantor wonders about the abuses of tramadol. Dr. Butler responds that it is dangerous and can lead to serious medical complications and it is in areas where purer opioids are not as readily available. Mr. Kim expands on Dr. Butler's descriptions of the health related dangers of tramadol. Mr. Henderson wonders if it is appropriate to schedule it as a schedule IVA controlled substance? The committee reviews AS 11.71.120(c) regarding the items that must be considered in which to schedule or change the current scheduling of a particular drug. Mr. Henderson asks Major Laughlin about the street value of tramadol and if it is still commonly proscribed. Mr. Kim responds that is now on the PDMP and thus more visible. Ms. Bell responds that she sees less prescriptions of it than hydrocodone. Mr. Henderson puts the question to the committee – is there any additional information the committee would like to know before making a decision on whether or not to work towards a recommendation? Dr. Butler and Mr. Coile believe the committee possesses enough information in which to make an informed decision. The committee unanimously approves to draft a letter of recommendation that tramadol be scheduled as an IVA. Dr. Van Hafften believes tramadol meets the necessary criteria for an IVA. Dr. Butlers poses a question to Major Laughlin regarding the "cold calls" to sell tramadol. Major Laughlin responds that the callers often sound like legitimate sellers of non-controlled drugs. These calls are made to members of the public, not health care providers. There appears to be links to family names in which calls are made based on searches. It is more of a white-collar solicitation as opposed to "guy on the street".

U-47700 – AKA "PINK" – GENERAL DISCUSSION REGARDING SUBSTANCE AND NEED FOR INCLUSION IN ALASKA STATUTE

Dr. Butler begins by providing the committee with a description of "pink". It is a synthetic opioid that is available illicitly, manufactured primarily in India and China, and can be ordered on the internet. It is mixed with or sold as heroin. Three overdose deaths, relating to the use of "pink", have been reported this year. These deaths were not clustered, but rather happened in three different locations. "Pink" was on the Federal controlled substance list as of November 10th as a schedule I controlled substance via emergency order. No one commercially manufactures it in the US. Mr. Henderson wonders if it is similar to what we have dealt with in "Spice" where once scheduled, it can then be quickly chemically altered. Major Laughlin responds that it is possible. However, that is not what DPS has been seeing. The federal government does not suspect it can be as nimbly altered as "Spice" is.

There is a bill being drafted to address synthetic opioids in order to avoid the problems that were encountered with "Spice". DPS has not physically seized it, but has good information that it is being handled through the same market venue as "Spice" was. Canada first started noticing the drug mixed with heroin. There is suspicion that the overdose death rates are underreported in the United States. Mr. Henderson wonders if it needs to be independently scheduled if being sold and seized as a stand-alone drug. Major Laughlin believes it is being sold both ways: both stand alone and spliced with something else. Mr. Henderson then adds that if the committee were to recommend that it is scheduled, would they reference it based on the DEA bulletin? Dr. Van Hafften comments that though "pink" were the most active, other compounds existed that were very similar. Ideally we would capture all of them, even those we haven't discovered yet. How do we do that? How do we capture all these chemical compounds? We know that "pink" has been identified, but the committee would likely be discussing analogs (similar compounds) in a year or so. Major Laughlin wonders if there is a way to come up with language that captures synthetic opioids that are continually being changed, etc. Mr. Henderson said that it would be very difficult because it is based on physiological effects. Perhaps it would be appropriate to determine how other states have tackled this issue. Dr. Van Hafften offers that Ohio and Oregon would be the top of his list because they have already been approaching this question. The committee unanimously approves to recommend that "pink" be scheduled as an IA controlled substance.

GW PHARMACEUTICALS' REQUEST TO DE-SCHEDULE CBD

GW Pharmaceutical manufactures cannabidiol (CBD), but it is not yet FDA approved. Major Laughlin wonders if it is currently federally scheduled? Mr. Coile believes it is scheduled as marijuana. Mr. Kim confirms it as being scheduled as an VIA controlled substance. Ms. Bell inquires whether given FDA approval CBD will be available to the public even with its current schedule, is it really something the committee needs to address? She adds that her belief is that it is not appropriate for the committee to have a recommendation at this time. The committee is in agreement with Ms. Bell. The groups mentioned in the materials provided by GW are not ones known to the committee. Mr. Henderson poses these questions to the committee: do we want more info, do we want to table it, or do we want to tell them we are aware of their request and ask to stay informed? Ms. Bell responds that she does not think the group is in a position to make any sort of recommendation absent the FDA approval this company is seeking. Dr. Van Hafften adds that based on his review of their provided materials that there is insufficient information and thus he is in agreement that the committee not do anything at this time. The committee is in agreement to take no position and table the discussion, pending further action by the FDA. Mr. Henderson asks if anyone has an objection to responding to GW with the committee's decision as a courtesy. No objection.

UPDATE REGARDING THE ALASKA OPIOID TASK FORCE

Dr. Butler gives a quick description of the Alaska Opioid Task Force. They are connected to this committee by way of their recommendation to change the mechanism by which we schedule drugs in an attempt to make it easier to pass emergency scheduling. Other issues the Task Force has discussed include: supporting drug take back programs, prescriber guidelines, increasing provider accountability to the boards, security and screening of travelers in the bush, the PDMP, reimbursement of treatment alternatives to narcotic pain meds, ways to encourage healthy child development, how to combat adverse child experiences, behavioral health services with primary care, and types of education

programs for providers, the public, and school based interventions. Meetings have been held over the last six months, covering this broad range of topics.

Dr. Van Hafften adds that they discussed the CSAC and its ability to regulate drugs. However, that is currently incorrect; the CSAC does not have that ability currently, but it could be a recommendation. A regulatory body would ideally be a combination between DHSS, Board of Pharmacy, LAW, and DPS. The current statutory scheme is inefficient. It is outside the committee's enumerated duties, but is there a better way to do what we are doing now? The current statute is not flexible. Mr. Henderson asks if the committee would like to take a position on this proposal or to encourage this recommendation of regulatory authority to come to the committee. Dr. Butler believes there is consensus that what they are trying to do is clumsy. Ms. Bell wonders how long these emergency regulations last. Major Laughlin offers an example of an agency, Fish and Game, that uses emergency regulations frequently. Statutory change would be necessary in order to allow for emergency regulations. There are several groups currently looking at this issue of the ability to quickly regulate and schedule drugs. Mr. Henderson believes that because extensive legislative revision would be necessary, it may be a request that should come from a specific department. Ms. Bell believes that this committee seems to be the perfect group for this sort of task. Dr. Butler is in agreement - this group is very interdisciplinary with members from different backgrounds. Returning to the example of Fish and Game, it is determined that their authority to establish emergency orders was given to them as a "department". Dr. Van Hafften wonders, from a legislative perspective, if it makes sense to include one or two legislators to the committee so their input is included in the decision making. Deputy AG Cantor notes that such an addition would be prohibited by the state constitution, unless their role is advisory only – *i.e.,* the legislators would have to be non-voting members.

Ms. Kraly informs the committee that there is a time limit on emergency regulations. They are adopted for reasons regarding our health, safety and welfare. Regulatory or emergency projects are able to be started if authority to do so is given by the legislature. An emergency regulation becomes effective upon adoption and is then open for public comment. They are effective for 120 days in which during that time there are public hearings, comments, etc. After the close of 120 days they can be permanently adopted and become law under the Administrative Procedures Act, 44.62.250 and 260. If never adopted, the emergency regulation will just "go away". Deputy AG Cantor adds that the time commitment for that sort of work is a lot more than the current commitment of public members. You need to think if the committee truly can take on this work-load and time commitment. Mr. Henderson follows that it would be much more rigorous process since it would change the committee to a regulatory/decision-making body, as opposed to an advisory committee, as currently designed. The hurdle the committee would be taking on is to take 11.71 out of statute and move it into regulation.

Dr. Van Hafften says we as a committee have identified a problem, we have thought of an avenue in which to fix the problem, now how do we do it? Mr. Henderson responds that we would need to make a decision collectively among all the different departments and agencies represented, especially because this would be outside the current scope of the committee. Ms. Kraly wonders if the committee would be recommending a narrow fix in which a particular agency is given this authority to create emergency regulations and take that out of the legislature's purview. Mr. Henderson responds that this is just for the scheduling, not the penalty or classification – that is, the ultimate penalty associated with any controlled substances would be left to the sound discretion of the legislature. Deputy AG Cantor adds that emergency regulations are things that must be done "now" but the normal regulatory process is 6-9 months to a year. He asks the committee if they are referring only to emergency regulation or the regular legislative regulation process. Mr. Henderson responds they are thinking possibly a hybrid. Ms. Bell wonders when we decide if an emergency exists in which an emergency regulation is warranted. Three deaths? Do we compare nationally to justify our emergency?

Ms. Kraly refers Ms. Bell to the administrative definition of an emergency. Ms. Bell wonders about the need for emergency regulation. Is it for a recurring problem? Mr. Henderson responds that it is a combination of a public health and public safety issue. So Ms. Bells offers that that there is the answer – both a health and public safety issue must be present. Dr. Butler also adds the need to bring our laws in line with the Federal ones regarding controlled substances.

If these recommendations from the Task Force are going to the governor and legislature to give the committee this power of regulation, do we have a better idea? The fewer entities involved would make it more efficient Ms. Bell offers. Mr. Henderson asks Ms. Kraly, is 120 days a sufficient amount of time for an emergency order to become permanent? She responds that the Administrative Procedures Act (APA) is set up for emergency regulations with the expectation that they will become permanent. The only way, as the APA is currently drafted, is to take 11.71 out of statute and into regulation – the schedules, not the penalties. It allows the scheduling to happen outside of the legislature process. If this recommendation goes forward, recognize that we are taking on a pretty major re-draft of current law. Dr. Butler said that we can all agree that what we currently have is not working for health and safety.

The governor is currently required to accept our recommendation and pass it to the legislature, but then nothing will necessarily happen. The unique thing is that the governor is obligated to pass along our recommendation. Mr. Henderson suggests we continue to make recommendations, but it could be tasked to a separate regulatory body to actually establish the emergency regulations. Major Laughlin adds that most regulatory authority is given to an individual department. Does there exist any that are across different departments? The answer is that they are only to one department. Mr. Henderson points out that the board of pharmacy has regulatory authority. Ms. Bell reminds the committee about the difficulty of identifying a drug versus a chemical compound, etc. The committee agrees that it will be difficult to define and schedule particular substances. Deputy AG Cantor says that this discussion is consistent with what he has been hearing about the call for taking the regulatory authority out of the legislature so these sorts of things can happen quicker, especially since drugs are able to be changed so quickly. Does the committee want to take a position on the Alaska Opioid Task Force's recommendation in regards to CSAC being the regulatory authority. The Task Force's draft recommendation in regards to CSAC is as follows:

> "The Controlled Substances Advisory Committee is granted statutory authority to add substances of abuse to the controlled substances schedule by regulation, including emergency regulation, to allow the State of Alaska to react to public health dangers posed by synthetic and other emerging opioids and substances of abuse."

The committee agrees that the CSAC should not necessarily have the regulatory authority. It should be housed in a particular department with this committee serving as advisors. Ms. Bell believes the emergency regulatory authority should be housed in a medical body based on their knowledge of the compounds, with input from public safety, as opposed to the authority be in public safety. The public process is the opportunity for other departments to take part. Ms. Bell offers that Dr. Butler's position is the most logical. Major Laughlin agrees that DHSS is more broadly focused on health and safety whereas public safety is more narrowly focused. The committee moves to adopt Mr. Henderson motion that the committee recommend that the Alaska Opioid Task Force adopt a recommendation in relation to the creation of a 'regulatory body' under the Chief Medical Officer/Director of the Division of Public Health, Alaska Department of Health and Social Services, to manage controlled substances schedules, including emergency regulations. This motion is approved unanimously by the committee.

GENERAL DISCUSSION

Update on the PDMP

The planned rollout is not set to begin till July. Dr. Van Hafften has questions about whether they will be addressing the issue of sharing information with non-authorized users, known as "secondary disclosures" in the PDMP. He wants to be sure that the providers understand what they are allowed to do and that they are following privacy laws so as not to make improper or illegal disclosures. The strictest interpretation, as it currently stands, is it is illegal to enter your suspicions of a patient's overuse as a provider since they information may be subsequently disclosed. Who would educate people on this? Ms. Bell provides the example of med-limits, a federal program, and their inclusion of education for providers. She does not believe there is a formal plan in place for the PDMP, but believes that sort of education is to be part of the second phase.[i]

There is currently no program coordinator for the planned rollout of the PDMP. Once one is in place, he or she could be invited to meet with the committee. The board of pharmacy is set to meet March 2nd and 3rd. Mr. Henderson wonders if we could recommend education for providers on the PDMP to the board. Ms. Bell says she can recommend that to the board. Dr. Van Hafften adds that there was a push to make this not mandatory so an approach will have to be taken that gets providers to go-along without causing a lot of resistance. The program coordinator position is still in classification being developed, so if the committee would like to influence what that position may entail, this is a good time. A decision is made to contact the state employee tasked with developing the program coordinator position and invite them to the next meeting. [ii]

Resources for Treatment

Dr. Van Hafften offers discussion on lack of treatment resources. Does this committee want to do more? Mr. Henderson recommends that yes, with a caveat. The Alaska Criminal Justice Commission, under SB 91, revised title 11 and how we address criminality, premised on the idea of treatment of substance abuse first. They have committed to tackle that issue. We could also tackle it. We could partner with them or just monitor what they are doing. Logistically the criminal justice commission has the support and resources that we do not have as a committee. Dr. Van Hafften would like for someone to give updates and monitor whether or not the Criminal Justice Commission is actually doing something about the issue; because, if not, it is within the responsibility of the committee to address. Major Laughlin adds that DPS is curious about the conversations in regards to the treatment for substance abusers. Mr. Henderson suggests the committee ask Barbara Dunham, the new Justice Commission coordinator, for an update on the commission's work in this area.

ASSIGNMENTS

- **Respond to GW with committee's decision to table the discussion pending further information and FDA approval.**
- **Contact Barbara Dunham, Alaska Criminal Justice Commission coordinator and ask for update in regards to the Commission's work in providing resources for treatment.**
- **Invite Sara Chambers to discuss the PDMP coordinator position.**
- **Prepare recommendation to the Task Force**

- **Prepare recommendation regarding Tramadol**
- **Prepare recommendation regarding Pink**

Next Meeting: Thursday, February 16th, 1-4 PM

[i] Dr. Von Hafften further clarifies that his intent was to communicate that there may be exceptions to submitting information to the PDMP.42 CFR Part 2 may prohibit substance use disorder treatment programs reporting dispensing information to the PDMP because of secondary disclosure. This is not addressed in the DCCED PDMP Q&A. The DCCED PDMP Q&A should include a Q&A regarding 42 CFR Part 2.

[ii] Dr. Von Hafften further clarifies that his intent was to communicate that he believes the Alaska State Medical Association and medical community consensus was supportive of the PDMP. However, there may not have been consensus that all prescribers should be mandated to register. And, there was not consensus that all providers be mandated to review the PDMP each time a controlled medication is prescribed for a patient. Yes, SB 78 includes a few exceptions. Educating physicians about the PDMP will be important for the acceptance of and support for the AK PDMP. As an interesting FYI, the recommendations of one of the AK PDMP references (Washington State AMDG - Interagency Guidelines on Prescribing Opioids for Pain) is not entirely consistent with what Alaska will be doing (see page 61).