Research Subcommittee Meeting Minutes

Date: April 20, 2018

Time: 11:30 am – 1:30 pm

Location: Portland State Office Building, 800 NE Oregon St., Portland, Oregon

Attendees:

OCC Attendees: Katrina Hedberg, Esther Choo
Subcommittee Members: Jane Ishmael
Subcommittee Members On phone: Julia Dilley, Mike VanDyke
OMMP/OHA Staff: Carole Yann and Shannon McFadden
Members of the Public as listed on the Sign in sheet: Mike Rochlin

Subgroups	Responsible Party
Research	Esther Choo and Katrina Hedberg (leads)

Welcome and Introductions by the Oregon Cannabis Commission

Topic	Key Discussion	Responsible

Review goals for research subcommittee	• Categories of highest priority research (e.g. clinical data on treatment efficacy, agriculture practices, plant genetics/ strains, public health impacts, policy evaluation) • Barriers for each category (e.g. lack of funding; federal prohibitions; possession of product) • Propose funding stream for priority cannabis research topics • Propose structure for conducting cannabis research in Oregon, both in the short and long term for priority cannabis research topics • Propose optimal strategies for conducting clinical trials helpful to medical marijuana patients (while you and I talked about this, I don't know if we should call out, or just include this as one of the potential categories of research needed…) Some of the barriers would be trying to do studies on a product that is not federally available. What are the hurdles and are the hurdles related to the product. I can't see that there would be very many hurdles other than the funding. We don't have adequate funding to do as robust data collecting. Funding would be the only barrier to do policy research or Public Health Surveillance kind of things. HB 2198 SECTION 4. (1) As soon as practicable after the effective date of this 2017 Act, the	Esther Choo/Katrina Hedberg

	Oregon Cannabis Commission shall determine: (a) A possible framework for the future governance of the Oregon Medical Marijuana Program, including: (A) Proper oversight and regulation of each of the following: (i) Registry identification cardholders and designated primary caregivers, as those terms are defined in ORS 475B.410; (ii) Attending physicians, as defined in ORS 475B.410; (iii) Marijuana grow sites, as defined in ORS 475B.410; (iv) Marijuana processing sites, as defined in ORS 475B.410; and (v) Medical marijuana dispensaries, as defined in ORS 475B.410; (B) Necessary amendments to the laws of the state pertaining to cannabis, including any necessary amendments to ORS 475B.010 to 475B.395 and 475B.400 to 475B.525; and (C) The future role of the commission with respect to the possible framework. (b) Steps that the state must take, whether administrative or legislative in nature, to ensure that research on cannabis and cannabis-derived products is being conducted for public purposes, including the advancement of: (A) Public health policy and public safety policy; (B) Agronomic and horticultural best practices; and (C) Medical and pharmacopoeia best practices. (2) In determining the possible framework for the future governance of the Oregon Medical Marijuana Program under subsection (1)(a) of this section, the commission shall consider: (a) Potential factors that could prevent access to cannabis for medical use; (b) Potential laws and rules that will facilitate access to cannabis for medical use; and (c) The impact of federal laws, regulations and policies on the possible framework.	

	(3) On or before December 15, 2017, the commission shall submit a report in the manner prescribed by ORS 192.245 to the interim committees of the Legislative Assembly related to health and judiciary on the findings and determinations made by the commission under subsection (1) of this section. As part of the report, the commission may make recommendations for legislation. (4) For purposes of making recommendations for legislation under subsection (3) of this section, after the effective date of this 2017 Act and on or before December 15, 2017, the commission may request an interim committee of the Legislative Assembly related to health or judiciary to direct the Legislative Counsel to prepare legislative concepts for the commission's consideration. Finding recommendations of the task force can refer to SB 844 and that report, we do not want to recreate that. So, some of the recommendations were creations of the Oregon Institute Cannabis Research and again talking about structure governess duties etc. Then one of the issues included, funding. And then data access recommendation. #2 had to do with clarifying expectations for licensed medical practitioners. But again, my point was still lots and lots of work went into this report we can potentially update the content but the real place sat on a shelf. It was presented to legislature and the legislature said thank you and no progress has been made. Now that we again have another mandate from the legislature to do this, I don't think our time is well spent recreating this but instead trying to figure out are there pieces that we could flush out so we could hand something to them either in terms of structure or funding etc. Again, I am not at all disputing	

	that spending a lot of time, but if we talk a lot about the areas that there are gaps in our knowledge about cannabis that could be the entire time we spend and will necessarily be helpful for getting something off the ground. Where we should house a research body – At a university level or at the state level. Going through the public health is do able and can be done similarly to Colorado with the appropriate funding, the extra step is making sure it has research integrity and the content or whatever would take time and expertise that the Public Health doesn't currently have. Doesn't mean Public Health couldn't build it but research with a capital R well why we do some of it at the state public health division we have an IRB is mostly projects where people are looking at public health interventions that we evaluate. When it comes to things like clinical trials informed consent and risks and benefits that is so understanding all of that is outside of the scope of what we do. More over understanding things like agriculture what do I know about agriculture practices. It isn't just me, is it finding a physician and what do they know about agricultural practices. To have this as a robust process it's probably better to have it within some institutions that already know how to do this work. If we had a couple universities to administer then we might have less bias over who wants which university to lead. I think it	

	would be best to have research done in the institutes that are used to doing this sort of research and evaluations. I think while it is good to have this housed with a university, it is very important to keep a collaboration with Public Health as well. There were three aims in the legislation and one of them was around public health policy etc., one was about agriculture and one was about clinical/medical uses. Institutes and figuring out funding really needs to come from all three of the aims. We just need to make sure it isn't all going into one of the three aims but covering all not necessarily equally but close. Whatever our proposal is that there is that integrated body every step to try and make sure that we fulfil the objectives of this research proposal that we are putting out.	
Review structure of state-funded research programs in other states	Research infrastructure Both states are using tax dollars to fund research, totally different mechanism for using those grant dollars. California California medicinal cannabis research program UCSD has been around for almost 20 years and the way it worked is that 20 years ago the legislature	Esther Choo/Katrina Hedberg

	appropriated 9million dollars, 3 million dollars per year for 3 for a program of research at UCSD. Essentially, they wanted it to move specifically cannabis to move from this "hey we are out in the field flowers, like fluffiness to a legitimacy." So, they are a very prominent national academic institution and they said what kind of things could you do and how would you do it. And they approached this physician Igor Grant who is a notable researcher in the area on substance abuse and cannabis use. They appropriated this entire thing to the center at UCSD and the way they administered the grant is rather than taking this into UCSD, the administered it like they were a grant funding organization so they issued a call for proposals and they created some limits so that all the research needed to happen within the state of California. They set up an external review panel and a review type process and unlike the NIH they were very interactive with their funders. So, they received the proposals and went back and forth and really tried to make the best kinds of research proposals they have and that they could find. At the same time they interacted very deliberately with the federal government so they had meetings with NIDA, DHSH, FDA and DEA all of the bodies that regulated the use of cannabis in research projects and the director and his team actually went to Washington and sat down with representatives from each of these organizations and that way when they finally selected their grant recipients and started moving the proposals forward there sense was that they were	

	known to be a legitimate academic body on cannabis research and it greased the wheels a little bit to get FDA approval and DEA approval and all the approvals they needed in order to actually get physical cannabis products on campus to do research. They didn't work through a third body and they still got the FDA's approval to do clinical trials. That 9 million dollars funded 7 studies that all went to other academic studies, almost all went to other academic institutions in California. Two studies were at UCSD and others at UCLA, UCSF and UC Davis. These are listed on their website. These were clinical trials and they focused on areas where they found some existing evidence of use already. 20 years ago, of course that was very different. They finished the last of that bundle of studies just a few years ago, but those studies lead to submitting the grants to NIH and when they had gotten funding from NIDA. They managed to sustain it with no other state funding. Prop 64 passed, so now recreational cannabis is legal in California and part of prop 64 is two chunks of money. One is continuing funding to UCSF center, so they will get 2 million dollars per year. There is another body of money that's 10 million dollars per year that would be administered by a different body that has not yet been determined, but the chunk of money has been determined and I believe will derive from the tax money from the Cannabis Industry itself. So, with that grant it's going to go partially to cover	

	the infrastructure but they think they probably will once again set up a competitive grant process and imitate the process that worked so well for them before. The conclusion to SB 844 was to set up an institute pragmatically speaking at least for the short term, it makes sense to follow the California model and committee to a university that has a track record of research and has the infrastructure and has the scholars that are there. OHSU is the academic medical center in the state. The research priorities are not just medical research, part of the bill is prioritizing Public Health Policy and Public Safety Policy so I think having a policy portfolio is key. But also, agronomic and horticultural best practices as well. So, thinking about it as an OHSU based entity or an OHSU/OSU collaboration. We know we will be asking for money from the legislature and then we need to figure out what is that money going to flow through, how are we going to distribute the funds, who is going to govern that. OSU has always had a strong history of expertise in natural products and the isolation of pure compounds for mixtures and must study those. OSU already has a collaborative agreement in terms of the college of pharmacy where it's a jointly confirmed degree.	

	OSU and College of Pharmacy clearly have agricultural expertise and OHSU clearly has more of the direct patient care, that whole services piece and then the pharmacies between the two. So, I would think that part of a proposal might fly. Are we thinking of a formation of a joint center or another way we have talked about in prior commission meetings was it can be as low investment for the first year as simply a body of grants to be administered in this joint OHSU/OSU body would be the scholar's responsible for deciding the wording of the request for proposals that goes out or organizing the grant review process and scoring grants or it could be just a grant funding body and the money can flow through us or it could be we can actually go for this center or institute proposal and start structuring it like that from the beginning. Colorado Funded medical marijuana research in 2014. We had a budget surplus in our medical marijuana cash fund which originated from cardholders. There were some strict restrictions on the money and how it could be spent. It had to be spent to benefit medical marijuana patients. So, we proposed research – the research bill went through legislature. The bill was pretty	

	much based on the California research bill. We have a scientific advisory committee in that bill that over sees and judges the research that is submitted and continues to meet to monitor progress on this research. We had 10 million dollars to spend on research, 1 million of that was for administrative costs over the 5year period of the grant. We released an RFA in 2014, that RFA has some priorities listed and the research was focused on medical. Allowed randomized clinical trials or observational studies and we got about 58 applications that needed to be reviewed. Members of the scientific advisory council as well as the other local scientists were recruited and it really was kind of a NIH process. We started off with a NIH review documents and modified those a little bit to make it less confusing where a high score is good instead of a low score. Three people reviewed each grant and then it was brought to a full meeting at the scientific advisory council and reviewers and based on that meeting they determined to fund 7 different studies. We funded were 3 clinical trials and 4 observational studies. This legislative session there is currently a proposal on the table to give us another 3 million dollars to fund additional studies. They currently want us to focus on pediatric conditions specifically use of medical marijuana for autism in our next RFA. We had another pot of money that was given to us, 3 million dollars to research focus on public health issues. Things like tests for driving under the influence, marijuana in breast milk and marijuana use in vulnerable populations. This RFA went out in 2017 and	

	this money was appropriated from the retail marijuana tax fund and at this point it has been only a 1-time thing. Currently put out about 5 or 6 studies looking at different public health issues associated with marijuana, but we didn't have a designated to review and recommend these. The executive director could approve funding for these public health grants vs the medical marijuana research has the scientific advisory council recommends proposals for funding to our state board of health. The state board of health would approve those and they go through our normal contracting process. The challenge with this is trying to get enough reviewers to match the applications that you have. Another internal challenge is not ever doing any research funding like this in the past, we've only done evaluation funding for things like tobacco grants and cardio vascular pulmonary grants which are much more along the lines of traditional public health. Getting people in line about the contracting process how that is going to work was a challenge. We have one physician who is sort of in charge of our Medical Marijuana program and he is the point of contact for all the grants and makes sure all the contracts go through and he's funded approximately 70% off Marijuana grants. In addition, some of the money goes towards the contract type people who are really putting the contracts and amendments through. Then we have some money that goes to a coordinator type position who really	

	coordinates the meetings and the review process when it happens in terms of rounding up all the cats to make sure they show up to the meeting. The biggest chunk of time of administrating these programs must do with contracting and making sure people stay on track with submitting their invoices and those sorts of things, so if you were thinking about that then I'd defiantly put someone in there to take care of that, someone good. Two of our studies were out of state. We wanted to study PTSD and the investigator was in Arizona, it was a good study so we ended up funding this. For the Public Health grants came from Colorado taxes, it could only go to Colorado institutions. You can have out of state collaborators but the PI must be in Colorado. Colorado state University Pueblo has gone down the other road in terms of setting up a research institute and they have been allocated roughly 1 million dollars a year for research.	
Identify need for further resources, information, expertise needed to outline the components of	Researches at Colorado State University Pueblo to talk about their experiences Will research a counterpart at OSU that would help with the structure for collaborating between OHSU	Esther Choo/Katrina Hedberg

an Oregon Cannabis research program, and develop our legislative proposal	Jeremy Riggle THC and CBD measurements – Easter Oregon University. School of Public Health between OHSU and PSU Colin Roberts whom does research on children - to present to the Subcommittee or join on the Subcommittee. He has FDA approval and DEA approval. Talk about high priority topics for Oregon and are also feasible within the kind of research structure that we are planning on setting up. How do we put emotional weight behind that so it rises to the top and feels like absolute urgency? The barrio that still sticks after SB 844 is how to get the product that Oregonians are using and the legalities of that and it's a huge issue. The big issue at the end of the day is that this is still a schedule 1 controlled substance. Most researchers are going to have a very difficult time without going through all those legalities. This will take a lot of time to get all the legalities like the DEA license. Finding out if there is anything Oregon can do to approve that.	

	We want to demonstrate that we will be cutting edge since there is a relative amount of cannabis related research. These cutting-edge things would be helpful - definition of chronic pain and where in fact cannabis or cannabinoids address chronic pain right now and neurologic symptoms as well. People whom are trying to get off opioids are using cannabis and what are the modalities used. Needing data so doing a survey of the patients with OMMP and finding out what aliments and potentially the reasons patients have left OMMP	
Public Comment	Michael Rochlin This is what we need to move forward, less stigma and more resolve of some of the issues to clarify. From what I heard earlier, the legislature wants it to be simple no pie in the ski. I think in the long term we are going to get that but in the short term the structure of some sort of institute where it sits however it sits to continue this, there needs to be some continuity overview so maybe some organizational institute whether it sits at OHSU which is our academic medical institute in the state with OSU PSU U of Oregon doing brain science.	Esther Choo/Public

	All this kind of stuff together, contributing and working together with collaboration is very exciting to me. Funding I am sure the industry will see to it that it gets funded. I think the tax dollars initially under the measure were arbitrary and nobody knew. So now we are going "oh" which we had said that and it has been changed so I think that will come again and when we have a place and sustaining effort and one of the focus issues heard is interesting is opioids so opioids and cannabis for pain contracts. We had two positions naturopath and internist both were on the training committee and they are both on the state pain committee too. They talk about commonalities nomenclators for pain which is good as an opposed to a nurse I am like 1 to 10 and that's very subjective but having people understand what pain means and understanding limits to what we can do and what they need to do is very important. Same thing applies to cannabinoids and opioids but I believe that we are going to find that cannabinoids are in majority of cases for less addicting is more behavioral addicting than anything and the brain itself, the way it works we need a lot more interest in that so I recommend including psychiatry. I think that is the whole specialty in medicine really needs to come to the table and be part of the conversation. So, what I'd like to see is maybe be a pilot to formalize	

	opioid withdrawals and injunction with the hospital healthcare system and universities here in study that and that could be an already written protocol for that for observational study. So, I'd like to see that done so that we can see, just a small pilot but then we'd be able to track records maybe help with the standardize station nomenclator and all that stuff see how it works to train some people and move on from there. That requires funding and I think we'd be able to get that. For patient care and records and doing your soap that information is important to collect. Electronic Health Records are still kind of all over the map you know ideally in enterprises we had more consistency but then we have insurance reimbursements and all these kinds of complicated factors so that is a whole nether piece that hasn't been brought into this conversation, Insurance. I want to bring them in as a participant but not to be able to direct the conversation that was brought up this morning. I think when that is done that's a different purpose so I am looking for risk in Public Health is important and should be at the top. Public Health is different than public safety though so for public health this applies. Public safety is what everybody in the newspapers all there's a fire and people over consuming and there's a child. Those are important those can be done but I don't think we need to, I think we got enough data literature	

	and observations stuff there to do that in a rapid fashion. So, I like what you said about low cost high reward type things and then collaborations on not only with our universities but cross the united states and global. Canada for example that is nearby being able to do some of these parse out these things and can share more things. Collaboration is a big deal and I hope that happens and I really look forward to better and like you said starting at this place with not much we can only go forward. Removing the stigma and contributing to the science is really what this is about. I think there is enough science our there already, I can't wait to get started.	