MEETING MINUTES
INDEPENDENT LABORATORY ADVISORY COMMITTEE

August 05, 2015

The Independent Laboratory Advisory Committee held a public meeting on August 05, 2015, beginning at 2:00 p.m. at the following locations:

VIDEO-CONFERENCE SITE:
Division of Public and Behavioral Health
4150 Technology Way, Room 303
Carson City, NV 89701

VIDEO-CONFERENCE SITE:
Rawson-Neal Psychiatric Hospital
1650 Community College Dr., Room B-193
Las Vegas, NV 89146

1. **Call to order; determination of quorum**
   ILAC Chairperson Ed Alexander called the meeting to order at 2:11 p.m.

   Present: Dr. Sue Sisley, Ed Alexander, Jason Sturtsman, Savino Sguera, Chao-Hsiung Tung
   Teleconference: Matt Haskin
   Absent: Glenn Miller, David Luttrull

2. **Public Comment (No action may be taken on this item of the agenda.)**
   Public comment was taken.

3. **Approval of minutes**
   July 01, 2015 ILAC meeting. July minutes will be approved in October when they are presented as corrected by Matt Haskin.

Committee Comments:

Matt Haskin stated there was a statement he made missing from the July 1, 2015 ILAC meeting pertaining to the THC equivalence calculated from an average potency of cannabis flower. Matt Haskin provided the example of a patient's allowance of 70 grams of flower at an average potency of 18% THC to arrive at 12,600 mg of THC. He stated by using this concept and formula we can determine an equal allowable amount of both concentrates and edibles based on total milligrams of THC.

Chad Westom stated the July meeting prompted many staff hours to create three reports and a draft policy. Open meeting law rules enable staff is able to take the minutes back and revise.

Ed Alexander recommended to not approve the minutes as submitted.

Laura Freed stated staff will amend the minutes and bring them to the next ILAC meeting for review.

Recommendation: Ed Alexander recommended staff revise the July 1, 2015 ILAC minutes to make the necessary corrections.

4. **Revision and approval of ILAC bylaws due to actions of 2015 Legislature.**

Jeff Hansen stated that Senate Bill 447gave the responsibility of producing an acceptable pesticides list to the Department of Agriculture. This changed the duties of the ILAC committee such that they are no longer responsible for this area.

Committee Comments:

Ed Alexander commented on the lack of attendance at ILAC meetings on the part of Department of Agriculture staff.

Laura Freed stated she recalls discussing the Department of Agriculture having a regular presence and possible making them a standing agenda item. She was unsure about making them part of the panel (ILAC plus State officials).

Ed Alexander clarified he would like them to have a specific location to sit while answering questions.
Robert Little, Department of Agriculture reported that Lynn Hettrick, Deputy Director was unable to attend the meeting today. The request to regularly attend ILAC meetings to answer possible questions was relayed to Lynn Hettrick. The request to attend was approved and the Department of Agriculture is willing to provide information pertaining to pesticides. Other agenda items would merit minimal feedback as it is not their role to set the standards for such topics.

Ed Alexander asked the Department of Agriculture about what has been determined concerning the concentration of pesticides in relation to the concentration of cannabis.

Robert Little called upon Chuck Moses of the Department of Agriculture, to respond to Ed Alexander's question.

Linda Anderson redirected the conversation to follow the agenda and complete the item #4 discussion.

Motion: Chao-Hsiung Tung moved to approve the ILAC Bylaws as revised as a result of the 2015 legislation in SB 447 (delete Article III (C). Second by Savino Sguera. Unanimous.

5. Presentation of and recommendation to adopt DPBH Cannabinoid/Terpenoid Policy.

Steve Gilbert stated that the Cannabinoid and Terpenoid Policy is still in a draft format, and **not** a finalized policy. The purpose of the policy is to provide the testing results of the product to the patients, labeling requirements as outlined in the regulations, and to direct laboratories what to test for. Based on an ILAC recommendation during the May 6, 2015 meeting, the Division adopted the recommended 4 Cannabinoids and 10 Terpenoids, and Division added an additional 5 Terpenoids beyond what was recommended by ILAC.

Committee Comments:

Chao-Hsiung Tung stated overall it is a good policy. When ILAC submitted their recommendations for Terpenoids, they provided justification. The committee would like to know what the state's justification is for adding the additional five Terpenoids.

Steve Gilbert answered that the additional Terpenes added were based on Herbal Pharmacopoeia.

Ed Alexander stated a problem: there is not one reference supplier and when you mix multiple suppliers the test accuracy decreases. One of the Terpenoids added that is not available in a standard mix. From a scientific point, this creates apprehension.

Chao-Hsiung Tung agreed.

Savino Sguera stated the Herbal Pharmacopoeia manual is not a scientific document it is a summary. There are hundreds of Terpenes, and the ten chosen are the most common. Anything beyond that is arbitrary.

Matt Haskin agreed with Savino. He is supportive of the original ten chosen and questions the rational for the additional five.

Sue Sisley agreed with Savino and Matt questioning the rational. She researched the additional five and found no support in reference journals. As a physician, clinical relevance counts and there is no supporting evidence. She believes the additional terpenes will only create added costs for the patients.

Jason Sturtsman agrees with the other ILAC members. He questioned if the additional five possibly came from the Nevada Cannabis Lab Association. He specifically agrees with Sue Sisley, believing it will impact patient costs.

Steve Gilbert thanked everyone for the suggestions and stated they will be taken into consideration.

Public Comments:

Public comment was taken (none)

Motion: Chao-Hsiung Tung motioned to have staff revise the proposed Cannabinoid/Terpenoid Policy. Second by Jason Sturtsman. Unanimous.

Revised Motion: Revise the policy by removing the five additional Terpenes. Approve the Cannabinoid/Terpenoid Policy as noted. Second by Savino Sguera.

6. Presentation of research from other states regarding what constitutes a serving size for cannabis flower vs. edible products, and possible recommendation to designate 10mg of active ingredient as a serving size.

Matt Livingston reported on staff research concerning what other states constitute as a serving size of flower and edible products as it relates to medical marijuana. Most states only address it in the recreational scope as opposed to the medical. Each states information was reviewed. (Handout provided)

Committee Comments:

Savino Sguera asked whether limiting 10 mg as an individual dose limit the number of doses sold in a complete package to only 10 mg. and if pre-divided products could be sold as one package.

Matt Livingston answered if we followed packaging and labeling guidelines like Colorado's, it would address those concerns.

Ed Alexander reiterated Matt Livingston's response for clarification.

Matt Livingston said the Division is looking into other forms such as topicals.

Sue Sisley asked for clarification that the report is based upon the recreational market.

Matt Livingston answered yes, everything staff found only provided information in relation to the recreational market.

Sue Sisley said that very sick patients need access to potent edibles. She advocates preventing overdoses but believes in provisions whereby patients can access high concentrations to manage their medical conditions.

Glenn Miller: In Canada they outlawed anything attractive to a child. If we are trying to limit the exposure then we should not allow anything that would be attractive.

Chad Westom replied that the regulations state that items cannot be attractive to children and must have a pharmaceutical look.

Glenn Miller stated packaging is one thing and having an attractive look is another. Will gummy bears be allowed?

Chad Westom stated there is nothing in the regulations that outlaw gummy bears so it is possible. The difference is the packaging would have a pharmaceutical look, similar to something you would get at a pharmacy.

Ed Alexander asked about patients requiring mega doses using tinctures or suppositories. If the patient needs a mega dose maybe edibles are not the best choice.

Sue Sisley stated patients should be able to utilize a capsules or access a variety of types/forms of medicine.

Chao-Hsiung Tung: Patients need options.

Jason Sturtsman: This is a medical market not a recreational and there are patients that would need over 100 mg of active THC especially in tinctures and suppositories. Supports patients being able to access medicine at higher amounts.

Savino Sguera believes the state regulations consider capsules as edibles. Capsules are medical and do not look like candy. Therefore, Capsules should be able to exceed the 10 mg or 100 mg mark.

Matt Haskins supports how Colorado's standards keeps patients from having to open five or six packages.

Ed Alexander said that as a patient or potentially a parent of a patient, he would be more at ease knowing there had to be numerous packages opened as opposed to one, to get to that high dosage.

Sue Sisley stated the Colorado model presented here is for a retail-recreational market. Many patients need access to medicine and cannot afford to purchase two or three candy bars per day.

Laura Freed said the research only relates to recreational markets. There may be a need for a higher doses, but overdosing is clearly a concern.

Chad Westom: We are talking about serving size not dosages. We want people to be clear about the serving sizes and labels on the packages. If there is more than 50 mg, then it should be declared on the package. Dispensaries are obligated to educate the patients about these things. Nothing we have produced or anything recommended in these documents says we are limiting a package from containing more than the allowed dosage of 10 mg. This is not about limits, it is about declaring it.

Ed Alexander: There is no limitation on the number of servings per package essentially?

Chad Westom: That is correct. No limitation is being suggested from the state's perspective for the amount of serving size in a package. As with food and beverage products, there are serving sizes. We want to help to create the patient awareness and educate them. Our position is that each package is clear and discloses contents.

Jason Sturtsman: To be clear, someone could purchase a 100 mg capsule or 100 mg tincture as long as the serving size is indicated on the label, is that correct?

Chad Westom: Defers to agenda item 7 and said it is possible that we could have an item containing more than 100 mg in the packet.

Ed Alexander recommended that as staff continues to explore serving size, we should consider homogenization. If patients break a candy bar into pieces, then we need to make sure the medicine is evenly distributed throughout.

Laura Freed: Ed would you would like research on homogenization regimes in other states to develop a policy on homogenized servings?

Ed Alexander: Yes if possible.

Matt Haskin suggested looking at Colorado's regulations.

Linda Anderson asked whether serving size is less urgent than educating patients to read product labels so they know what to look for.

Laura Freed: The idea behind all of this is public health, safety and welfare. We must provide the consumer as much information on milligrams and percentages of THC so they know they are getting. If the advisory committee wants to table that is fine.

Glenn Miller stated there doesn't seems to be a problem, it is stated very clearly. One issue that remains is a certification of and/or required homogenization techniques.

Chad Westom: Ten mg THC will be discussed more in agenda item #7. That does not limit a patient from consuming multiple servings or a production facility from producing items containing more than one serving.

Recommendation: Ed Alexander recommended that as staff continues to explore the serving size we consider homogenization.

Committee Member Glenn Miller arrived at 3:08 p.m.

7. Presentation of research from other states regarding: regulation by weight vs. active ingredient; and limitations on purchase of flower vs. edible products (information only).

Matt Livingston reported on regulations on measuring MM by weight versus active ingredient. Equivalence is about determining what 2.5 oz. per 14 days of flower is compared to a 2.5 oz. of concentrate. Matt said staff reviewed regulations from Colorado, Washington, Illinois, and New Mexico in reference to topic. They asked:
Will the state consider the limit of 70 grams (2.5oz) of concentrate the same as 70 grams of flower? Answer: No.
How will products of extractions be measured? By weight or cannabinoid strength? Answer: Products of extraction should be regulated and limited by a specific weight of THC per 14-day period.

Committee Comments:

Ed Alexander asked Sue Sisley about metabolism rates associated with edible THC and how frequently patients require dosing.

Sue Sisley: It varies as some can dose once per day while others need to dose edibles multiple times per day.

Jason Sturtsman stated for retail it will be difficult to determine an active THC over a 14 day period. The intent of NRS 453A is not to restrict patient access to concentrates or useable marijuana. He opposes any limits of the right to consume more than 2.5 including concentrate and other products.

Savino Sguera: 10,000 mg over 14 days = 759 mg per day, which essentially is setting a limit.

Glenn Miller stated the equivalency of dosages depends on the method of dosing. It makes a difference.

Jason Sturtsman asked about THC monitoring and whether it is the state's job or the dispensaries'.

Steve Gilbert: Milligrams purchased at a dispensary will be converted in the tracking verification system into ounces to track the 2.5oz per 14 day limit.

Glenn Miller: Are all purchases made by a patient tracked to prevent them from using multiple locations?

Steve Gilbert: Yes.

Glenn Miller: Is this true for all patients, even nonresidents?

Steve Gilbert: Yes. Nonresident purchases must comply with the same requirements as Nevada patient purchases.

Glenn Miller: Do they track in California?

Steve Gilbert: No.

Ed Alexander expressed concern about whether 100% of the THC is being extracted. He is unsure when a product is CO2 or butane extracted if 100% of the THC of overall product is extracted. This could be confusing and he recommended staff talk to extractors to find out.

Glenn Miller replied he performs extractions daily, it's complicated and recommended not to get into the details of extraction.

Matt Livingston reported that staff took into account the idea of extraction efficiency.

Matt Haskin works with many extractors and the material can range from 8-12% average. He doubts this is relevant because once the final is tested it does not matter what the efficiency was on the extraction
.
Savino Sguera reiterated his previous statement of calculating 759 mg per day as maximum and suggested if we start at maximum of THC such as 1000 mg per day should cover all patients.

Chad Westom stated that our obligation is to ensure patients do not acquire more than 2.5oz in 14 day period, and if we put it at 1,000, we would need to demonstrate that the amount of THC they get is not greater than 2.5oz of flower.

Savino Sguera: That is possible as he has seen flower THC go high as mid-20s. Remember the flower itself does not have THC, it is all THC acid which is not activated, and then it is decarboxylation taking more THC from it. Then it all depends on how the patient consumes it.

Chao-Hsiung Tung thanked staff for their time and research it is appreciated. He believes the state should make a policy where it is required to disclose the potency of the extracts such as oil on the label.

Ed Alexander agreed and believes those provisions have been put forth but the challenge is establishing what the conversion weight is as there can be significant differences.

Matt Haskin stated they have tested over 10,000 samples for potency and would say that the average active THC after decarboxylation is closer to 18%. That said, 15% gives a nice margin and still allows 10,000 mg every 14 days. One concern is the very popular treatment of the Rick Simpson Oil that suggest 7,000-8,600 every 2 weeks. Supports having a 10,000 mg based on a 15% average.

Ed Alexander questioned whether we can be that specific with the amount of usable product in edibles.

Glenn Miller stated every environmental lab is certified and accepted if they are in a certain percent range. This is a certification issue. What if there was a 20% difference in THC analysis? Would that decertify the lab from being acceptable? This is criteria that every certification agency deals with but has the division dealt with those questions?

Savino Sguera stated every lab will have their extraction deficiencies in their NCL studies when testing for edibles. This will provide a range within a certain percentage. Savino performed calculations: if the percent of THC in flower is 19.7% rather than 15%, then we have enough for a 1000 mg per day at maximum which is not unreasonable.

Jason Sturtsman stated he believes it should be kept simple and not restrict patient access, and go with the 2.5 oz. including concentrates. He disagrees with using calculations and other restrictions on patient access.

Ed Alexander clarified that there is difference between dried flower and other means of usable marijuana.

Matt Haskin stated he thinks the concerns about the certification will be established through the proficiency testing policy. He believes the issue at hand is the standard deviations.

8. **Review of Nevada law/regulation regarding testing process for edibles and infused products (information only). Committee Comments:**

   Glenn Miller asked about testing not only flower, but also non-flower trim for extraction purposes.

   Laura Freed said the short answer is yes and that we need to explore the notion of pesticide bioaccumulation.

   Ed Alexander said the potential is there for bioaccumulation and asked Department of Agriculture for confirmation.

   Chuck Moses said sampling protocol would be needed in order to answer.

   Glenn Miller suggested that pesticide levels would accumulate like THC does.

   Chad Westom indicated that regulation changes are coming and that interested persons are encouraged to provide comment.

9. **Discussion and recommendation regarding labeling of marijuana products.**

   Ed Alexander indicated that NRS and NAC 453A say it all and that he is fine with this area.

10. **Public comment – No action may be taken on a matter raised under this item of the agenda until the matter itself has been specifically included on an agenda as an item upon which action will be taken.**
    Public comment was taken

11. **Adjournment.**

    The meeting adjourned at 5:08 p.m.