

WHITE PAPER: Why Standards Matter

Thought leaders look at the development of standards in the cannabis-derived product industry

Introduction

Recently ValidCare interviewed a small group of industry thought leaders who are setting the stage for the development and adoption of standards in the cannabis-derived product industry. The roundtable discussion explored issues related to safety, quality, credibility and reliability of products, including:

- Origin and Composition: plant derived versus synthetic, U.S. grown versus other locations, processing and extraction
- Bioavailability and safe serving amounts, recommended use and labeling
- Changing regulations and how can industry prepare
- What consumers need to know – and what industry needs from them

Participants

- *Steve Bevan, President, GenCanna Global*
- *Joy Beckerman, Regulatory Officer and Industry Liaison, Elixinol; President, Hemp Industries Association*
- *Dr. Robert Kaufmann, Director of Research, Shaman Botanicals*
- *Patrick McCarthy, Esq., CEO, ValidCare*
- *Christopher Stubbs, Chief Science Officer, GenCanna Global*
- *Marielle Weintraub PhD, US Hemp Authority*

Question 1

Patrick McCarthy (moderator): I believe implementing meaningful standards will strengthen the canna-based product ecosystem. Standards adoption provide the opportunity for objective data to be used to power industry legitimacy, credibility, trust and sustainability. ***So the first question to the group, beginning at the highest level, why DO standards matter when it comes to CBD products?***



Joy Beckerman: Why standards are important to Elixinol and to the industry is because consumers need to be assured of quality, of safety in the products that they're consuming.

As we move from historical prohibition into delivering on the full promise of this versatile plant, we must assure what's in the bottle is being sourced from legal hemp. Standards are very important for us to continue to be leaders and to shape the industry and to provide safety and quality products for consumers.

Dr. Bob Kaufmann: As a physician, vantage over the production of CBD and hemp oil are extremely important to me and to my patients. When a patient is controlled on a specific amount of product, that product must consistently be the same day-to-day, week-to-week and year-to-year. If it isn't, the patient won't be controlled adequately and if too much of certain compounds exist, they'll experience adverse side effects. With hemp oil, because it's derived from the biological plants, standards to maintain purity and, also the exclusion of impurities are necessary along the chain of production. Once they have experienced relief, my patients want that relief to be maintained. They must be able to ingest a consistent amount of product with consistent results. All these strict standards all along this chain of production can produce such an outcome.

Marielle Weintraub: Standards protect not only the consumer, but companies as well. As we've seen the amazing growth in the hemp market, we have also seen an increase in enforcement action in the food industry, due to false label claims, adulterated products such as those that are containing above an acceptable limit of heavy metals or pesticides, as well as adverse reaction reporting. Better understanding how standards protect you and your company, as well as your consumer base, can assist you in making higher quality,

safer products and build consumer confidence in the process.

The US Hemp Authority Certification Program and seal was developed over the last two years, and was designed to be an easy way for consumers to identify products that have gone through a third party audit and have been reviewed for safety and quality standards. Understanding the standards and regulations like FSMA, the Food Safety Modernization Act, including the different codes of federal regulations and labeling regs, can help your company stay in front of the regulatory curve that the FDA and the FDC will expect.

Chris Stubbs: Standards are incredibly important for all the reasons mentioned. We need additional standards and accreditations to create a quality management system. In my career, I've seen issues related to

medical recreational cannabis as well as dietary supplements. As stewards of the industry, we're here to make product available in a sustainable fashion, so people can have good experiences at the consumer level. That's just not possible when you have adulterated product, dirty product or product that doesn't meet specifications. It's extremely important to us at GenCanna and we hope to be able to continue to inform industry legislation and regulation through our partnerships like this one and others going forward.

“To sum it all up, standards are important to all of us because we need a way as we produce hemp that involves a greater standardization of our agricultural products. What we are all trying to do is take our hemp derived product in ways that are useful to the end consumer, and allow the consumer to have full confidence in our compliance.” – Steve Bevan



Steve Bevan:

To sum it all up, standards are important to all of us because we need a way as we produce hemp that involves a greater standardization of our agricultural products. What we are all trying to do is take our hemp derived product in ways that are useful to the end consumer, and allow the consumer to have full confidence in our compliance.

Question 2

McCarthy: *Why is the approach of using the Hemp Authority better than using some preexisting associations?*

Weintraub: The US Hemp Authority Certification Program was designed for the hemp industry specifically. We took into account the need for those that are using dietary supplements in order to follow specific dietary supplement code that would be expected later down the line. Because we aren't normal dietary supplements and the fact that hemp is a bio accumulator, we also take into account the need for good agricultural practices like soil testing and making sure that THC levels are below 0.3%. Where that gets more complicated, and the reason we developed the program the way we did, is because of the patchwork of regulations coming from all across the US from different states.

Specifically, one of the first ones we had to deal with was when Indiana required not only third party testing for laboratory testing but also required the laboratory be ISO accredited. Then they went further by telling you whose ISO accreditations they would accept. Within our seal, we wanted to make

sure we not only took into account the patchwork across the US, as well as hemp-specific industry testing, but also helped the hemp companies. As they grow and we all evolve, we all need to fall in line with the FDA regulations as we become a larger and larger industry.

Question 3

McCarthy: *Does the Hemp Authority have an opportunity to work with companies that might bring seed from outside US or bring product that might be grown outside of US and allow for certification of those products?*

Weintraub: Yes. Because it is the hemp industry and we're constantly growing and evolving, in our 1.0 version, companies can have products coming in from outside the US. Exporting was originally the only way for these companies to create and then blaze the path for the rest of us, who now have CBD and hemp products. We've started working on 2.0 and our new guidelines will be posted online [so people can make comments. We need those comments.](#) With 1.0, the comments we got most often were questions about GMOs and country of origin. We have a standards technical committee that takes comments and questions and works them into the new draft. You'll see very specific information now regarding country of origin and genetically modified plant material and how we plan on developing that, and dealing with that with audits and certification.



Beckerman: If I could just elaborate, as Vice President of the US Hemp Authority, and it's not just for genetically modified plant material, which I'm not sure we'd even be allowing under version 2.0, but all non-GMO ingredients would need to be put on that label. And country of origin is extremely important to many organizations, it was an overwhelming area of comment for version 2.0 was for this labeling. US Hemp Authority is partnering with [WhereFoodComesFrom](#) as the third party auditing service. It's the nation's leading premier verification service on a number of ag food and feed programs, such as US Organic and the NON-GMO project.

We need to be able to verify those seals.

There is a big problem internationally on counterfeit seals. Then we need to make sure that whatever seal it is actually meets our standards. While that is happening on some levels, the reality is that under version 2.0, it's going to have to be included on the label. Groups like the US Hemp Authority, the US Hemp Round Table and the US Hemp Farming Alliances are here to nurture and deliver on the US industry, and our farmers, manufacturers, and our processors here.

Stubbs: We've got 25 or 26 farms that'll go through the growers audit soon, we've done our CGNP and BRC audits and accreditations as well. I don't think there's ever really one answer. The consumer – the marketplace – speaks to the demand and what they'll require on labels. There's a lot of interest in farm to table transparency. Larger retailers and distributors coming online with interests

in CBD products are requiring a lot of this work to be done. It's been interesting to put it all together and meet those needs in an organic way. We know that the plant is healthful and helpful, and what we do as an industry is professional. We've said, "we're producing food and to be regulated that way, it shouldn't be overly complicated." We appreciate the efforts of the round table and the candor to say, "Look, we know this is version 1.0. Now, let's reach out and see what else the industry is going to require."

We need to garner that input and continue to improve going forward. I don't think any of us today are trying to say, "We've solved it. We're done. It's all over." This is going to be a process. We have to do it together.

"It's nothing new that hemp will also have standards. But cannabinoid quantification is what makes the hemp plant unique from other crops." – Joy Beckerman

Question 4

McCarthy: *Let's consider the seed that's planted. We know there's genetics and great science behind a seed to be planted. When we look*

at farmers, they've got choices to make about what they actually plant. What plant do they grow and why? How do standards help farmers have a reliable crop they can grow predictably and mitigate risks?

Beckerman: To answer the question about what role do or should standards play in a farmer's decision to plant hemp over another crop, I think it's important to understand that good agricultural practices and standards already exist for all crops.



Whether you're farming corn, wheat, sorghum, hay, certainly things that are human consumption and animal consumption, there are very high standards. It's nothing new that hemp will also have standards. In fact, really, the only difference around hemp for those standards for human consumptions would be cannabinoid quantification because where we are already wanting to test for heavy metals, pesticides, and micro toxins. But cannabinoid quantification is what makes the hemp plant unique from other crops.

Then, the decision that a farmer makes isn't really based on standards. It's based on, is there a market for my crop? Is there nearby infrastructure for my crop? Is there value here, more value than the crops that I'm already planting? There are many factors – and a key one is simply will it grow and does my soil need to be rebuilt? Is my soil good enough to grow hemp? Hemp is a hungry crop. We really do need our best soil, particularly when we are growing for human consumption because, as Marielle said, this is a bio accumulator. We may also use the word phytoremediation. It will uptake contaminants and heavy metals and so on, in soil. Soil is a big factor too.

Stubbs: Let's think about the farmers and genetics. Genetics are the first pillar of how this informs the rest of production and processing. It starts on the farm. The farmers want to be compliant and consistent. They want to be able to understand the risks involved, to mitigate those risks the best way possible. When you try to liken this to other very predictable crops, there's still a lot to be desired. We need to start with best practices, transparency and traceability. We're all coming to a much better understanding of

how to implement best practices and standards so everybody's successful and our efforts are sustainable over the long term. The only way to do that is to take a ground zero approach with those same very people – the farmers – and empower them to come to the table and be successful with us. We're just getting started but I think there's a lot of early alignment and people are really excited to jump onboard and take the best next steps for future years and generations.

Weintraub: Hemp is an agricultural product that provides a novel cash crop to small family farms. It can be grown in a small amount of acreage for a decently large return and this crop has helped to relieve some of the increasing costs of growing traditional crops, like the equipment and technology costs that you have to pay in order to grow things like corn and soybeans. It's a nice relief for farmers who have smaller acreage to give up, but a larger return on their agricultural crops.

Bevan: I've spoken with even thousands of farmers around Kentucky and the nation, and they're all interested in compliance. Nobody wants to grow noncompliant crops. As Marielle said, they understand there is a patchwork of regulation all around the nation. The development and evolution of standards via the US Hemp Authority is significantly important because it allows the farmers to start making one to one comparisons. Right now, we have genetics and farming practices that are all over the map: different standards for fiber, different standards for seeds, different standards for



floral material, and they're all evolving, so the area of error and misunderstanding is very large. The ability to define or write out a new taxonomy or lexicon around these terms and to evolve the standards really matters. Farmers want to be able to make a one to one comparison with their corn, beans, tobacco, so they can decide. Do these genetics work well in my area? It's critically important for them to know.

Question 5

McCarthy: Dr. Kaufmann, you made an interesting point about protection of workers, where exposure to various hemp products have caused allergies and other complications. Can you tell us more about what you've seen?

Kaufmann: As we look at protection of workers, we're seeing incidents where exposure to various hemp products have actually caused allergy and other kinds of complications for some workers. We've seen this in Europe especially. What we don't know yet is how are these things happening and what do we have to do? As we learn more about the cause of these problems to the workers, like allergy and other kind of complications is, we'll develop more standards on how to handle the material. This will be coming in the future – today, I don't yet know how to best help someone with protection of workers because we don't yet

have all the answers, but we do know there's a risk.

Stubbs: It's good point. We have folks working in extraction and material handling and find from time to time, there are allergies to hemp just like grasses and pollens. Although we necessitate personal protective equipment, eyewear, hairnets, beard nets, lab coats, etc., there's still some exposure that some folks can't tolerate. At GenCanna, we

have an internal transfer program to let people move laterally through the business and find another area of work. We want lifers – people who are passionate about the process. And most importantly, we want them to work in a safe environment but there are unknowns. We're considering some pre-employment screening for extraction areas, for example, can we work with a physician and do an allergy test with the

raw material somehow, to understand what's a non-starter for some people? There are definitely levels of environmental health and safety risks that we have to consider at every step.

Kaufmann: This is personal to me because I have an adverse reaction to hemp. It's not a typical allergy reaction but it's an adverse reaction. As far as testing for allergies, there's no commercially available testing right now for allergy in the United States.

“It’s important to understand when you’re labeling that you need to have allergy claims on any label going to a consumer, in case there’s an issue. Sometimes, the farmers growing hemp also grow peanuts...We want to make sure suppliers are doing allergen testing so they have the right label claim on finished product.” – Marielle Weintraub



Some have been developing testing procedures in Europe, but they aren't here yet. It's one of the things I'm pushing for as an allergist immunologist, so we can have ways in which to test for allergies and help people avoid having adverse experiences when they come into contact.

Weintraub: Along with the workers, the consumers. It's important to understand when you're labeling that you need to have allergy claims on any label going to a consumer, in case there's an issue. You do need to build that testing program into your finished product in order to avoid consumer allergies because sometimes, the farmers growing hemp also grow peanuts and if at some point, it doesn't get processed correctly or get processed together, or transferred together, shipped together, we want to make sure suppliers are doing allergen testing so they have the right label claims on finished product.

Stubbs: When you're dealing with labels and so many processes and ingredients, there are layers and layers of investigation and initiation. What we do has to be substantiated and use best practices to do so. I think we've danced around lexicon and industry speak. We need to think about how to interact with adjacent industries and

food/beverage supplements, cosmetics, etc. There are existing definitions we need to adopt so that we're all talking the same language. I think that's an underlying point that's going to be important.

Question 6

McCarthy: *How do you see FDA treating CBD from hemp as a food or drug? I know it's a crystal ball question, but what's your take on what we heard and how standards will matter in this area?*

“Anybody that tries to predict what a government agency is going to do is always going to fail. As a physician looking at the science of the issue, I don't care where CBD comes from, whether it comes from marijuana or whether it comes from hemp because basically it's the same plant. What's important to me is, what are the levels of cannabinoids that are present? What are the terpenes? And there are other factors we just don't know yet.” – Dr. Bob Kaufmann

Kaufmann: Well, anybody that tries to predict what a government agency is going to do is always going to fail. As a physician looking at the science of the issue, I don't care where CBD comes from, whether it comes from marijuana or whether it comes from hemp because basically, it's the same plant. It's just been bred for different characteristics. What's important to me is, what are the levels of cannabinoids that are present? What are the

terpenes? And there are other factors we just don't know yet. It's hard to say where they'll end up on this. The risks that people have if the cannabinoids come from a marijuana plant is to meet the regulation of having less than 0.3% THC. The THC has to be removed, and technically, that's not always easy to do.



So to answer your question, I don't have an answer to your question. We've been hampered because CBD was a class five drug for so long, so in turn we weren't able to do the research to keep up with where the public wants to go, to try to determine what is right? What is wrong? What do we need to do now and what needs to be changed? We're behind the eight ball when it comes to research for cannabidiol or hemp oil at this point and I just hope we can catch up.

Stubbs: There are going to be a lot of discussions about toxicity issues of cannabis doses. The World Health Organization, the University of Kentucky, have both looked at safety of products. And we need to know, what else is in there? Are there particular solvents? Are there carriers or vehicles that have completely different protocols than the CBD itself? We just received preliminary data from a study that showed nothing like what GW Pharmaceuticals reported in the FDA hearing.

There are more questions we need to ask about safety in terms of lack of efficacy. Then we can comprehensively consider what we're talking about. What was the product? If it wasn't the hemp CBD, it might be the CBD carrier. There are other considerations that can impact the safety profile of that product. We've been speaking terminology but we can give more justice to the discussion with more context and specifics about what the issues might be.

Some of the safety studies that we've done so far show that a person would literally have to drink almost 50 bottles of a 500mg liter per day to even come close to some kind of hepatotoxicity. That seems like a nonissue. We have to continue to substantiate that data and look at being more comprehensive our discussions. This will really matter future forward. We can't just take a piece of a publication and turn it into a negative. Or a piece of a publication and turn it into a positive. Instead we need to start saying, "This is an observation, here is the context and this is what could be done better in the future."

ValidCare is committed to the implementation of standards. With the development and adoption of standards, everyone involved in the industry – from supplier to consumer – can achieve their goals.

We aim to provide our clients with data driven solutions to advance research, product development and commercialization of cannabis derived products to improve human and animal health.

ValidCare is working to reveal insights from global communities to fuel healthier generations.

<https://validcare.com>

