

# Seed2Health Learning Health Alliance Testimony LD 104\_An Act to Protect the Health of Medical Cannabis Patients and Streamline the Mandatory Testing of Cannabis

My name is Arleigh Kraus. I am the owner of a small organic vegetable and poultry farm and Windhill Organics, a medical cannabis company in Warren, Maine. Many of you know me through my work with the VLA and on other civic and policy matters.

I am speaking today on behalf of my fellow volunteer members of Seed2Health Learning Health Alliance regarding LD 104.

Seed2Health is an open grassroots community of people who are re-imagining how to gather, learn from, and safely share knowledge through the lens of our common health experiences. As we help others and they, in turn, help us to understand what is working and what is not, we see a "pay-it-forward" approach taking shape for getting and staying healthy. We call this *learning health*.

Our collective perspectives are those of registered "patients" in Maine's Medical Cannabis Program, academics and researchers, experts in learning health sciences, clinicians and pharmacists, therapeutic formulators, as well as licensed cannabis caregivers in the medical program.

We are supported in our collaboration by Andrew Thacher and a company he co-founded in 2017, Seed2Health, LLC, which is located at Tech Place in Brunswick, Maine. Andrew serves as the manager of the alliance and the services and innovations we are shaping to reduce the cost and grow the value of learning health.

Next year, we are launching *Consensus 26* – a series of online forums to engage broader community awareness and participation in shaping learning health consensus guidances. These forums are organized within three learning health communities: *Plant Health Balance, Member Health Balance* and *Learning Health Exchange*. Key to the value and growth within these communities are the trusted and transparent product labels that connect them and the information they contain, including "whole plant" testing results.

Pertinent topics we are exploring within the *Plant Health Community* are "Balanced Testing" and "Connected Labeling". Our focus is on risk-balanced testing, sampling, chain of custody, range-based reporting, untested products, audits, recalls, safe action limits, warnings, tiered pricing, inter-laboratory comparative testing, and open access to test results for tested retail products.

While these guidances are needed to enable learning health as determined by Seed2Health alliance members, we also see them helping to reduce unnecessary tests and failures (a significant and wasteful cost to market registrants and ultimately consumers) while improving inter-laboratory testing consistency and overall program integrity.



It is with this understanding that we ask the committee to pursue deeper learning before legislating LD 104 and other bills regarding Maine's Medical Cannabis Program. The matters in these bills are complex and inter-connected. And the science informing them is dynamic and - frustratingly – often unsettled.

Specifically, we encourage the committee to consider the two following suggestions:

- Host a second testing education session for members of the VLA committee like the session held on February 13, 2023.
- Encourage and/or empanel a study group wherein program registrants and testing labs conduct a systematic review that brings together research and insight from subject matter experts on cannabis testing science. Along with Maine, every state desperately needs to know what such a study will reveal.

To refresh memories, the documents and recordings linked below describe two examples of pertinent learning in which members of the VLA committee and Seed2Health along with others engaged in 2023 and 2021:

- The first document presents the written comments (see online version here) we presented at the VLA testing education session held in 2023. Recordings of all presentations made can be viewed at the following links: see <u>Part 1</u> and <u>Part2</u>
- The second document (<u>see online version here</u>) presents excerpts and a link to the recording of the open forum on cannabis testing that Seed2Health hosted in 2021 among Chris Hudalla, Founder, Chief Scientific Officer of ProVerde Labs, members of the VLA committee, MMP registrants and our Seed2Health colleagues.

As before, we stand ready to help however we can. Only together will we realize the innovative approaches needed to assure that all registrants – especially smaller and home-based caregivers who work closely with their patients – can thrive.

When we succeed, we anticipate large health and healthcare markets taking shape around all beneficial plants including cannabis. To get there, we first must ensure that quality therapeutics are informed by accurate testing, trusted labeling and ongoing learning.

# STATE OF THE CANNABIS STATE: TESTING AND MAINE

Sharing understandings with Chris Hudalla, Chief Science Officer of <u>ProVerde</u> Laboratories on May 6, 2021



Attendees: Rep. Barbara Wood, Sen. Craig Hickman, Rep. Jay McCreight, Rep. Lynne Williams, Rep. Chloe Maxmin, Sen. Dave Miramant, Alysia Melnick, Mark Barnett, Arleigh Kraus, Kevin McAloon, Eben Sumner, Samantha Brown, Susan Meehan, Chris Wolfkiel, Asher Putterman, Andrew Thacher and John Jemison – <u>See Recorded Video</u>

# On The Maine Opportunity

MAINE AS THE MODEL

"I mean, in all seriousness, you have the opportunity to be the model, because I don't see this happening. There are groups that have components of this, you know, it's too new to most of these regulatory processes. And there wasn't, it seems like everybody's just reacting instead of being proactive. They're just reacting. Most regulators were all of a sudden thrust with this requirement to develop a regulatory program in a very short period of time, without the opportunity to seek appropriate consultation or industry experts. You guys are in a position where, from what I know, you have a very, very strong caregiver network. You have some of the leading cannabis physicians up that are known globally. You have the opportunity to bring these people together and, you know, do exactly what you're suggesting, I have not seen it happen anywhere else yet. Doesn't mean it hasn't. I just have not seen it. And I try to stay on top of these things. But I just haven't seen anybody that really pulled the different aspects together to create really sound regulatory guidelines." – Chris Hudalla

## LEARNING TOGETHER

"Thank you. I really appreciate your offering this...everybody who's offering this because. This is what we need to hear as non-experts and those of us who aren't caregivers. I did have the question that you addressed, Dr. Hudalla, about smoking versus other forms of ingestion. I really appreciate that. I've been struggling with that. And your last comment is really helpful. A different way of thinking about it. Because there, you know, is where I'm hearing a lot of concern...I have concern about making sure with safety but not putting people out of business. So what you were just describing is an interesting thing we need to think about. And when you get the answer, call me." - **Rep. Jay McCreight** 

#### COLLABORATING

Will you have participation? Absolutely. It's in everybody's best interest. It's in my best interest to have a sensible program. Again, I don't survive as a laboratory unless the industry survives. Patients and caregivers I know are committed to this. Physicians are committed to this. Can you get a clear picture of it? I would say no. You can't get a clear picture of it [by next legislative session]...but you can get a clearer - you can get a better vision. This is a complex topic...we're not going to be there for years. But it doesn't mean you wait years to start working on it. It means you do the best that you can. And that means exactly what you're saying - pull these people together and get a clearer picture, a better understanding of what's possible and where we are today and where we could be. – Chris Hudalla

# **On Regulating**

## MANDATORY TESTING

I would not be a proponent of waiting on mandatory testing just because, again, I think testing is important. But I do think that the testing that is implemented should be cognizant of that uncertainty and those limitations of understanding and permit some broader, broader guidelines for acceptability for what's required. Some testing is better than no testing. So even if it's, even if it's not completely appropriate, it's better than what's done today, in many cases. – **Chris Hudalla** 

## ✤ BALANCING COST & VALUE

"From a regulator's perspective, oftentimes they want the most stringent testing which makes sense until you realize that the financial burden can crush the industry. And so there's some industry perspective that I think is important to include in these discussions." – Chris Hudalla

"It is a challenging question. I struggle with it. I've been working in this since 2013 to try and understand what is the best approach? And I don't have all the answers. It is a very difficult position because I do believe in protecting the consumers. I do believe in testing to demonstrate that. But I also believe based on watching other states over-regulate the industry that it has the capability of crushing the industry. And I urge people when they're in the rulemaking process to make sure that the rules being implemented, actually provide value - actually provide safety to consumers. If that safety to consumers is not obvious, then I think that there should be discussion about what is the value that it brings. And I think that's a critical discussion that is happening now in Maine. And I'm happy to participate in any way that I can." – Chris Hudalla

## BENEFICIAL INGREDIENTS

"The microbial testing as well. I haven't seen one state get that completely right. But what does right look like? I don't know exactly. If you look at states like Massachusetts, where we are based, we based on total microbial counts: total yeast and mold, total bacteria. That means that we're failing product, which is not unsafe, because there's many things in your refrigerator at home, like yogurt and blue cheese that would fail our limits. And so having a total microbial count may not be the most appropriate approach." – Chris Hudalla

"When we look at microbial testing we have a very low tolerance for microbial contaminants in Massachusetts. But we are also asking our cultivators to grow without pesticides. Common ways to get away from pesticide use are integrated pest management that includes beneficial microbes, beneficial bacteria, and beneficial insects. Unfortunately, under our regulatory platform, growers will be penalized for using those because they'll fail the microbial contaminants because these things that are used in place of chemical pesticides will fail them." – Chris Hudalla

## GOOD ACTOR MOTIVATION

"I have proposed multiple times in different state regulatory organizations to have a kind of a graduated testing program where producers, cultivators would be subject to the most stringent testing across the board. But as they....as they prove that they can create product without contaminants that that batch size be escalated to a larger batch size, thereby reducing their overall cost per pound for testing. And if they again prove that they process is tight and they're producing without contamination, that that batch size is again expanded. This is all in an effort to reduce the cost burden to testing." – Chris Hudalla

#### HEAVY METALS REMEDIATION

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"Heavy metal contamination is very common in cannabis, especially if it's outdoor grown. Outdoor cultivated cannabis probably will never pass any heavy metals specifications. Indoor cultivation is susceptible to heavy metal contamination through nutrients. That's the most common source of heavy metal contaminants. In a recent discussion with the CDC - I'm sorry, it was the OMP in Maine - I learned that remediation of heavy metals is not permissible under the Maine Guidance, which to me was surprising because every other state permits remediation. One of the ways to remediate heavy metals in cannabis is to do an extraction. If cannabis flower material is contaminated with lead or arsenic or cadmium - when that plant material is exposed to ethanol, or supercritical CO<sub>2</sub>, or hydrocarbons, like butane. These are the most common methodologies for extracting the CBD or THC out of the cannabis plant. Those metals are not soluble in those solvents and get left behind with the waste material. We have documentation in our lab to demonstrate this. But the solvent extraction is a...is a wonderful way to remediate cannabis that is contaminated with heavy metals." – Chris Hudalla

# **Co-Innovation** Opportunities

PIONEERING STANDARDIZED TESTING FOR MEDICAL MARKETS

"As part of my journey. I have been involved in many scientific organizations. One of the most recent was the United States Pharmacopoeia. I'm part of their expert panel, which only has two representatives from the cannabis industry. Every other member of that panel is from regulatory. There's members from Health Canada on that panel. And our task has been to recommend what a standardized testing program looks like for the eventuality that cannabis is somehow federally regulated. Working with USP and with some of these other regulators, I've had the opportunity to bring some realistic industry perspective to what testing might look like from a regulatory perspective." – Chris Hudalla

INHALABLE VS INGESTIBLE PRODUCT STANDARDS

"Yeah, most states that are moving forward have [recognized bifurcated use-based standards]. So for instance, California has a more stringent pesticide limit for an inhalable product than they do an oral. Massachusetts has done that for heavy metals, but they have not done that for pesticides, unfortunately. But that is the future you have to look at the route of administration. Certainly, if I'm looking at Aspergillus mold, that would be incredibly harmful as an inhalation mechanism. But if it's ingested it would be destroyed by your stomach acid if it's put on a topical may not be concern, but certainly you don't want mold spores in your lungs. So, like route of administration is a critical component." – Chris Hudalla

#### A MAINE REFERENCE LAB

"So I would love to see regulators have their own reference lab. I mentioned that previously, but their own reference lab staffed with scientists that can help assess the competency of the laboratories that are participating in that market." - Chris Hudalla

"But I think there's some, some critical components that a referenced laboratory can help the state understand in its own program. And I think that's kind of part of the state's responsibility. To be able to understand their program, they have to understand the testing variability that exists in their state between the different laboratories, they have to be able to understand the variability of their producers. Again, just having a producer, having lab x test results presented isn't necessarily the final word, you know, you have to be able to assess the quality of that data." – Chris Hudalla

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#### TIERING

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"One of the things that we do as a laboratory is we have a sliding fee scale. The fees for our testing range from zero to \$600 for a full panel. I will frequently get a parent who has - they found some marijuana that they found under their child's bed - they don't know what's in it - or their child is sick. And I know that they don't have the financial wherewithal to test for a full panel. And I will do that for free." – Chris Hudalla

"But if you're going to full panel test at every point in the process, there's just no value added. And so with the expense of testing, I think you have to look at alternative testing programs. I still believe that a big operation, because there's so many, so many points where contaminants can be introduced... if you're a small cultivator and you have two people working in your grow room, you know, maybe you're with your spouse, or you know, you're a couple of people, you have a lot tighter control. If you're a big operation and you have 250 people coming in every day to work, you have so many different points of introduction of contaminants. There's a different level of concern when you have that many influxes into your facility. We're talking about both people and you're talking about raw goods and supplies, packaging materials, soil amendments, nutrients, the volume coming into those big operations just increase the number of opportunities for contaminants to penetrate your facility, which would be different than a small craft grower who probably can take a little bit more time to pick really high quality ingredients or things that are coming into their operation, easier to monitor. Oftentimes, microbial contaminants are coming in on your shoes on your person. And it's easier to control if you have two or three people that are working in a facility." – Chris Hudalla

So Chris, I think what you're calling for, because we're thinking about this in Seed2Health, is a "tiering concept" that not only product, but provider and perhaps even labeling a product, depending on what the use case is, would be in some kind of a stratification that would be cost-justified based on the use case. And in the case of the provider itself, the supplier has got a home-based caregiver or commercial-based caregiver, Etc. - these are very different environments. – Andrew Thacher

# Other Perspectives Shared by Dr. Hudalla

The first two links are video files that should start playing simply by tapping the picture (the sound improves after the first minute or so). The third and fourth links are PDF files that can be downloaded or viewed online by tapping the image.

- <u>Analytical Testing for the Cannabis Industry: From Chaos to Standards</u>. This video of a presentation by Chris in April, 2019 at the Patients Out of Time conference. Much of what Chris discusses is relevant to discussions now taking place here in Maine.
- <u>Keeping Up with Emerging Contaminants</u>. This video is a presentation by Chris on May 28, 2020 at the General Session of the Waters Virtual Event 2020. It provides a more technical look at emergent issues associated with constituents introduced by people in the growing, manufacture, packaging and consumption of cannabis.
- <u>Cannabis Inflorescence for Medical Purpose: USP Considerations for Quality Attributes</u>. This
  PDF file summarizes the multi-year collaboration among a panel of global scientists and
  researchers including Chris supported by the United States Pharmacopeia, an independent
  science-based public health organization. For those interested, an article published by USP,
  <u>Cannabis for medical use: consistent quality to help protect patients</u> adds further context to
  how USP sees its role in shaping understanding of medicinal cannabis and USP's hope for
  the research developed by Chris and his colleagues.



# Seed2Health Testimony, VLA Education Session on Testing, February 13, 2023 with regard to LD 48 (An Act to Clarify Provisions of the Cannabis Legalization Act Regarding Labels, Packaging and Testing)

Following is the written testimony provided by the volunteer members of Seed2Health Learning Health Alliance on February 13, 2023. As per text of an email received on Friday, February 9 from the VLA legislative analyst, education about testing was sought by the Chairs of the Veteran and Legal Affairs/"VLA" Committee to assist in committee's review of LD 48, *An Act to Clarify Provisions of the Cannabis Legalization Act Regarding Labels, Packaging and Testing:* 

"The chairs are asking each invited person/group to speak for about 10 minutes and then be available for questions from the committee.

The committee is interested in the efficacy of the current mandatory testing requirements, the variance in test results, the efficacy of audit testing, and any comments on the changes proposed by the Office of Cannabis Policy in LD 48.

The chairs ask that everyone attend in-person (except any out-of-state invitees)"

# **Statement of Arleigh Kraus**

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My name is Arleigh Kraus. I have a BS in biochemistry and 20 plus years of experience in laboratory sciences. I am a registered medical cannabis caregiver in the State of Maine and the Chair of the Adult Use and Medical Cannabis Committee for the Town of Warren, Maine, and serve as a founding member of the Maine Craft Cannabis Association, a founding member of Seed2Health Learning Health Alliance, and as a board member of Medical Marijuana Caregivers of Maine. I am the owner of a small organic vegetable and poultry farm and Windhill Organics, which is a medical cannabis company located in Mid-coast Maine.

I come before you today in my role as a member of Seed2Health Learning Health Alliance along with Andrew Thacher, Greg Newland and Kevin McAloon who are also members.

We are speaking about testing on behalf of all of our members. These people include registered "patients" in Maine's Medical Cannabis Program, academics and researchers, experts in learning health sciences, clinicians and pharmacists, therapeutic formulators, as well as licensed cannabis caregivers in the medical program.

These cannabis caregivers work closely as guides with people who find cannabis helpful in living more fully with chronic diseases, and others who use cannabis to recover from injury and sickness, or simply to live a more balanced life.

In many instances, these cannabis caregivers work in concert with treating clinicians, pharmacists, herbalists, other practitioners of complementary and alternative medicine many of whom consider themselves as healthcare caregivers - people whom we refer to within Seed2Health as "Member Guides".



To each of us as Members and Member Guides, testing is a critically important component of Maine's medical cannabis program. Tests inform us not only about safety *and* efficacy associated member health. Tests also inform us about environmental health, plant health and worker health.

In addition to contributing perspectives from my experience in cannabis, testing, and growing many farm products and beneficial plants, a primary role for me within Seed2Health is to connect and make compliant the voluntary consensus guidances that we are creating with the rules, law and policies in Maine.

As an example, within Seed2Health guidances, we support and are working hard to advance one of the stated goals of LD 48 to eliminate redundant and/or unnecessary tests, while building in a smart, cost-effective approach that is value-based. If there is not true value to the end consumer in a given rule or law, we look for ways to find that value. When we can't find that value, we will inform regulators suggesting steps that could be changed or eliminated. Some of us refer to this as "intelligent testing."

Given the enormous complexities of testing within contexts of the cannabis plant, the varied ingredients in the many forms of end products, and ultimately the varied needs of different types of people - and animals - consuming the therapeutic, we hope that members of the VLA will concur that our cannabis programs in Maine must engage and rely on consensus building among those directly affected by testing and those who bring expertise and clarity - before legislative debate. This has not happened with LD 48.

As you will hear from my Seed2Health colleagues, the issues associated with testing cannabis are extremely complex - in many instances the market is, as some say, "ahead of the science."

Secondly, we should seek and build upon cross-market transparency in testing data to inform our consensus building so that we can learn together what is working and what is not - the tagline of Seed2Health.

We need to replace top down approaches to policy and rule setting by a single "expert" perspective with access to data - and engage together with that data in learning and shaping what's best. We need research and insights to do this that do not impose on our privacy or legitimate proprietary interests. This type of data and cross-market learning is missing and needed - especially as it comes to the best use and value of testing.

Andrew will tell you a bit more about Seed2Health and how it is seeking to advance an innovative type of immersive learning that we call learning health. This learning lies within our collective experiences and is informed significantly by lab testing. He will touch upon what we call consensus guidances, and various education and awareness initiatives that members of the Alliance have hosted, as well an event we are shaping for this summer where Testing will be a major topic.

Greg Newland, a co-founding principle of Nova Analytic Labs (which hosted an educational event last summer) will shed light on the various ways that we have been educating ourselves on

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Testing as well as developing consensus guidances to address issues regarding inter-lab testing variability.

And then Kevin "Mac" McAloon will speak briefly to the critical role of testing in his work within Maine's Medical Cannabis Program with people and their treating clinicians who are seeking to restore health following disease and injury, or live with pain and other symptoms associated with cancer and other chronic diseases. In each case, Mac supports how the patient is leading the way and the roles that testing can and does play.

Andrew?

# **Statement of Andrew Thacher**

Thank you Arleigh and good afternoon, members of the VLA Committee. My name is Andrew Thacher. I am a registered medical patient in Maine's Medical Cannabis Program and the co-founder of Seed2Health LLC, a self-funded research-stage firm that is supporting Seed2Health Learning Health Alliance and is headquartered in Brunswick at Tech Place.

I have been a grateful summer resident of North Haven Island for all but one of my 67 years. Of note, I am working with Melissa Parkerton, a registered medical cannabis caregiver on North Haven, where we are teaming with patients whom she serves on some very innovative developments. We are learning together what patients, their loved ones and their health providers are seeking from the medical program. Notably, the group recently explored with Greg Newland the use and value of a Certificate of Analysis from a certified testing laboratory -a topic that nobody knew much about.

You've asked us to shed light on the work we are doing with regard to Testing in collaboration with Greg Newland, Chris Hudalla and their labs here in Maine along with others both here in Maine and across the country.

For starters, if you have not seen it, I would urge you to watch an excellent one hour video on testing that we hosted in May, 2021 with Chris Hudalla of ProVerde Labs. The discussion explains many cannabis testing complexities and was found to be very helpful by our colleagues and members of the VLA. See <u>State of The Cannabis State: Testing And Maine</u> for a summary of the discussion and link to the video recording.

In collaboration with many Mainers as well as experts from across the country, we are developing what we call voluntary consensus guidances and other resources to support something we call *learning health*. The guidances we are creating together are open source and expected to continuously evolve as new understanding is introduced in conjunction with various services and innovations that we are developing.

Simply stated, learning health is a different way of understanding and advancing one's own health; and in so doing, creating the possibilities for understanding what we might learn collectively for the benefit of others. In short, learning health learns safely, usefully, and verifiably from our experiences. The tagline we use is: *Learning what works together...and what doesn't*.



We began synthesizing and harmonizing perspectives of members, member guides and experts in many fields nearly six years ago within the context of learning health using medicinal cannabis as the initial therapeutic catalyst. And there is a not a day that goes by that we do not encounter something else we ought to know about testing

Today, we are collaborating around 15 plus topics comprising Seed2Health Test Guidance for Cannabis. This is one of many classes of Consensus Guidance being developed.

We see these consensus guidances continuously evolving as they learn with deep expertise of Alliance members who are scientists, researchers and practitioners and the lived experiences of members who are seeking health and health restoration on their own or in collaboration with member guides.

Target objectives of the Testing guidances include:

- Implement aspects of the Seed2Health Label Guidance for Cannabis addressing both an untested product market (a market similar to the "cottage industry" standards for small, craft markets) and three classes of tested products which we currently group by business size and safety risk. The three tier sizes are intended to level the cost for testing which grows considerably on a per unit basis when not spread across large batches of tested product.
- Reduce test result variability across testing labs by working together to detect test result differences when they occur, mitigate adverse impacts and make corrections that reduce future variability;
- Eliminate redundant testing and test requirements that do not create value and determine new capabilities and innovative ways to enhance testing value where it is needed.
- Create as open source content reference points a knowledgebase for research use especially among federal, state and other rules and guidelines bodies to help them evolve and implement laws, rules and guidelines associated with testing.

When it is possible to connect a therapeutic profile to a member profile for purposes of safe and secure learning - the ultimate goal of "learning health" - we see testing becoming even more valuable. This is because the immune compromised individual or an individual taking potentially contra-indicated pharmaceuticals is different in terms of safety and efficacy related criteria. Accurate and cost-effective testing will add value to the health of both beneficial plants as well as those engaging with them.

Complicating testing are at least three big factors:

- 1. The route of administration by which an individual will use the therapeutic. Our digestive system and our skin protect us in ways that are different from when we inhale cannabis. This affects what tests are beneficial as well as the correct detection limits to accept.
- 2. The variability among labs. Each lab employs their own equipment and there are no standardized methodologies as of yet. Inter-lab test result variability depends on



cross-market adoption of well-considered processes for sampling and many other steps to minimize the consequences of not yet having standardized methodologies.

3. The complexity of cannabis as a plant and a final product, its myriad matrices or product types and the 600+ chemical "constituents" expressed by cannabis. These realities call for varied testing approaches that can affect cross-market consistency within acceptable standards of deviation - a problem that is not a significant issue when labs practice with integrity.

With an initial eye on reduction of inter-lab testing variability, our work developing testing guidances is focused on transparent, consensus-based understanding that is aligned with the goal of an informed member at the lowest possible cost and the highest possible value in terms of safety and efficacy.

Importantly here, we must balance all costs in order to support smaller market participants and a testing market that can thrive and successfully compete against untested and unregulated markets that support neither testing nor regulatory and reporting costs.

So as you can hear, in this very high-level fly over, testing is complex. Regulating testing without engaging the expertise within our labs and those who understand the science makes little sense. And perhaps most importantly, we must educate and support a future of engage with an increasingly informed consumer, patient, clinical and health practitioner base.

To this end, I will close letting everyone know that we will be hosting this summer a more comprehensive event for anyone interested in learning from experts about many topics including testing - explained in each case by experts from the vantage point of a registered patient (including Seed2Health Alliance Members), their loved ones, and physicians and health guides.

## Statement of Greg Newland

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Good afternoon. I am Greg Newland and the Co-founder and Chief Scientific Officer at Nova Analytic Labs. I have more than 25 years of experience working in, managing, owning and operating testing laboratories under the regulatory requirements of the FDA, CDC, CLIA, CAP, ISO, and GMP. I Co-Founded Nova Analytic Labs in Portland in 2019 and began operations in October of 2020.

I am also a founding member of Seed2Health Learning Health Alliance where I am working with other members to educate them and others on laboratory testing and create with them voluntary consensus guidances that meet the goals stated by Andrew.

Mandatory testing on products that serve the largest communities of patients as well as recreational users should not be debated. The manner testing is performed and the tests that are performed can surely be discussed by means of intelligent data gathering. The scientists and other participants in this alliance have worked tirelessly on a volunteer basis to provide as much information as possible and have met to discuss the most intelligent approach to testing that serves not only the consumers and patients but the market as a whole. This group is focused on ensuring that the end user is well informed about the safety and efficacy of the product that they are using. The only way to ensure this is through a well thought out Intelligent Testing approach. The only way to have the information we need to make these decisions, is to have mandatory



testing for all products. Data analytics can then be used to craft Intelligent guidelines that benefit all consumer and market participants.

We hosted an event last summer under a tent where we gathered individuals from multiple disciplines of the Cannabis business to share the work they were doing to help educate all of us on the value of this plant and its uses.

My role in Seed2Health is to bring laboratories from not only Maine but from any other state that is willing to share their knowledge and experiences to build this Intelligent testing approach.

We have done deep dives into all of the currently required tests from the AU market and determined their value to the consumer and to all other business participants. We bring panels of volunteers together to determine what tests are sufficient, which may be redundant, and what needs to change to ensure that the information that is shared with the consumer is reliable. All work done within this group is intentionally not self-serving and is consensus based.

Our goal is to be able to present a set of well thought out testing guidances that accommodate a diversity of products based on factual information and a multitude of experiences from across the country. Spanning edibles, concentrates, tinctures, lotions, flower and even suppositories, the list is virtually limitless. Some of this work has already been presented to the OCP. Later this Spring, we will be publishing our first set of over 15 open standard guidances that cover everything from field sampling to water activity.

## Statement of Kevin "Mac" McAloon

Hello my name is Kevin McAloon. I am a registered caregiver with the OCP and I am a partner in Canneutics, LLC a manufacturer of whole plant cannabis oils used in low dose formulations. We serve many patients in Maine through our distribution network. Our goal is to make our fully tested and properly labeled formulations available to as many patients in Maine as possible.

Medical use of cannabis is a reality that ailing citizens rely upon. But to serve them well, we need a policy to inform patients through proper labeling and accurate, cost-effective testing.

The importance of a transparent label is tantamount to good public health policy. A policy promoting full transparency on lab testing is good for patients and it is critical to us at Canneutics where we strive to "help patients lead the way forward."

Quality control and testing is a methodology that informs good natural medicine. When we see the State collecting all the revenues from the cannabis market, it would make sense to have an testing/packaging/labeling audit capability sponsored by the State no to punish errors in any audits but to promote good medicine.