cbd oracle

A Comprehensive Framework for Evaluating Cannabinoid Products

Expert Panel Responses

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Introduction

The following interviews were conducted by CBD Oracle via email between October-November 2024 and are provided here for full transparency. Learn more about <u>CBD Oracle's Editorial Policy</u>.

Expert Panel



Expert Panel Responses



EXPERT PANEL RESPONSES



Dave Baugh

Co-Founder, R&R CBD

CBD Oracle: If you were to recommend a product to your own family, what would you look for?

Dave: First thing: Lab results. Is it full-panel? (Most folks don't even know what full panel is mycotoxins, microbials, heavy metals, residual solvents, pesticides should be included at the very least; and this is further than most other CPG products go or anything at the grocery store - frankly, (R&R) and many others in our industry go to a standard well above and beyond what people consider when having milk, produce, or anything else from the store!) Is it tested by an ISO-accredited and credible lab with a good reputation? Do the results meet the industry requirements in their state? Is there a result for the "mother" extract as well as the finished product? Is there a test for each batch? Are the results consistent across all batches? Cannabinoid and terpene profile? (This is important - you can quickly deduce if a "full spectrum" or "broad spectrum" really does have multiple cannabinoids, and the prevalence of each. We know some other companies out there use CBD isolate, then pepper in some other isolates like CBN/CBG, but this is NOT the same thing as a true wholeplant full spectrum extract - that omits many of the flavonoids, terpenes, antioxidants, and other phytonutrients that we include that many others don't. This is my whole - "they sell white bread, we sell whole grain nut bread... better yet, that Ezekiel bread from the freezer! ;))

Second: Is it USDA organic? Genetic strain? (Strain is great to know, but not critical - the efficacy will be shown in the COA) Is it true Full Spectrum? (See above on this) Our extract contains up to 9 cannabinoids which is difficult to achieve (or even test for - many labs don't have the matrices to even test for many cannabinoids, which is why knowing HOW a company extracts and WHAT hemp material they are doing it with can inform you on the "fullness" of the spectrum; also see above on this). We found the right genetic strains to produce efficacious results because of the amount of cannabinoids, terpenes, and other phytonutrients present in the plant; this is truly our "secret sauce" of why we staunchly have proven the efficacy of R&R's products over our competitors.

Third: Extraction method. We use CO2 supercritical and we also incorporate subcritical which results in more acid cannabioids like CBDA, CBGA, etc. Our extract stays more true to the plant because it extracts as much of it as possible. We use food-grade ethanol, which is the safest and FDA-approved, which is effective for extracting all the good stuff from the plant. It's like whole wheat bread vs white bread. Some brands say they have broad spectrum but it's really just CBD and one other cannabinoid. Our extract has a rich amount of all cannabinoids which makes it more effective.

Fourth: Third-party certifications. USDA organic holding the most authority.

Fifth: Ingredient list. Carrier oil. Vegan. Natural, nothing artificial. No dyes or coloring. No fructose corn syrup. No parabens or sulfates.

Sixth: Farm. Is it coming from a mass distributor or someone who actually owns the farm? We use a family-owned farm that's been operating for generations; they really care about the plant and the process. Geography and climate matters but the farmer is more important than the geography. You want a farmer who cares about growing the best plants. Many companies source from bulk distributors (who mass purchase biomass / mix strains from many different grows) or even low grade hemp (if making isolate, since most contaminants can be stripped out during refinement to isolate), which makes the biomass cheaper and more available. You'll find very few companies are transparent about where they get their hemp.

Seventh: Is it white label or do they actually control the entire process? Most companies white label. In 2019, there were 10,000 hemp brands; a lot of get rich quick schemes. Now it's been consolidated down to about a 1,000. If you don't own the farm and can't touch the plant, how do you know what's going on. I avoid white label. It's like Whole Foods vs Kroger. There's no way to really verify if a company is white label vs owned; if you ask specific questions you'll be able to know how much they actually understand about the process.

Eight: Outdoor vs indoor. We grow outdoor and keep it as natural as possible. Growing indoor is like putting your kid in daycare all day, they need sunlight and all the natural environmental factors (side note: Biosphere project). It's more efficient to grow indoor and you can grow all year but it's less environmental friendly because of all the lighting. It's like a cattle factory vs free range pasture raised.

Ninth: Are the personals professionally educated? We work with a doctor and two

chemists. Do they have expertise about the strains, planting, harvest, biomass, extraction? Are they able to answer technical questions? Many companies use a distributor who gets the hemp from 10 different small farms. The plants are grown at different locations and may not be consistent.



Kelly Lombard

Founder, Forge Hemp Company

CBD Oracle: If you were to recommend a cannabinoid product to a family member, aside from your own brand, what specific factors would you consider? What criteria would you use to evaluate the quality and effectiveness of different options available on the market?

Kelly: I tell friends and family to shop for hemp companies, not just products. Reputable hemp companies want to build a relationship with you. They want to help you navigate your options and be transparent with you about their products. Their websites should be informative, not just marketing spin. If you have a question, it should be easy to contact them and you should get a prompt response from someone who knows what they're talking about.

CBD Oracle: What are some common quality control shortcuts that companies might take in the hemp industry? How can consumers spot these red flags and choose more reliable brands?

Kelly: It's harder to spot products that contain unsafe ingredients or incorrect potencies because bad actors are leveraging the public's trust in third-party testing. Shady brands used to post "in-house" test results, stolen and/or edited Certificates of Analysis (COAs), or no COA at all. These days, most products feature legitimate testing documents, but they may not reflect what's really in the product.

One issue is hemp testing standards that are only looking for a specific list of cannabinoids and can't spot certain synthetics, cutting agents, or other potentially dangerous ingredients, like muscamol. A recent example is the Diamond Shruumz recall. While those weren't hemp gummies, they were sold at many CBD stores and smoke shops alongside hemp products. The Diamond Shruumz website included a prominent link to "View Our Labs" and every full-panel COA from a highly respected testing lab looked good -- because they weren't testing for the undisclosed ingredients that made people sick.

Another issue is bait-and-switch testing, where the test is performed on a sample that will meet specifications, but that's not what goes into mass production. And an ongoing issue for the hemp industry is variation between third-party testing labs. Even accredited labs can each test the same sample and report different results.

Six years after the 2018 Farm Bill legalized hemp, the public still needs to be diligent about evaluating cannabinoid products for quality and safety. This means looking past flashy marketing and slick packaging, seeking details that show transparency in supply chain and manufacturing, and getting in touch with a real person at the company to answer any lingering questions.



Mike Sill CEO, Sunday <u>Scaries</u>

CBD Oracle: If you were to recommend a cannabinoid product to a family member, aside from your own brand, what specific factors would you consider? What criteria would you use to evaluate the quality and effectiveness of different options available on the market?

Mike: If a family member asked me to recommend them a cannabinoid product, I'd ask them the following questions:

1. What problem, ailment or effect are you trying to solve or achieve? The usual answers are: stress relief, sleep aid, pain management or for recreational use. This will give me a sense on whether I should direct them to CBD, CBN, CBG or THC or a certain blend of these depending on their use case. ***(Happy to dive into blends if you want)

2. Do you like psychoactive effects? If so, do you like mild or high intensity? If they said no to psychoactive effects, and mention that they need to take a drug test or are super sensitive to THC, then I'd direct them to an isolate or broad spectrum product. If they wanted psychoactivity, I'd gauge their intensity response. For a microdose feeling, I'd tell them to start with 1 - 2.5mg of THC. For an extreme dose with intense euphoria I'd suggest they take 25mg - 50mg. We have an article called <u>THC Gummies Dosage</u> that shows a chart for this, with THC per Dose, Dose Category, Effects and Side Effects.

For the criteria, I'd send them this comprehensive breakdown:

A) Raw Materials Source: If they are ordering online, to make sure that the products contain cannabinoids that are derived from hemp vs. marijuana. The broken down compounds are identical, but the former is federally legal per the 2018 Farm Bill and the latter is still a Schedule I narcotic per the Controlled Substances Act. They should make sure the cannabis is grown using organic methods and sourced preferably in the U.S.

B) Cannabinoid Spectrum: Explain the difference between full-spectrum, broadspectrum and isolate products on the market. I'd also break down the theory called the 'entourage effect', which states that all the cannabinoids used together, synergistically, increases the overall efficacy.

C) 3rd-Party Lab Testing: I'd have them look for products that provide Certificates of Analysis (COA's) showing third-party lab results for potency, purity, and ensuring that there are no contaminants like pesticides, heavy metals and mold. Reputable brands showcase these on their websites.

D) Method of Extraction: I'd have them look



for brands that use clean extraction methods for their products, like CO₂ extraction, which ensures no residual solvents pop on the COA's.

E) THC Content: See above.

F) Assess Product Type and Dosage: I'd figure out what vehicle they want, whether it be gummies, oil tinctures, beverages, capsules or other edibles). Would also review the dosing with them.

G) Other Active Ingredients: Based on their use case, I'd have them look for products that incorporate other active ingredients in their products. For example, if they want a CBD sleep product they should get an oil that also has valerian root in it. Or, if they want a THC gummy, have them choose one that also has ltheanine in it to counterbalance the negative side effects, like paranoia.

H) Brand Reputation: I'd have them search for the brand on Google and see what type of credible publications have written about them. These articles will not say "Sponsored" at the top, they are considered earned media and unbiased. They should also ensure the brand is using a review tool, like Okendo, which only allows reviews from verified buyers.

I) Price Analysis: I'd tell them to compare the price per milligram of CBD or other cannabinoids, since many brands have different amounts of gummies per bottle or amount of milligrams per gummy. This way they get an apples to apples comparison.

J) Targeted Benefits: Consider specific cannabinoids or formulations tailored to address certain issues (e.g., anxiety, sleep, pain). See above for this.

CBD Oracle: What are some common quality control shortcuts that companies might take in the hemp industry? How can consumers spot these red flags and choose more reliable brands?

Mike: Some quality control shortcuts include: Falsely advertising the amount of CBD or other cannabinoids in their products (Pretty much all products on Amazon, as an example), paying for cheap reviews from fake customers (this is why Okendo or a similar review tool is so important), using cheap extraction methods like butane which can leave behind contaminants and sourcing low quality extracts from firesale wholesale companies.

The best way to spot these brands is to follow H) Brand Reputation above.

CBD Oracle: Are there any standardized practices or benchmarks that you follow to improve product safety and effectiveness? Or is it primarily up to each company to set its own standards?

Mike: The industry itself is self-regulated, at least for the credible players. The FDA has yet to classify CBD as a dietary supplement, so there are no formal standardized practices or benchmarks in place. That being said, because we're self regulated we go above and beyond to ensure product safety and consistent dosing. For example, pre-workouts, weight-loss pills or other dietary supplements may actually be more potentially harmful since those industries don't voluntarily adopt practices like 3rd party lab testing. Our industry is under a magnifying glass, so we push for higher accountability. We do this by working with GMP certified manufacturers that have FDA registered facilities. Also, all of our raw materials have ISO certifications and are grown using organic methods.

CBD Oracle: Your website mentions Scott, the farmer who supplies your hemp. This level of transparency reassures customers about your brand's oversight of the hemp's origin. Are there any documents that could further confirm the hemp's US origin?



Mike: Yes, we've personally flown out to Greeley, Colorado to walk through the farms and meet the workers. We've also toured the facility that breaks down the raw materials into distillate and isolate. The facility we use is called <u>KND</u>. Click the link to find all of their compliance certifications.

Another document is called a Chain of Custody. This follows the record of the product's journey from seed to sale, tracking all steps in the production process.



Chris Fontes

CEO, Trojan Horse Cannabis

CBD Oracle: If you were to recommend a cannabinoid product to a family member, aside from your own brand, what specific factors would you consider? What criteria would you use to evaluate the quality and effectiveness of different options available on the market?

Chris: First and foremost, I always recommend low and slow. I drive this point home more than any other concept, as I feel it is the largest hurdle to onboarding with cannabis use, and so many folks are given horrible advice (eg, "start with 10mg - that's like a microdose").

Second, I teach them the difference between natural and converted Delta-9 and why - at this point in time - they should look for natural Delta-9.

Third, I explain what a COA is, why it is important in this category (but not important in other categories like tobacco and alcohol), and how to read one.

Lastly, I will teach them what to look out for. Does the COA potency get close to the advertised potency? Are the panels complete with mycotoxin, heavy metals, pesticides, microbials, potency, and residual solvents? Are there a bunch of random cannabinoids you don't recognize? Does the batch number match the batch on the product you have in your hand? With enough time, I would also get into the difference between Delta-9 and 11-Hydroxy-Delta-9 and how those affect people differently, then discuss what formats lead to what experience.

CBD Oracle: What are some common quality control shortcuts that companies might take in the hemp industry? How can consumers spot these red flags and choose more reliable brands?

Chris: 1. Not getting a full panel COA at all (potency only);

2. Getting full panels, but not for every batch;

3. Shipping out a product with tons of conversion byproducts in them; and

4. Shipping out products that are drastically over or under dosed. ■



Elisabeth Mack

RN, CEO, Bloom Hemp CBD

CBD Oracle: If you were to recommend a cannabinoid product to a family member, aside from your own brand, what specific factors would you consider? What criteria would you use to evaluate the quality and effectiveness of different options available on the market?

Elizabeth: We are USDA Organic CBD and minor cannabinoids, and offer supreme value in our range of potencies from 600mg to 3000mg.

The most important questions are the COAs by batch, and to have them verified by 3rd party labs - which we do and post on our site at all times. The next things we're implementing - already on our new Immunity blend softgels - is the QR code back to the product which displays all of the essential points consumers need.

CBD Oracle: What are some common quality control shortcuts that companies might take in the hemp industry? How can consumers spot these red flags and choose more reliable brands?

Elizabeth: Many shortcuts people take is to mislead customers, to not have customer service, and to overcharge for crap. We overcome ALL of that with Bloom Hemp CBD.



Jesse Karagianes

SVP of Revenue Growth, CV Sciences/+PlusCBD

CBD Oracle: If you were to recommend a cannabinoid product to a family member, aside from your own brand, what specific factors would you consider? What criteria would you use to evaluate the quality and effectiveness of different options available on the market?

Jesse: If I were to recommend a cannabinoid product to a family member, I would prioritize brand integrity, focusing on companies that demonstrate transparency, strong quality control, and a history of consumer trust. I'd research and evaluate the source of ingredients, along with third-party lab testing to ensure purity and potency. Consumer reviews and personal experience with the product would also play a major role in me feeling confident in a product's effectiveness and reliability. Understanding the brand's marketing targets and primary sales channels is also important to me, as it shows me whether the company is motivated by a commitment to quality health products or simply driven by profit, potentially offering mass-produced, lowvalue products with inferior ingredients. For example, sold in a natural channel retailer or a gas station or vape shop.

CBD Oracle: What are some common quality control shortcuts that companies might take in the hemp industry? How can consumers spot these red flags and choose more reliable brands like +PlusCBD?

Jesse: In the hemp industry, companies may take shortcuts such as skipping third-party lab testing and use their own internal laboratories to avoid expenses using independent 3rd party laboratories, or using non-accredited 3rd party laboratories, or sourcing inferior ingredients, such as using artificial additives. Look for labs with solid track record and expertise in the industry. Selecting a good third-party laboratory is crucial to ensure quality, safety, and compliance with industrial regulations. Consumers can spot red flags by looking for brands that lack transparency in lab results or do not clearly disclose their hemp's origin. Reliable companies like +PlusCBD tests every single lot manufactured with reputed laboratories in the industry and openly provide third-party lab reports on our website and ensure high-quality standards. Customers can scan the QR code on the labels to check the reports themselves even before buying the products at the store. By choosing brands with clear ingredient lists, transparent practices, and positive consumer reviews, buyers can avoid products from companies that cut corners.



Jan Brandrup

CEO, Neurogan

CBD Oracle: If you were to recommend a cannabinoid product to a family member, aside from your own brand, what specific factors would you consider? What criteria would you use to evaluate the quality and effectiveness of different options available on the market?

Jan: When I recommend a cannabinoid product to a family member, aside from our own brand, the first thing I look for is whether it's full-spectrum and made from high-quality hemp. Additionally, I check for an updated Certificate of Analysis (COA) or lab report, which should never be older than a year. Another key factor is the company itself—are they reputable, or are they just in it for the short term? While well-known companies like Charlotte's Web are trusted, there are many smaller players that might be questionable. I prefer brands that make me feel comfortable and have websites that are informative, with real people you can reach out to if needed. For product recommendations, regardless of the form-whether it's droppers, mint oil, or capsules,—I personally prefer high-potency products, like 120mg CBD gummies. I can cut them in half and save money compared to lower-potency options. For tinctures, highpotency versions like 12,000mg CBD oil per bottle are also a great option. If you don't like the taste, just mix it with something. The effects usually take about 20 to 50 minutes to kick in, depending on how long you hold it under your tongue or how your digestive system processes it.

CBD Oracle: What are some common quality control shortcuts that companies might take in the hemp industry? How can consumers spot these red flags and choose more reliable brands?

Jan: First, I always check how long the company has been in business. Too many "Wild West" companies come and go without doing things properly. Second, always check the production date and batch number, and make sure the lab report is no more than 12 months old—ideally, between 3 to 12 months. If the lab report is older than a year, it's a major red flag.

CBD Oracle: Are there any standardized practices or benchmarks that you follow to improve product safety and effectiveness? Or is it primarily up to each company to set its own standards?

Jan: As for standards in the industry, certifications like cGMP, AB45/CDPH certification, and FDA Facility Registration are essential, along with up-to-date training in areas such as foreign supply verification, HACCP, and others. These certifications need to be renewed regularly-usually every year or two-so make sure everything is current. Spend the time to do your research; it will help you avoid disappointment.



JJ Coombs

CEO, Mellow Fellow

CBD Oracle: If you were to recommend a cannabinoid product to a family member, aside from your own brand, what specific factors would you consider?

JJ: When recommending a cannabinoid product to someone, I first try to understand their specific needs. This could involve discussing their symptoms, desired effects, and previous experiences with cannabinoids.

Once I have a clear understanding of their needs, I would recommend specific cannabinoids and milligram dosages based on their individual requirements. For example, if they're seeking relief from pain, I'd suggest a product with a higher CBG or CBD concentration. If they're struggling with sleep, I would recommend a product with Delta 8 or CBN.

If they mentioned they like to get high but tend to get anxiety from smoking weed, I'd steer them toward a product with higher CBD content or replace Delta-9 THC with Delta-8 THC. Overall, I would advise them to stay away from products that contain only Delta-9 THC.

CBD Oracle: What criteria would you use to evaluate the quality and effectiveness of different options available on the market?

JJ: To evaluate the quality, I would emphasize

the importance of third-party testing to verify the product's cannabinoid content and potency. This ensures that consumers are getting what they pay for and can make informed decisions about their purchases. To evaluate the effectiveness, it'd really depend on what the consumer is seeking and the cannabinoid blend and dosing.

CBD Oracle: What are some common quality control shortcuts that companies might take in the hemp industry?

JJ: One of the biggest quality control shortcuts I see in the industry is deceptive packaging. Brands will highlight certain cannabinoids, like THCa or THCp, while actually putting minimal amounts in the product, then they price them lower than products that are similarly advertised. This often confuses consumers and they end up going for the cheaper option without realizing they're not getting what they expected.

Another big deception is THCa edibles. Consumers aren't aware that THCa isn't psychoactive unless it's combusted. Some brands jumped on the excitement of a new cannabinoid and started labeling edibles with THCa to drive attention. The consumers then buy THCa edibles expecting a strong high, but the real potency comes from other cannabinoids like Delta-8, Delta-9, or HHC.

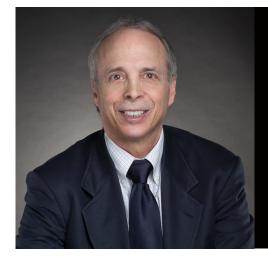


CBD Oracle: How can consumers spot these red flags and choose more reliable brands like Mellow Fellow?

JJ: To spot red flags, there are a few key things to look out for. The first is checking for third-party lab results. Reliable brands will be transparent with easy-to-find Certificates of Analysis (COAs). If this isn't provided by a company, that's a major red flag.

The second thing is check the packaging for cannabinoid concentrations. Be wary of products making big claims on cannabinoids, like THCa or THCp, without listing the specific amount on the packaging. If it seems too good to be true– especially at a super low price– it probably is.

At Mellow Fellow, we're all about transparency. We clearly list all cannabinoids on the front of the packaging and provide detailed formulas with milligram amounts on the back. This helps consumers make informed decisions about their cannabinoid intake.



Ethan Russo

MD, Founder/CEO, CReDO Science

CBD Oracle: If you were to recommend a hemp or cannabis product to a patient, what specific factors would you consider? What criteria would you use to evaluate the quality and effectiveness of different options available on the market?

Ethan: It is a very complicated proposition for a patient to evaluate cannabis products. The ideal approach is for this to occur in the context of a doctor-patient relationship, but this requires the additional difficulty of finding a doctor or advisor who is educated to the available offerings, their content and quality, and particularly matching the product to the patient's needs---not simple. The more common scenario is the potential consumer is left on their own for this process. Under those circumstances, the first criterion on quality of a product is detailed knowledge of its composition. This can only come from advice from a knowledgeable vendor (e.g., "budtender") and/or, failing that, the availability of a current certificate of analysis (COA) on the product that details its cannabinoid and terpenoid content, screening tests for microbial contaminants, pesticides and heavy metals.

CBD Oracle: Are there specific cannabinoid profiles or terpene combinations that you find to be more effective for certain conditions?

Ethan: Yes, but that is the specialized knowledge that a consumer has to seek from a caregiver or develop on their own. In general, broad-spectrum cannabis extracts are favored over isolates, especially those solely composed of cannabidiol (CBD). CBD is a very versatile and safe agent, but when it is the sole ingredient, it most often requires high dosages to achieve therapeutic effects, making additionally quite expensive. I like to say, "There is nothing that CBD does that will not be enhanced by at least a small amount of THC." The availability of additional cannabinoid components, especially cannabigerol (CBG) will likely enhance the efficacy and safety of a given preparation. We like to see a generous terpenoid fraction that can similarly boost benefit: beta-carvophyllene for anti-inflammatory and analgesic (painkilling) effects, alpha-pinene to reduce short-term memory impairment from THC, limonene to boost mood, and linalool to reduce anxiety from THC. While cannabinol (CBN) has been widely touted for sleep benefits, there is little objective evidence to support its inclusion.

CBD Oracle: Can a cannabinoid and terpene analysis reliably predict the quality or efficacy of a cannabis product? For example, does a higher number of detected cannabinoids or terpenes necessarily indicate a more effective product?



A COA on a product can only predict quality or efficacy if it is current and applies to the same batch of material that is being sold. While consumers tend to be attracted to the most "potent" preparation, particularly where THC concentration is concerned, that is not a reliable metric! With THC, often "less is more," but recognizing that at least some is necessary for best effect.



Abraham Benavides

MD, Cannabis Health Coach, GW Center for Integrative Medicine

CBD Oracle: If you were to recommend a cannabis product to a patient, what specific factors would you consider? What criteria would you use to evaluate the quality and effectiveness of different options available on the market?

Abraham: The quality of the product is the most important feature, which can be established or verified in many ways. The first and easiest thing to look for is a certificate of analysis (CoA), which is a lab report that is supposed to independently verify the safety and purity of the product at hand. If a product doesn't have this, you shouldn't buy it.

However, we are in a confusing time when certain labs are not fulfilling their roles honestly and may be subject to corruption for favorable results – commonly called "lab shopping". This means that we can't solely rely on CoAs for selection, though its absence is still a ruling out factor.

You should also avoid companies that make dubious health claims or are overseas. There can be many more impurities and falsifications found in foreign products from China, India, etc. due to contaminated soils.

I'd be further reassured by a domestic brand that achieves distinctions like being USDAcertified organic, good agriculture and manufacturing processes (e.g., GAP and GMP, and the current versions), or cannabis safety and quality (CSQ) certification. Local laws for testing and safety certification may also vary by state.

CBD Oracle: Are there specific cannabinoid profiles or terpene combinations that you find to be more effective for certain conditions in your patients?

Abraham: These days, the most common conditions I run into are chronic pain, cancer, depression and anxiety, dementia, IBS, IBD, and insomnia or other sleep disturbances.

For the people that are okay with impairing, psychoactive effects, I generally pair twice daily, non-impairing cannabinoids like 1:1:1 CBD, CBDA, or CBG with low-medium dose THC after hours, nightly, or as needed depending on severity.

Working or busy patients sometimes microdose THC (5mg or less) in the morning, which is fine and effective during the daytime for mild to moderate anxiety and depression, so long as it's not noticeably impairing.

People with severe pain needs, cancer, or dementia may need strong and frequent THC dosing to stay on an even keel. They typically require two or three times daily THC longacting oral dosing, with an inhalational route



(usually a vape cartridge) on hand for spikes of pain, nausea, or low appetite as needed.

Once I've noted a patient's major symptoms, preferences, and lifestyle, I also select a variety of terpenes to complement the cannabinoids. I've found certain terpenes work better for pain and inflammation, such as beta caryophyllene and myrcene. For anxiety, and insomnia, calming terpenes like linalool and eucalyptol are great, and in higher doses help with sedation. Persons with gut conditions like IBS and IBD should consider the rose terpene geraniol as well, based on evidence.

Depression and low energy may be better served by the addition of limonene and citrus terpenes (e.g. citronellol, etc.), that carry stronger antidepressant and activating functions typical of sativa cultivars.

CBD Oracle: Can a cannabinoid and terpene analysis reliably predict the quality or efficacy of a cannabis product? For example, does a higher number of detected cannabinoids or terpenes necessarily indicate a more effective product?

Abraham: It's helpful, but not necessarily reliable because of modern day "lab shopping" by retailers looking for labs that will "promise" higher or outright falsified numbers. So the most "potent" products aren't guaranteed the best.

Reputable and 3rd party-tested tinctures are my recommended products of choice because they are the second most bioavailable and fastacting, second only to inhalational routes. But they are much easier dosed, controlled, and tolerated, without adverse pulmonary side effects.

What's more important than potency is a practical concentration of the product (in mg/mL) and how easy it is to use.

If a product is overly concentrated or potent, it starts to become impractical to measure.

Products that are too strong will be difficult for patients to continue using. It also opens them up to be more likely to experience the side effects of highly concentrated cannabinoids or terpenes.

On the other hand, you don't want a product that is too dilute because it becomes cost ineffective and opens you up to side effects of the vehicle (e.g. excess olive oil or MCT oil causing loose stools or heartburn).

In my experience, most patients don't want to consume more than 0.5-1 mL of sublingual oil at a time. Finding a product that fits this volumetric criteria with the right dosing is the sweet spot you're aiming for.

I also don't like recommending edibles, which is basically like prescribing candy. That is, unless the patient has severe dementia and cannot tolerate any other means or have practical control over ingesting tinctures properly. Edibles are also the least efficient systemic delivery system.

CBD Oracle: While some test results show trace amounts of contaminants within acceptable safety limits (e.g. 0.029 ppm of Lead, or 0.02 ug/g of Arsenic), could repeated consumption of such products over time pose any health risks?

Abraham: Cannabis plants are really good at <u>pulling heavy metals</u> and contaminants out of the soil. However, these natural purification efforts cause contaminants to accrue mainly within the leaves and roots of the plant, and then in your body with repeat use.

The possible soil contaminants may be highly toxic or even proven carcinogens (e.g. arsenic, cadmium, chromium, and nickel). Lead and mercury are probable carcinogens that are known to bioaccumulate and cause various neuropsychiatric, gut-related, and other chronic illnesses. Problematically, lead can imitate calcium and hide in the bones for over 30 years.



Even though there are acceptable safety limits established by USP, there aren't any known safe amounts of ingestion for these. It's recommended that they be tested at even lower levels than currently done (PPM), such as parts per billion (PPB) or lower. This is also why it's important to buy domestic brands which are more likely to be grown in high-quality soil.

CBD Oracle: What are some concerning additives present in cannabis products that might lead to adverse reactions? For example, some companies use melatonin or valerian root in hemp gummies to improve sleep; is this concerning?

Abraham: The most concerning additives are probably the unintended byproducts and contaminants that evade third-party testing and typically end up in illicit or semisynthetic cannabinoid products (e.g. delta 8, etc.)

Beyond that, when you venture into the world of combining cannabinoids with nutraceuticals - it becomes more difficult for us to keep track of what is actually working for you, and you tend to lose control over the dosing. If you keep the products separate, you can try one thing at a time to see if it works for you and at what doses.

Once the products are combined, you have to take the dosing they prepared. If you have to take two or more doses simply for the cannabinoids, the other ingredients start to accumulate fast and lose their effectiveness (i.e. too much melatonin can become unhelpful or counterproductive for sleep). This also makes it difficult to parse out what may cause side effects you encounter during your regimen.

I always try to keep the cannabinoids and terpenes separate from other nutraceuticals. The other nutraceutical (e.g., St. John's wort, grapefruit juice, etc.) are also much more likely to cause metabolic drug interactions, possibly increasing or decreasing the metabolism of prescription drugs. The more information and control you have over the ingredients, the better you can guide your treatment plan. For nutraceutical questions and management, I defer to naturopathic doctors (NDs) and my Integrative Medicine colleagues at GW CIM.



Chris Hudalla

PhD, Chief Scientific Officer, ProVerde Labs

CBD Oracle: If you were recommending a CBD product to a family member, what specific features or certifications would you look for to ensure its safety and efficacy?

Chris: I do recommend CBD products to family members, and only recommend brands that do lot specific, full panel testing by a 3rd party ISO 17025 accredited lab. That panel would include pesticides, heavy metals, solvents and microbial contaminants. So far. there is no industry standard or certification program, other than a couple of labs that have put together their "stamp of approval", which is just a marketing thing. Unfortunately, the consumer has to be their own advocate. The consumer has to verify any lab results that they are given with a product. We put QR codes on every COA so consumers can verify the authenticity of those results. We had to do that because we had so many fraudulent COAs circulating with our name on them. The consumer has to investigate a producer to get a level of confidence in the quality of their products. Quality products are more expensive. You can buy lots of inexpensive products on the internet, from less reputable or unknown producers, but as in most things, you typically get what you pay for. A few years ago, there were a couple of organizations (websites) that would maintain a database of CBD/hemp products. To be included, producers had to do full panel, 3rd party testing, and these organizations would then do the work to qualify the brands on their site. Consumers

could go there to get product recommendations. Kind of like the "Consumer Reports" of CBD. However, I do not see these around anymore, it was probably difficult to monetize.

CBD Oracle: What do you believe are the most essential testing standards that should be enforced in the cannabis industry to guarantee product quality and safety?

Chris: Yikes! Testing for the cannabis industry, whether hemp or marijuana, is a disaster! For state regulated marijuana programs, the testing program is only as good as the regulators, and so far, I have not seen a single state that is doing a good job at managing this. My home state of Massachusetts is among the worst! Michigan is trying to correct lots of flaws in their program. Colorado has a great State Lab. But for the most part, the regulators have made a mess of things. USP, AOAC and ASTM are creating decent standards to address testing and quality for the industry, but they are not complete, and individual states may reference them, but as they are not complete, I do not know of any state that mandates following the guidance from these organizations. Here at ProVerde, we are collaborating with all those organizations to provide input based on our 10+ years of experience in cannabis. There is lots of collaboration between these three organizations, so I am optimistic that their



efforts will coalesce, and result in a workable standard in the next year or two, but much of it is already being rolled out as it is developed. That will give individual states something to point to, something to latch on to.

For hemp, again, there is little regulation regarding testing. No Good House Keeping Stamp of Approval. There are multiple organizations that are trying to implement their standard, but so far, there does not seem to be any industry consensus. The standards being created by USP, AOAC and ASTM are for cannabis, and can be applied to hemp or marijuana.

For "hemp", as in the hemp derived synthetics, the situation is even worse. The synthetic byproducts are challenging to test for, most labs do not have appropriate instrumentation or staff to test accurately. Out of the 30+ synthetic byproduct signals we see, only two of them have certified reference standards available. Most labs are part of the game, and do not report the level of contamination in these samples, either out of ignorance or out of complicity. If you report the contaminants, you lose that business.....you get kicked out of the game.

CBD Oracle: How can companies guarantee the quality and consistency of their cannabis products throughout the manufacturing process? Should testing procedures include both the base extract and the finished product, as well as regular testing of each batch and SKU?

Chris: Producers should start with cGMP certification, or at least start looking in that direction for their internal quality systems. This entails extensive training, documentation, testing raw inputs to your process, intermediates, as well as comprehensive, batch specific, testing of final products. We have had clients make the highest quality tincture, then flavor it with orange flavor, bottle it and have it tested, only to find out it is contaminated with pesticides. Under investigation, we found that the orange flavoring they added (which they had not considered) was contaminated with

pesticides. This is not uncommon. So they were left with hundreds of bottles of packaged tincture that they could not use. GMP certification is not a "cure all". MC Nutraceuticals just advertised that they received GMP certification, and they make contaminated "hemp-derived" synthetics, that are not even hemp derived. There is something called "Truth in Labeling", which I would think would be required under GMP, so I am not sure how they resolve that one...... The US Hemp Authority is moving forward with their own "certification" which permits up to 5% of unknown impurities in their products. No regulated or scientific body would take this certification seriously. Consumers don't know any better, and that is what they are counting on.

CBD Oracle: While some test results show trace amounts of contaminants within acceptable safety limits (e.g. 0.029 ppm of Lead, or 0.02 ug/g of Arsenic), could repeated consumption of such products over time pose any health risks?

Chris: I do not believe this to be much of a concern. When results are reported against some safety limits, those limits most frequently used are USP limits. The USP limits are established for drug products, most often administered through oral or inhalation pathways. The limits are established with consideration of children to geriatrics, with the most frail or compromised health conditions, and consider the quantity of product that may be consumed in the worst cases, with regular and repeated dosing over time. If these limits are used for assessing safety of cannabis products, I think they are already taking into account the worst possible level of contamination, with the highest possible dosing regimen, relative to the toxicity concern for that particular contaminant.

Sometimes, there is no established safety limit for a contaminant (i.e. for synthetic contaminants). In that case, I would like to see the industry defer to either FDA or ICH guidelines for the limits on contaminants, which can be between 0.05 and 0.1%. Maybe



even permit a 2x multiplier on that, establishing a limit of 0.1 to 0.2% for unknown impurities. Put that in context with the US Hemp Authority limits of 5% for the same contaminants.

CBD Oracle: Is there anything you can look for based on a COA to determine if a product is genuinely "full spectrum" hemp?

Chris: A couple of years ago, it would have been sufficient to look for minor cannabinoids in a full- or broad spectrum product. For both, there should be low levels of minors like CBC, and CBG, maybe THCV or CBDV. For full spectrum, I would expect to see additional low levels of THC.

But as most of these isolate are readily available commercially, many producers take a CBD-isolate product, and throw in small amounts of isolate minors. To really tell if it is full/broad spectrum, I would say the COA should include terpene results. Still, if it is a low concentration CBD tincture, sometimes the minor cannabinoids and terpenes will be diluted by the bulk carrier (i.e. MCT oil), below the level of detection for standard sensitivity methods.

When we have a client, whose full/broad spectrum claim is crucial for their product, we will often recommend a higher sensitivity testing approach, relative to our standard testing methods. Most labs can offer this, so even if these trace level full/broad spectrum constituents are below normal detection limits, we can still detect them with the higher sensitivity instrumentation.



Bob Miller

PhD, Chief Scientific Officer, ACT Labs

CBD Oracle: If you were recommending a CBD product to a family member, what specific features or certifications would you look for to ensure its safety and efficacy?

Bob: When thinking about safety and efficacy the first thing I would consider is making sure that you are purchasing product from a reputable source. The second item I would be looking at is getting a copy of all testing that was performed on the product. If there is no testing available, I would not use the product. When looking at the testing results for the product, I would pay particular attention to the level of cannabinoids present as well as the specific cannabinoids which are present. Specifically, if there is d9THC and/or d8 THC present. If the product is naturally derived hemp, there should be little or no presence of either d8 or d9. If d8 and d9 are present, it is likely that the product has been chemically treated. The next item I would look for is the level of contaminants seen (particularly heavy metals and pesticides). If there are heavy metals seen, that would be indicative of the fact that the CBD product had been chemically modified. Finally, an examination of the level of microbes should be examined. Specifically, the presence of Aspergillus species would be a cause for concern.

CBD Oracle: What do you believe are the most essential testing standards that should be enforced in the cannabis industry to guarantee product quality and safety?

Bob: The two areas where standards are needed are in the areas of potency and microbial testing. With potency testing, particularly with lower, the higher the potency the more the product can be sold for. As a result, there needs to be periodic assessments done of labs using "blinded samples" coupled with data trending done by regulators to ensure what is "on the label is in the product". The second area where standardization is needed is in micro testing. There are many different methods available for testing of total yeast and mold as well as Aspergillus species. Depending on the method used, the results generated can vary significantly. In addition, for the Aspergillus test, the specification is that none can be detected. It is important that a minimal detection limit is needed for such a test.

CBD Oracle: Can a cannabinoid and terpene analysis reliably predict the quality or efficacy of a cannabis product? For example, does a higher number of detected cannabinoids necessarily indicate a more effective product?

Bob: Efficacy is dependent on a number of factors including the level of cannabinoids seen. With that being said, there are over 20 different cannabinoids that we routinely test for with many of the cannabinoids showing different pharmacological effects (e.g. sleep, mood elevation, stress reduction, etc.). Therefore, efficacy is dependent on not only the level of the cannabinoid seen but also which cannabinoid is seen. In a similar fashion,

terpenes are reported to have differing effects also as well as potentially reacting with cannabinoids to provide a synergistic effect. Therefore, it is not necessarily true that more cannabinoids is better.

CBD Oracle: What is the optimal extraction method for producing a high-quality, fullspectrum cannabis extract that is both safe and effective?

Bob: There are three main approaches used to extract cannabinoids, butane, CO2 and ethanol. Each of the approaches have advantages and disadvantages. CO2 is reported to be the most efficient but tends to be more expensive. Both ethanol and butane tend to [be] less expensive and somewhat less efficient however, care must be taken for both to make sure there is not residual "solvents" remaining in the product. ■



Ryan Bellone

Chief Commercial Officer, KCA Labs



Richard Sams

PhD, Chief Scientific Officer, KCA Labs

CBD Oracle: If you were recommending a CBD product to a family member, what specific features or certifications would you look for to ensure its safety and efficacy?

Ryan/Richard: The answer depends on what is meant by "CBD product". If the CBD product is prepared from plant materials or CBD isolate without any conversion of the CBD to other substances and does not contain added cannabinoids, I want the product to have a certificate of analysis from an ISO/IEC 17025 accredited laboratory with a reputation for excellence and commitment to high-quality testing. I want to see a certificate of analysis that includes a chromatogram from the analysis of the cannabinoids. I want to review the chromatogram for evidence of appropriate product analysis. Finally, I want to see a certificate of analysis that is easy to read and interpret.

On the other hand, if the product contains materials like HHC or Delta-8-THC that are prepared by the conversion of CBD and its homologues, I want to see evidence that testing laboratory personnel use methods that are fit for purpose for correctly testing these substances. Conversion materials contain side products of the conversion process that are not present in plant materials or plant extracts. Therefore, test procedures that are used for plant materials may not be and often are not appropriate to determine cannabinoids, conversion materials, and side products in these consumer products. I want to see evidence that the laboratory knows the additional challenges of testing these materials.



CBD Oracle: Can a cannabinoid and terpene analysis reliably predict the quality or efficacy of a cannabis product? For example, does a higher number of detected cannabinoids necessarily indicate a more effective product?

Ryan/Richard: The short answer is "No". The chemical analysis will provide quantitative data for all targeted cannabinoids and terpenes, but it will provide no information about substances that are not targeted. Since quality and efficacy both depend on these and other factors that are not part of the laboratory report, the analysis results may not reliably predict the quality or efficacy of the product. Efficacy is highly dependent on the rate and extent of the systemic availability of the cannabinoids. If the product is formulated such that the absorption rate of the cannabinoids is increased or the extent of bioavailability is increased, efficacy may be affected. However, these factors are not determined by the laboratory testing that was described.

CBD Oracle: What is the optimal extraction method for producing a high-quality, fullspectrum cannabis extract that is both safe and effective?

Ryan/Richard: The optimal method removes cannabinoids from plant materials and minimizes the extraction of unwanted substances. Solvent residues must be readily reduced to irrelevant concentrations in the consumer product.

CBD Oracle: What are some of the most frequent issues you encounter when testing products? What concerns you the most about the quality and safety of hemp products?

Ryan/Richard: A frequently encountered issue is the use of a method that is appropriate for the analysis of plant materials being used for the analysis of conversion materials. These are HPLC methods that have not been demonstrated to be able to resolve conversion byproducts from natural cannabinoids. When such methods are used, the results for some of the critical cannabinoids are probably incorrect due to the co-elution of the byproducts and cannabinoids.

Another issue is the presence of detected but unidentified substances in converted materials. Toxicity studies have not been performed on these substances. Acute toxicity is not very likely because they are being used without any apparent adverse consequences. However, the potential for chronic toxicity arising after exposure to these substances over ten to twenty or more years is unknown.

A third issue is that as much as 10-30% of the total mass cannot be accounted for in some conversion materials. Analysis of these samples by different methods accounts for less than the total mass. Since the substances making up the rest of the sample mass are not detected, their effects, if any, are unknown.



Adie Rae

Phd, Assistant Scientist, Legacy Research Institute

CBD Oracle: If you were to recommend a cannabinoid product to a friend or family member, what specific factors would you consider? What criteria would you use to evaluate the quality and effectiveness of different options available on the market?

Adie: I would only recommend two types of cannabinoid products. First, look for products sold by licensed brick-and-mortar retailers (where lab testing, accurate labels, child-proof packaging, and age restrictions are the norm). Gas stations, grocery stores, and smoke shops are not licensed in this way. For cannabinoid products that are available online, I would only recommend cannabidiol (CBD), and only if the company proudly provides lab testing results for every single batch of their products. Lab tests should include not only the potency of CBD, but test for the presence of other cannabinoids like delta-9-THC, pesticides, and other toxins like residual solvents. Because "effectiveness" means different things to different people, I cannot make a blanket recommendation about this. "Quality" products are always lab tested, always accurately labeled, always have suggested serving sizes, always come in childproof packaging, and are age-restricted to adults 21 and over.

CBD Oracle: Are there specific cannabinoid profiles or terpene combinations that you find to be more effective for certain conditions?

Adie: I recognize that the public is very hungry for exactly this kind of information, but the reality is that we are decades away from understanding this. Currently, here is what is true for everyone: CBD and delta-9-THC are powerful molecules with medicinal value. When using them for symptom relief, start with a low dose, and work your way up slowly (and only if necessary). Your body will develop tolerance to THC, so take a 48-hour break once a month. If you start to experience daily stomach pain or nausea, ask your healthcare provider about cannabinoid hyperemesis syndrome. If you feel like you can't bear taking a break for two days, talk to your provider about managing tolerance and dependence. If you think that certain cannabinoid profiles or terpenes might be helping you, document these results carefully in a health journal. Keep in mind that what is true for you may not be true for everyone. Novel and emerging hempderived molecules (even non-impairing ones like CBN and CBG) haven't been studied enough for me to stand behind them. Until the evidence is clear, I recommend avoiding them, especially inhalable products like vapes.

CBD Oracle: Can a cannabinoid and terpene analysis reliably predict the quality or efficacy of a cannabis product? For example, does a higher number of detected cannabinoids or terpenes necessarily indicate a more effective product?



Adie: There is absolutely no evidence to support that certain phytochemical profiles are any "better" or more "efficacious" than any other product. It is all relative to the person, their unique endocannabinoid system, their unique sensitivity to THC, their unique lifestyle, their unique ability to tolerate side effects, and their unique health goals. I'd highly encourage folks to focus less on medical efficacy for the population, and turn their focus toward safety and tolerability for the individual.



Sibyl Swift

PhD, Founder/Partner, Swift Strategy Group

CBD Oracle: If you were to recommend a CBD product to a family member, aside from your own brand, what specific factors would you consider? What criteria would you use to evaluate the quality and effectiveness of different options available on the market?

Sibyl: I would suggest that anyone interested in taking a CBD product look at the following:

- cGMP certs on products or the site. Are they third party?
- COAs available for any product they are interested in purchasing and they COAs are current (less than 18 months old). Do the COAs provide methods (you don't want a coversheet)?
- Does the product page or packaging make claims that are too good to be true? If the product says it can treat, cure, prevent, or mitigate a disease then the company is not following federal (or state) laws.
- Has the company performed any testing on the ingredients or products? Do they have safety data or efficacy data (to support their claims)?

CBD Oracle: What are some common quality control shortcuts that companies might take in

the industry? How can consumers spot these red flags and choose more reliable brands?

Sibyl: I do believe that every industry has responsible companies and then not so responsible companies. The dietary supplement industry and also the hemp space within that is no different. I always try to ensure I highlight the positive when I'm publicly discussing the potential negatives to avoid making the entire industry appear to be disreputable because that is not the case. Some brands invest heavily in quality, safety, and efficacy, which is the baseline requirement if you are going to feed something to people. The brands that choose to skirt the rules and focus on profit over consumer safety and efficacy are likely to take the below shortcuts:

- Old COAs on the site or no COAs on the site.
- Products that are under the label claim for potency. Many hemp products (as well as dietary supplements in general) are slightly over the label claim. Products within an approximately 20% range over label claim are allowed to do so in order to provide products that "hit label claim" at the end of their shelf life.
- Shelf life claims without the appropriate stability data to support it.



Swathi Varanasi

CBD Oracle: If you were to recommend a cannabinoid product to a patient or family member, what specific factors would you consider? What criteria would you use to evaluate the quality and effectiveness of different options available on the market?

Swathi: Before recommending a cannabinoid product to a patient or family member, I would have a comprehensive discussion about their lifestyle–including but not limited to their daily diet of food, movement, and mindfulness–as well as a thorough review of their prescription medications, herbal supplements, over-thecounter medications, nutraceuticals, and other vitamins and minerals they take regularly. Once I have deemed them an appropriate candidate for adding a cannabinoid product into their regimen, when recommending a cannabinoid product, I would consider several factors:

- Source of Hemp: The product should ideally come from organically grown, non-GMO hemp to minimize exposure to pesticides and heavy metals.
- Extraction Method: CO2 extraction is generally preferred as it tends to yield a cleaner product, free from residual solvents.
- Third-party Testing: A reputable product

will have a Certificate of Analysis (COAs) per batch of product from an independent, third-party laboratory, which verifies the potency, purity, and safety of the product.

- Cannabinoid Profile: The cannabinoid ratio (e.g., CBD, THC, CBG, CBN, etc.) should align with the intended therapeutic use.
- Terpene Profile: Specific terpenes (e.g., myrcene for relaxation, limonene for mood elevation) can enhance the therapeutic effects through the entourage effect.
- Delivery Method: The method of administration (e.g., tincture, capsule, topical, transdermal) should match the patient's needs and condition.

CBD Oracle: Are there specific cannabinoid profiles or terpene combinations that you find to be more effective for certain conditions?

Swathi: When looking at the published literature, much of it falls into three or four distinct categories: pain, anxiety, sleep, and inflammation. Depending on the potential therapeutic use, I would recommend a combination of cannabinoids and terpenes. Given the entourage effect, I am more inclined to recommend a full-spectrum or broadspectrum product regardless of the ailment in question.



- Pain: A balanced CBD product with terpenes like myrcene, beta-caryophyllene, and pinene that can provide synergistic anti-inflammatory and analgesic effects.
- Anxiety: CBD-dominant products with low THC (like 0.3%-the legal limit for hempbased products with mass distribution in the US) and terpenes such as linalool and limonene.
- Sleep: CBD products with added cannabinol (CBN) and terpenes like myrcene and linalool can support better sleep quality.
- Inflammation: CBD-rich products with terpenes such as beta-caryophyllene and humulene can have anti-inflammatory effects.

CBD Oracle: What safety concerns do you have about the cannabis products available on the market today? Are there any red flags you look for in terms of product quality or ingredients?

Swathi: At the moment, much of my safety concerns primarily revolve around the presence of contaminants, inaccurate labeling, and deceptive advertising:

- Contaminants: Patients should only purchase products that have undergone rigorous third-party testing for each batch of product from a manufacturer. Again the Certificate of Analysis (COA) tests for active ingredient quantities as well as the presence of pesticides, heavy metals, mold, and residual solvents in the products.
- Mislabeling: Products often lack detailed labeling and sometimes misrepresent the concentration of cannabinoids which can be ineffective or potentially harmful.
- Additives: Products often have unnecessary additives, artificial colors, or

flavorings, which can potentially cause adverse reactions.

- THC Content: For patients not wanting to consume THC or are living in areas where THC is not legal, it is important to ensure that the third-party testing indicates the product's THC content is within legal limits and is tolerable by the user.
- Misleading Advertising: Some products are marketed with unsubstantiated health claims or promise unrealistic outcomes, which can mislead patients into using products that may not be effective or safe.

CBD Oracle: How should healthcare professionals monitor the long-term efficacy of cannabis treatment for patients, and what indicators suggest that a product is consistently effective over time?

Swathi: Monitoring should involve regular patient assessments that include:

- Symptom Tracking: Patients should maintain a diary–I call it a 'cannabis diary'–to record changes in their condition, including improvements, side effects, new symptoms, and the dose and frequency of cannabinoid product use.
- Products Show-and-Tell: Patients should bring their products to all of their in-office or telemedicine visits with their healthcare providers for review.
- Dosage Adjustments: Assessment of the patient's response to dosage adjustments over time to find the optimal therapeutic window depending on the use case.
- Quality of Life Evaluation: Validated scales that assess improvements in quality of life, sleep, pain levels, and mental health can provide a perception-based perspective on the benefits of the product.

- Lab Testing: Depending on the therapeutic use, periodic blood work may be helpful to monitor for benefits, potential effects on liver enzymes, and/or interactions with other medications.
- Open Discussions: Patients should feel encouraged to have open, honest discussions with their healthcare providers to ensure their treatment is tailored to their needs and concerns.



Eloise Theisen

NP, CEO, Radicle Health

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CBD Oracle: If you were to recommend a cannabis product to a patient, what specific factors would you consider? What criteria would you use to evaluate the quality and effectiveness of different options available on the market?

Eloise: With so many different products on the market to choose from, it can be difficult to determine which product is best for a patient. When choosing a product for recommendation, I look at the patient's needs first. It is important to consider previous cannabis history, age, gender, health history, medication and supplement use, activity level, budget, and best route of administration. I also look for the root cause of the symptom we are treating. For example, if the patient is having a hard time sleeping due to pain at night, I will try treating the pain first and see if that improves the sleep. Once I have identified what I am treating, then I look into finding the best product. To find the best product, I start with a Certificate of Analysis (COA) which will show me test results for potency, cannabinoid content, terpene profile, pesticides, fungus, molds, and residual solvents for each batch. After I have identified a quality product, I evaluate which route of administration would be most appropriate for the patient. In a new, inexperienced user it may be most appropriate to start with a tincture to help control the dose and start low and slow. Others may benefit from a topical if they are concerned about side effects or drug-drug interactions. Once a product and route of

administration are chosen, it is important to follow up with the patient to determine if the product is providing consistent results. In some cases, even the high quality products may not work well for patients.

CBD Oracle: Are there specific cannabinoid profiles or terpene combinations that you find to be more effective for certain conditions in your patients?

Eloise: It depends. Everyone is different and it is one of the great benefits and challenges of working with cannabis. Having a variety of cannabinoid and terpene profiles allows for individualization and customization of a cannabis regimen. Many patients can benefit from exploring different cannabinoid profiles which can help them find the right fit for their needs. On the other hand, it can be difficult to get consistency with the variations in cannabinoid profiles and there may be less predictability. In general, I look at THC for pain and sleep and add in CBD as needed to help with possible side effects related to THC and/or to help increase the effectiveness of THC. CBG has been shown to help anxiety and nerve pain in some people. Terpenes can play an important role in finding the right profile for specific conditions, but the profile is not always readily available. I think as the science continues to grow and reflect the value of terpenes as an additional medical benefit, cannabis retailers will provide that information



with the product testing. Most consumers and patients are undereducated about the importance of terpenes and therefore, companies do not see the demand for that information.

CBD Oracle: Can a cannabinoid and terpene analysis reliably predict the quality or efficacy of a cannabis product? For example, does a higher number of detected cannabinoids or terpenes necessarily indicate a more effective product?

Eloise: In my opinion, no. There are so many other factors that influence the efficacy of cannabis that an analysis is only a small part of the equation. The COA can be a good foundation to finding the right product, however, the patient's age, gender, medication profile, and metabolism can also influence the efficacy of the product. And we still do not have research establishing dosing for many conditions. Some patients may respond to low doses, while others can need significantly higher doses than most. The best approach is to start low and slow and ramp up based on the patients tolerance and response to the regimen.

CBD Oracle: While some test results show trace amounts of contaminants within acceptable safety limits (e.g. 0.029 ppm of Lead, or 0.02 ug/g of Arsenic), could repeated consumption of such products over time pose any health risks?

Eloise: I think it is reasonable to worry that some of those trace contaminants can accumulate over time with daily use. The health risks are not well known at this time and the amount of exposure will depend on how much and how often one uses the product. I do try to recommend products that are free of molds, fungus, pesticides, residual solvents, and bacteria.

CBD Oracle: What are some concerning additives present in cannabis products that might lead to adverse reactions? For example, some companies use melatonin or valerian root in hemp gummies to improve sleep; is this concerning?

Eloise: I tend to be a purist and like working only with one thing at a time. If I am using cannabis to treat symptoms, I prefer not to use products with other ingredients as it can complicate the results. If I use a product with melatonin and cannabis for sleep and it is working. I cannot say with confidence that it is one or the other that is working. And the same goes for when a patient may experience an unwanted outcome, it can be difficult to isolate the culprit. Supplements like valerian root and melatonin are unregulated and it adds another element of concern to product safety. Just because it is available over the counter does not mean it is safe and it is always best to ask a qualified healthcare professional before starting any new regimen.



Megan Mbengue

RN, Founder, Trusted Canna Nurse

CBD Oracle: If you were to recommend a cannabis or hemp product to a patient, what specific factors would you consider? What criteria would you use to evaluate the quality and effectiveness of different options available on the market?

Megan: When recommending products to patients, we often use the FLOW criteria, which means the product is Flower-Derived, Labtested, Organic, and Whole plant. Products that meet flow criteria are evidence-based for optimal therapeutic outcomes.

Because these are so challenging to find on the market (only 10% of products meet this criteria), we crafted our own line of products that meet FLOW criteria here <u>https://www.trustedcannanurse.com/productcategory/cannabis-nurse-approved/</u>. There is also an article linked there, explaining flow criteria.

If products don't meet flow criteria, then I make sure they don't contain any synthetic or semi-synthetic cannabinoids. Delta-9, CBN, and THCV are often semi-synthetic and converted from other cannabinoids, and I'm not comfortable with our patients consuming those (which is why none of our products are semi-synthetic.

CBD Oracle: Are there specific cannabinoid

profiles or terpene combinations that you find to be more effective for certain conditions in your patients?

Megan: We have a few different combinations of cannabinoids and terpenes, targeted for various reasons. For stress and anxiety often seen in our autistic children or adults with dementia, a low dose of CBD + CBN, in combination with linalool and myrcene, is a great option to start with.

People love our CBGA and CBG for physical symptoms of stress and anxiety, and that's because of the unique action that CBG has on receptors involved in our fight or flight response.

For pain, I really like to start people on high CBD with beta-caryophyllene and humulene, of course in whole plant formulations, like a tincture or suppository for period pain.

There are many combinations that work well for different reasons!

CBD Oracle: Can a cannabinoid and terpene analysis reliably predict the quality or efficacy of a cannabis product? For example, does a higher number of detected cannabinoids or terpenes necessarily indicate a more effective product?



Megan: Efficacy of a product is dependent on more than just cannabinoid and terpene profile. It often depends on extraction process, delivery method, as well as the individual's ECS. That's why it's really important to start low, go slow, give it time to work, and work with a professional to find the right combination for you. ■



Cynthia Cabrera

Director, Hemp Industries Association

CBD Oracle: Are there any standardized practices or benchmarks that hemp companies can use to improve product safety and effectiveness? Or is it primarily up to each company to set its own standards?

Cynthia: Since the FDA deferred regulatory responsibility to Congress, states have developed their own laws. For instance, Texas has regulated hemp since 2019, requiring company registration, full panel testing, licensing and labeling. This patchwork of regulations can be challenging, especially for businesses operating across states, but many companies thrive by setting their own high standards, which is just a good business practice. Good manufacturing practices are essential to ensure consistent, high-quality production, minimizing contamination risks and ensuring traceability. At Hometown Hero, we source all our hemp locally from Texas farms using organic and sustainable methods, meeting stringent quality standards. Testing is also key, not just for THC levels but for contaminants, plus, all our test results are easily accessible via QR codes on packaging.

CBD Oracle: For new CBD consumers, what advice do you have for selecting a trustworthy company? What criteria should they consider when evaluating the available options? **Cynthia:** Reliable hemp companies should provide transparency by offering detailed product information, including third-party lab test results. These results should verify cannabinoid content, THC levels and screen for any potential contaminants.

Look for companies that adhere to high standards in labeling, age restrictions and child-resistant packaging. Certifications such as ISO 17025 for testing labs or USDA organic certification can be strong indicators of a company's commitment to safety and quality.

A well-rounded hemp company will offer a diverse product range, including CBD oils, edibles, topicals, and other cannabinoid products, to meet various consumer needs. An extensive product portfolio often reflects a company's expertise and dedication to addressing different preferences. Customers should see how easy it is to reach the company if they have questions; do they answer emails, is there a person they can speak to?

Lastly, a company's reputation speaks volumes. Review customer feedback, testimonials and ratings both on the company's website and independent platforms to gauge its reliability and trustworthiness.



Erica Stark

Executive Director, National Hemp Association

CBD Oracle: Are there any standardized practices or benchmarks that hemp companies can use to improve product safety and effectiveness? Or is it primarily up to each company to set its own standards?

Erica: While there are general benchmarks that responsible companies should follow such as food safety standards, heavy metal and contaminant testing, and providing authentic Certificates of Analysis (COAs) - there is currently no uniform, enforced standard across the industry. Without proper FDA oversight, it's largely up to individual companies to set their own standards for safety. As a result, practices can vary significantly which makes it hard for consumers to discern a good product from a bad. Consumers should look for companies that voluntarily comply with thirdparty testing and transparency in their practices, but true, consistent industry-wide regulation is still lacking and there is no substitute for it.

CBD Oracle: For new CBD consumers, what advice do you have for selecting a trustworthy company? What criteria should they consider when evaluating the available options?

Erica: For new CBD consumers, it's important to choose a company with a solid reputation for transparency and safety. Look for brands that

provide third-party lab testing results (COAs) for their products, showing that they've been tested for contaminants like heavy metals and pesticides.

However, even when doing research, consumers must exercise caution. There's a degree of trust involved because the third-party lab itself must be reputable and independent. It's essential that the testing company is wellknown and trusted, as some results could potentially be forged or manipulated by less scrupulous brands. It's also wise to get recommendations from trusted sources, such as friends, family, or even to purchase from dispensaries that operate under state regulations.

Additionally, for cannabinoid products containing any form of THC, consumers need to be extra cautious and understand their state's laws regarding THC content. Legal limits on THC levels vary by state, and it's important to ensure you're complying with local regulations to avoid any legal complications. Lastly, consumers should avoid buying from mini-markets or corner stores, where products may not be held to the same safety standards and be wary of making decisions based solely on price.



Shawn Hauser

Partner, Vicente LLP

CBD Oracle: If you were to recommend a cannabinoid product to a friend or family member, what specific factors would you consider? What criteria would you use to evaluate the quality and effectiveness of different options available on the market?

Shawn: I generally consider the cannabinoid profile (different cannabinoids have specific benefits and effects), THC content, dosage, test results and credibility/compliance of the brand and manufacturer. To evaluate quality and effectiveness, I look for companies who have clear, truthful labels that do not make unsubstantiated claims and have compliant labels (consistent with food and dietary supplement regulation) that clearly indicate the product's serving size cannabinoid and THC limit. I also review a company's website to confirm they are cGMP compliant, use safe ingredients, clear testing results, are registered with the FDA, have professional marketing, and have a qualified team.

CBD Oracle: What steps can hemp companies take to protect their customers from legal repercussions related to their products? How can they mitigate the risk of customers being caught in legal trouble due to mislabeled or inaccurate product claims?

Shawn: Companies can ensure they have adequate safety data supporting the safety and efficacy of their products. Companies should

also comply with fundamental FDA and FTC regulations including not making false and misleading statements such as unsubstantiated medical or health claims. These claims are also illegal under most state hemp and consumer protection laws.

Companies can also ensure their social media, blogs, and other marketing content does not include unsubstantiated or false or misleading claims. This includes citing to articles or posting certain comments/reviews.

CBD Oracle: Are there federal-level labeling rules that apply to hemp products, or is this mainly handled at state level?

Shawn: Yes, the labeling rules under the Federal Food, Drug and Cosmetic Act, the Fair Packaging and Labeling Act, and certain FTC regulations that apply consumable hemp products. Since the 2014 Farm Bill's legalization of some commercial hemp activity, the FDA and FTC have enforced federal laws against hemp companies, but have generally limited enforcement to products that make unlawful drug claims or raise material public safety concerns.

CBD Oracle: What are the most relevant consumer protection laws that apply to hemp products?



- Federal Trade Commission Act (prohibits deceptive trade practices)
- State Unfair and Deceptive Acts and Practices
- Federal Food, Drug, & Cosmetic Act
- State Food and Drug Laws
- State Hemp Laws

CBD Oracle: How can companies ensure that their marketing and labeling practices comply with consumer protection regulations?

Shawn:

- Ensure compliance with applicable state laws, and FDCA (to the extent possible given its position that CBD and THC are illegal)
- Do not include claims indicating product can be used to treat a medical condition
- Conduct safety studies to ensure all health claims are substantiated by competent and reliable scientific evidence
- Maintaining a strong testing program with a reputable testing lab to ensure the label accurately indicates the product contents and that the product is safe and free of contaminants or harmful byproducts
- Especially given the FDA's failure to adequately regulate finished products and the complexity and constantly changing nature of state hemp law, ensure there is a compliance and legal team reviewing all labeling and marketing, and staying up to date as to requirements
- Training and educating staff

CBD Oracle: What do you expect to be the main legal challenges for the hemp industry going forward?

Shawn: The FDA's failure to establish regulations (And its resulting 50 state patchwork of constantly changing laws) for finished hemp products remains the primary legal challenge for the hemp industry. After 5 years assessing potential regulations, FDA decided to defer to Congress to develop appropriate regulations, while it maintains iurisdiction. This has left hemp businesses in a legal gray area with federal food and drug laws, and has forced states to adopt robust statelevel product safety regulations. For the hemp industry, this means 50 different state rules as to whether hemp products can be manufactured and sold, licensing, product potency, serving and container size, packaging/labeling, marketing, testing, and points of sale. Until we have a uniform federal regulatory framework, federal FDCA legality and the 50 state patchwork, and the extreme frequency in which the state laws change will remain the fundamental legal challenge.



Rod Kight Attorney, Kight Law

CBD Oracle: If you were to recommend a cannabinoid product to a friend or family member, what specific factors would you consider? What criteria would you use to evaluate the quality and effectiveness of different options available on the market?

Rod: As with any consumer product, I would first look at online customer reviews to see if the customers are happy and if the company engages with its commenters/reviewers. Next, I would look at the ingredient list to ensure that they were things I would want to consume. Finally, I would review the certificates of analysis (COAs) to determine if the product is compliant (ie, are the delta-9 THC concentrations within the 0.3% limit) and to ensure that there are no contaminants. If any of the above are "off" or difficult to obtain then I would pass on the product and look at another one.

CBD Oracle: What steps can hemp companies take to protect their customers from legal repercussions related to their products? How can they mitigate the risk of customers being caught in legal trouble due to mislabeled or inaccurate product claims?

Rod: The days of off the cuff labeling in the hemp industry are over. In addition to federal labeling requirements (ie for foods, dietary supplements, or cosmetics), many states have

specific labeling regulations for hemp products. Unfortunately, this is currently a patchwork and it can be a challenge to stay on top of all of these regulations. It's important for a company to discuss its labeling plans with an attorney and to have an attorney review the labels. Also, it's important to provide warnings about restricting access to minors, not passing a drug test after use, intoxication, and for pregnant, nursing, and people with health conditions.

CBD Oracle: Are there federal-level labeling rules that apply to hemp products, or is this mainly handled at state level?

Rod: There are not federal level labeling rules that are specific to hemp; however, there are labeling rules about consumable products. For hemp-specific labeling rules, about 30 states have them.

CBD Oracle: What are the most relevant consumer protection laws that apply to hemp products?

Rod: State product liability laws, Prop 65 (California), and FDA rules regarding adulterants.



CBD Oracle: How can companies ensure that their marketing and labeling practices comply with consumer protection regulations?

Rod: This is really important to discuss with an attorney and the risks can be variable depending on the product type/category.

CBD Oracle: What do you expect to be the main legal challenges for the hemp industry going forward?

Rod: Obtaining national/unified labeling standards. There is a big push for states to make their own decisions about hemp products; however, when it comes to labeling, this needs to be federal/top down, just like every other consumable product.



The Food and Drug Administration

CBD Oracle: How widespread are deceptive and/or illegal marketing practices in the CBD industry?

FDA: The FDA continues to be concerned about the proliferation of products asserting to contain CBD that are marketed for therapeutic or medical uses although they have not been approved by FDA. The FDA will continue to work to safeguard the health and safety of U.S. consumers by monitoring the marketplace and taking action when companies sell products that present a threat to public health.

THC or CBD cannot be added to food for humans or animals under the FD&C Act. CBD and delta-8 THC are unapproved food additives for use in any human or animal food product, as the FDA is not aware of any basis to conclude that the substances are generally recognized as safe (GRAS) or otherwise exempt from food additive requirements.

THC or CBD products cannot be sold as dietary supplements under the FD&C Act. Both CBD and THC are excluded from the dietary supplement definition and cannot be sold or marketed as such.

CBD Oracle: What are the risks of buying CBD and/or delta-8 THC products with false or unsubstantiated medical claims? **FDA:** Selling unapproved products with unsubstantiated therapeutic claims is not only a violation of the law, but also can put patients at risk, as these products have not been proven to be safe or effective. This deceptive marketing of unproven treatments also raises significant public health concerns because patients and other consumers may be influenced not to use approved therapies to treat serious and even fatal diseases.

Unlike drugs approved by FDA, products that have not been subject to FDA review as part of the drug approval process have not been evaluated as to whether they work, what the proper dosage may be if they do work, how they could interact with other drugs, or whether they have dangerous side effects or other safety concerns.

CBD Oracle: What key factors should consumers consider when choosing a CBD product that is not in violation of the FD&C Act?

FDA: Aside from Epidiolex, there are no other FDA-approved drug products that contain CBD. Please see Q&A #4 on this <u>page</u> and this <u>article</u> for more information.

As stated above, CBD cannot be added to food for humans or animals, or sold as dietary supplements, under the FD&C Act. We are



concerned that people might mistakenly believe that using CBD "can't hurt" and that the FDA has evaluated CBD products and determined they're safe. Data on CBD points to real risks, and the FDA is especially concerned about the risks to children, people who are pregnant or breastfeeding, and people taking other medications. Consumers should be aware of the risks and should speak with a medical provider about the use of any CBD product.

CBD Oracle: What steps should a consumer take if they believe they have been harmed by a CBD or delta-8 THC product? How can the FDA assist in such cases?

FDA: If a consumer thinks they are having a serious side effect that is an immediate danger to their health, they should call 9-1-1 or go to a local emergency room. If a child has consumed these products, immediately call the local poison control center (1-800-222-1222). Do not wait for symptoms to call.

Health care professionals and consumers are encouraged to report complaints and cases of accidental exposure and adverse events to the <u>FDA's MedWatch Safety Information and</u> <u>Adverse Event Reporting Program</u>.

The FDA is actively working with federal and state partners to further address the concerns related to these products and monitoring the market for adverse events, product complaints, and other emerging cannabis-derived products of potential concern.



The California Department of Public Health

CBD Oracle: Are there any standardized practices or benchmarks that hemp and cannabis companies can use to improve product safety and effectiveness?

For new CBD consumers, what advice do you have for selecting a trustworthy company? What criteria should consumers consider when evaluating the available options.

CDPH: California's laws and regulations for hemp and cannabis growers, manufacturers, and retailers are aimed at protecting consumer safety. Manufacturers of industrial hemp food products must follow all applicable California statutes as well as the current federal good manufacturing practices for food and dietary supplements. Consumers may want to consider purchasing through licensed retailers. Additionally, California law provides that industrial hemp food products sold at retail must include a label, scannable barcode, internet website, or quick response (QR) code linked to the certificate of analysis of the product.

For cannabis products, the Department of Cannabis Control, which licenses and regulates cannabis businesses, maintains a webpage that lists <u>product recalls and safety notices</u>.