

## Conversation with Dave Neundorfer

Interview by Sheldon Baker

*Dave Neundorfer is the co-founder and chief executive officer of Open Book Extracts (OBX), a cGMP-certified manufacturer known for premium cannabinoid products, exceptional customer service, and industry-leading transparency. Prior to OBX, Neundorfer co-founded Greenleaf, a leading Ohio medical marijuana company that won and now operates the maximum number of licenses allowed by the state. While Neundorfer's commitment to cannabis is driven by the firm belief in its efficacy, his engineering background drives his commitment to data and traceability. Neundorfer started his career as a quality engineer in the automotive space and then served Fortune 500 semiconductor companies as CEO of LineStream, an automation software company he co-founded and sold in 2017. He studied engineering and studio art at Dartmouth College and received his MBA from the Stanford Graduate School of Business.*

**Integrative Medicine: A Clinician's Journal (IMCJ):** Hemp and CBD products have been known to have numerous healing powers. Discuss the healthy alternatives such products offer vs. pharmaceuticals.

**Mr. Neundorfer:** As the U.S. emerges from nearly a century-long prohibition on cannabis, labs across the globe are accelerating their research efforts buoyed by millennia of medicinal use by humans, a groundswell of anecdotes and grass-roots education from legalized markets, decades of publications from researchers in cannabis-friendly countries, and post-legalization research that has been conducted by labs and industry leaders in a growing, global market.

We now have a body of knowledge around the safety and efficacy of Cannabidiol, or CBD, the active in the first FDA approved cannabinoid-based drug, Epidiolex, which targets childhood epilepsy caused by Dravet and Lennox-Gastaut syndromes, conditions which typically do not respond to pharmaceutical antiseizure medications. We expect a similar pattern to emerge for other non-psychoactive cannabinoids (often referred to as "rare cannabinoids" or "minor cannabinoids") that boast tremendous therapeutic benefits despite occurring naturally in much smaller concentrations than CBD or THC in the cannabis sativa plant.

While CBD is often thought of as THC's non-psychoactive counterpart, there are actually 145 other

cannabinoids which the industry is evaluating as plant-based alternatives to prescription drugs that target specific need states. Here is a quick overview of some of the cannabinoids and the functional benefits for which they are being researched and commercialized.

**CBD:** Cannabidiol is typically the most prominent cannabinoid by volume in hemp and is a naturally occurring non-psychoactive component of the cannabis plant. It has shown to be effective at addressing anxiety, inflammation, and chronic pain.

**CBG:** Cannabigerol has shown potential in soothing inflammation, stimulating appetite, inhibiting cancer cell growth, and killing drug-resistant bacteria. CBG is further thought to help regulate mood thanks to its ability to boost anandamide, the body's native bliss molecule, as well as act as a GABA reuptake inhibitor, which provides a range of benefits including mood elevation, anxiety relief, muscle relaxation, seizure relief, and more.

**THCV:** Tetrahydrocannabivarin is a highly sought-after cannabinoid due to its potential to suppress appetite, making THCV-dominant products ideal for weight management. THCV also has the potential to increase energy and focus. On the topical side, in the same study that identified CBC as a potential acne-fighting ingredient, THCV was found to be even more effective than CBD or CBC at fighting the causes of acne, which when combined with the anti-inflammatory effects of THCV and other cannabinoids, may one day lead to the development of acne medications with these cannabinoids as active ingredients.

**CBN:** Cannabinol shows promise in promoting restful sleep and sedation, as well as pain relief and appetite stimulation. We see an opportunity to use CBN in topical products, where CBN might be helpful for treating psoriasis, dermatitis, and other skin irritating conditions.

**CBC:** Cannabichromene works well with other cannabis components like cannabinoids and terpenes and holds promise in elevating mood, reducing pain and inflammation, and supporting immune functions and bone growth. On the topical side, one of the most interesting potential applications for CBC is as a treatment

for acne. A recent study found that several cannabinoids, including CBD and CBC, are effective for targeting the bacteria that cause acne and for reducing skin inflammation that causes reddened pimples and painful swelling.

**CBDV:** Cannabidiol is structurally quite similar to cannabidiol (CBD), but has few different properties. Not many studies have been carried out on the effect of CBDV on the body, but researchers are currently studying its effects on various conditions including epilepsy, nausea, pain, inflammation, and mood disorders. CBDV can also boost the development of bones, possessing components that stimulate bone growth.

**IMCJ:** Traceability and safety are two key items regarding product safety. What processes does OBX have in place to ensure products are in compliance and high quality?

**Mr. Neundorfer:** As a GMP-certified processor with international distribution, OBX's quality management system enables and validates the safety, quality and consistency of cannabinoid ingredients, a critical step towards ensuring that all finished formulations and products abide by the governing law across markets with different regulatory requirements. Further, we have traceability protocols that provide our team with an understanding of the origin of every product.

At OBX, robust testing is conducted at every step of the production process. Our quality control manager, David Temelkoff, a seasoned research scientist who spent 15 years at GlaxoSmithKline, designed and implemented a rigorous set of internal testing standards for our work-in-progress and finished products to verify the chemical and physical makeup of each compound and apply a baseline safety analysis test. This quality control program touches all aspects of our ingredient sourcing, production, and finished product formulations. It also serves as the foundation for every international quality assurance and compliance standard that exists in the market.

For every product, OBX provides a 3rd-party, full panel Certificate of Analysis (COA) that includes analysis on potency (HPLC), terpene profiling and ensures no presence of pesticides, heavy metals, residual solvents, and organic toxins. For select products and clients, we will complete supplementary analyses that include mass spectroscopy, thermogravimetric balance, high-performance liquid chromatography, gas chromatography, polymerase chain reaction (PCR), NMR analysis, LC-MS and/or GCMS tests.

**IMCJ:** Do you see health professionals increasingly suggesting CBD and hemp products to their patients, especially to those with a debilitating condition?

**Mr. Neundorfer:** We have established a Medical Advisory Board, which is led by Dr. Martha Hackett, Director of

Integrative Medicine for Lake Health, and Lead Practitioner of Hackett Medical, a family medicine practice. She has provided us with great feedback and stories behind the efficacy of CBD and hemp products in helping her patients with an assortment of ailments, from chronic joint or back pain to sleep support. We have seen increasing numbers of health professionals become advocates for these natural therapies because their patient's success with hemp and CBD products and look forward to providing the research needed to accelerate adoption by health professionals.

**IMCJ:** People often ask if they can overdose on CBD. Please set the record straight.

**Mr. Neundorfer:** No, you cannot overdose on CBD. This is a general consensus from professionals and researchers which is supported by the World Health Organization, which in a 2018 review shared that 'Across a number of controlled and open label trials CBD of the potential therapeutic effects of CBD it is generally well tolerated, with a good safety profile.'

There have been studies, including the GW Pharmaceuticals' safety testing for Epidiolex, that showed liver toxicity at dosage extremely high concentration levels, many multiples beyond the typical dosage in marketed products. If a consumer were to drink an entire tincture bottle of the highest concentration products on the market, they would still be well below the detected toxicity risk based on GW's studies. So, irresponsible consumption of CBD would likely result in a nap, not an overdose..

**IMCJ:** THC-Free broad-spectrum distillate and various isolates are often areas of confusion to health professionals and the public. Is there a simple way to explain these processes?

**Mr. Neundorfer:** There are two primary ingredient categories that formulators utilize to make CBD finished goods – distillates and isolates.

For distillates, there are two general categories--full and broad-spectrum. Both categories contain high concentrations of CBD (typically >80%) and smaller concentrations of the minor cannabinoids (typically <5%). The difference between them is that full-spectrum distillates include legally compliant amounts of THC whereas the THC is removed from broad-spectrum distillates. Both full- and broad-spectrum can activate the aforementioned entourage effect, which is a more holistic stimulation of our body's endocannabinoid system.

Isolates, such as CBD Isolate or minor cannabinoid isolates (CBN, CBC, CBDV, CBG, THCV, CBT, etc.) are highly pure ingredient inputs (generally >99% purity) that formulators utilize for more precise dosages in their finished products. CBD isolate is used to formulate many

of the current finished goods in the market. As we continue to understand the therapeutic potential of each of these cannabinoids, having isolated minor cannabinoids will be instrumental to develop products that have specific and precise dosing that helps formulators curate products that address specific ailments and need states. This is one of the most exciting things to look out for in the cannabinoid product category.

**IMCJ:** It has been said there is a surplus of hemp in the market. What does 2021 and beyond hold?

**Mr. Neundorfer:** The passing of the 2018 Farm Bill led to a 2019 growing season that caused a major supply-demand imbalance. Experts estimate that there was four times more hemp grown than the market could digest. This supply glut continued into 2020 and still exists today. Unfortunately, the demand side of the market has been tempered by the lack of FDA regulatory clarity on CBD products in categories like food and beverage.

That said, we are pleased by the positive momentum behind HB 8179 that would permit CBD to be regulated as a dietary supplement, a change that could happen within the next twelve months. At OBX, we are seeing distributors, retailers, CPGs, and nutraceutical companies accelerate their R&D and product development in preparation for the regulatory clarity that will trigger a dramatic market expansion and, finally, supply-demand equilibrium.

While the FDA has taken a conservative approach in regulating CBD and hemp derived cannabinoids, we support their efforts and think the clarity on understanding the impact these products have on human health will optimize health outcomes over the long term. OBX is playing an active role in the research requested by the FDA before establishing dietary supplement, food, and beverage additive policy.

**IMCJ:** What trends, if any, are taking place in the CBD/hemp marketplace?

**Mr. Neundorfer:** One of the trends we are most excited about in the category is the use of minor cannabinoids to create targeted therapeutic effects and solve for specific consumer needs.

We often use ice cream sundaes as an analog. The market has been focused on vanilla (CBD) and chocolate (THC) ice cream for decades, and now OBX is bringing the toppings (minor cannabinoids) like fudge, nuts, cream, sprinkles, and the cherry on top, to create a more desirable product that can be customized to consumer preferences.

Minor cannabinoids are changing the paradigm of plant-based health and wellness, as they, in concert with CBD, optimize user experience with tangible, perceptible benefits. This is a cross-category trend with the potential to disrupt stress, sleep, immunity, beauty, skincare, and pet markets, as it aligns with the organic, natural, and clean label macro trends impacting every consumer category.

**IMCJ:** Should consumers purchase CBD products from their doctor, if they are sold there, through a reputable retail location, or online?

**Mr. Neundorfer:** That is a great place to start, as you can work with your doctor to understand the best dosage protocol for you. But today's hemp derived cannabinoids and CBD supply chain has improved dramatically over the years, driven by a more educated consumer base demanding consistency, safety, and efficacy. There are many reputable brands both online and in different retail distribution channels. A great way to check if you are buying a quality product is to see that the product has been tested by a third-party certified lab with a Certificate of Analysis (COA). Many products now have QR Codes on the package that you can verify the product has no pesticides, heavy metals, residual solvents, and organic toxins.

*Sheldon Baker is CEO of the Baker Dillon Group LLC. He has created numerous highly visible nutraceutical brand marketing communications campaigns for well-known supplement and food industry companies. For more information contact him at [sbaker@bakerdillon.com](mailto:sbaker@bakerdillon.com).*