

## On the cover

# New Certification Program for Hemp Oil Benefits Manufacturers, Healthcare Practitioners, and Consumers, Part 1

by Chris D. Meletis, ND

Cannabinoid-rich hemp oil has emerged as a promising botanical therapeutic with both clinical experience and published studies to support its use. The Stanley brothers are largely credited for first awakening the public to its benefits. The six Colorado siblings developed a hemp extract low in  $\Delta^9$ -Tetrahydrocannabinol (THC), the psychoactive component in marijuana, and high in cannabidiol (CBD), a phytocannabinoid that is not associated with the intoxicating effects of the plant. That hemp extract came to be known as Charlotte's Web after the parents of a little girl named Charlotte Figi convinced the brothers to provide their daughter with CBD-rich hemp oil.<sup>1</sup> Charlotte suffered from a severe type of medication-resistant epilepsy known as Dravet syndrome. She was having 300 seizures per week and her heart frequently stopped. After consuming three to four milligrams of the hemp oil per pound of body weight, Charlotte's seizures disappeared. The case received a lot of publicity in major media outlets such as CNN.<sup>1</sup>

Since then the demand for hemp as a medicinal has skyrocketed and so too has the number of companies producing it and doctors prescribing it. Its benefits have been demonstrated both clinically and in the scientific literature. Based on that scientific research and clinical observations, I employ hemp oil in clinical practice to support the health of patients with epilepsy, anxiety, depression, post-traumatic stress disorder, schizophrenia, inflammation, and pain among other applications. Upcoming articles in *Townsend Letter* will discuss its clinical applications and the evidence in the medical literature. In this article, I will discuss a new cannabinoid certification program for both manufacturers and healthcare practitioners.

### Why Manufacturers and Practitioners Need a Certification Program

When new segments of most fields of commercial enterprise enter the marketplace, there are the initial well-intentioned pioneers. This is also true in the hemp oil marketplace. However, like the dietary supplement industry in its early years, the hemp oil marketplace is a Wild Wild West. Up until now, no entity was ensuring the consumer that optimal quantities of the beneficial cannabinoids found in hemp oil were actually contained in the purchased product. As a manufacturer, in order to maintain a respectable reputation and avoid legal complications, it's important to ensure that the hemp oil you're producing lives up to its label specifications. A 2017 article in *JAMA* tested 84 CBD/hemp oil extracts purchased online and found that although CBD oil labeling had the highest degree of accuracy compared to other products tested, 55% of the CBD oil products tested were either underlabeled (more CBD was detected in the product than claimed on the label) or overlabeled (CBD content that was negligible or less than 1% of the amount on the label).<sup>2</sup> In this study, the overlabeled CBD products contained insufficient levels similar to concentrations that resulted in Food and Drug Administration (FDA) warning letters sent to 14 businesses in 2015-2016. Some of the products also contained more THC than noted on the label. In the United States, only cannabinoid-rich hemp oil brands that contain less than 0.3% of the psychoactive cannabinoid THC are legal. Therefore, certainty surrounding the THC content of a particular brand is essential.

The International Center for Cannabis Therapy (ICCT) found similar inaccuracies when its scientists tested hemp oil products sold mainly in online shops in Europe. Not one

of the products tested was legally compliant as European legislation requires zero THC in hemp oil. Furthermore, the vast majority of products contained very little CBD and/or high concentrations of heavy metals and pesticides.

Another challenge that has arisen with the availability of hemp oil is that up until now, healthcare practitioners could not tap into a centralized knowledge base where they could have their cannabis questions answered. Because of hemp oil's relative newness in the dietary supplement arena, there are many healthcare practitioners who are unclear of the proper dosage. Some of them have employed hemp products in their practice with little success not realizing that the product may have contained insufficient CBD. I have also encountered uncertainty among practitioners about the best way to incorporate hemp oil into already-prescribed supplement regimens, whether there are any contraindications to its use, and how its effects differ from marijuana. In interacting with attendees of lectures I have conducted on the endocannabinoid system, it became clear to me that a number of healthcare practitioners have many questions and concerns about the prescribing of hemp oil as well as the endocannabinoid system on which it acts.

"It is essential that health professionals know what the cannabinoid content of a product is because depending on the illness being treated, too much or too little CBD can affect the outcome," said Petr Kastanek, PhD the director of the ICCT. "A Dravet syndrome patient for example will get strong relief from seizures using CBD, but too much CBD can actually trigger a seizure."

This echoes my clinical experience that as functional medicine providers we must always remember that all receptors throughout the body have an optimal tolerance – not only receptors for CBD – and there is such a thing as too much. This is particularly the case when there is an endogenous pathway which is being augmented, such as the endocannabinoid system. After all, achieving and sustaining homeostasis is the goal.

The ICCT's certification program will instruct practitioners (based on proven protocols) on the ideal amount of hemp oil. "Due to its non-toxic nature, a healthy patient won't suffer side effects, but flooding the CB1 and CB2 receptors with cannabinoids is not necessary or advised," said Petr Kastanek. "Micro dosing cannabinoids to activate the receptors creates a potent medical benefit in ICCT's experience."

Clearly, standards are needed both for all cannabis products *and* for practitioners prescribing them.

### **The International Center for Cannabis Therapy (ICCT)**

The ICCT recognized the need for standards in the cannabis industry and consequently introduced three new certification programs: product certification, manufacturing facility certification, and medical certification for practitioners prescribing CBD and other active constituents of hemp. The ICCT is a Czech-based partnership of qualified doctors and scientists who specialize in the medical application of all forms of cannabis. ICCT scientists have spent decades conducting extensive research on the health benefits of medical cannabis as well as product development

and medical treatment with an emphasis on enhancing the patients' quality of life.

The organization's certification programs are based on a decade of research conducted by more than 70 ICCT scientists from the Czech Republic and Israel. I recently became aware of the impressive ICCT's mission, clinical work, and the high-caliber of people associated with it. In addition to maintaining my naturopathic practice in Oregon, I accepted the role of Chief Medical Officer-USA of the ICCT.

### **ICCT Certification for Hemp Oil Manufacturers**

The ICCT certification will standardize CBD-rich products and raw materials for human consumption. It uses metabolomic fingerprinting technology to construct a metabolic profile of the cannabinoid product through the pairing of data-rich analytic techniques with multivariate data analysis. The product will be analyzed for cannabinoid profile, pesticides, and contaminants. Manufacturers also have the option to obtain certification for their manufacturing facility similar to cGMP or NSF certification. The ICCT certification ensures that the manufacturer is compliant with local and state regulations. It also tests the quality and consistency of raw materials and provides staff training, product formulation, and compliant labeling. Annual randomized facility inspection is also a component of the manufacturing facility certification.

American Nutritional Products was the first hemp oil manufacturer to become certified by ICCT. "It is because of my 28 years in the supplement industry that I first realized what challenges were going to lie ahead for cannabis and hemp," said Maria Watson, president and CEO of American Nutritional Products, Inc. and former co-owner of Vitamin Research Products (VRP). "The supplement world started out with no known certification body and little control on quality. When we owned VRP, as an industry leader, we drove the movement to clean up our industry – that now needs to happen in the cannabis space."

### **The ICCT Medical Certification**

Medical certification from ICCT for healthcare practitioners involves eight online webinar modules, plus one bonus lecture on marketing your certification to the community and to prospective patients. Conducted by myself and other experts, the webinar modules are based on ICCT research by a team of 70 scientists, the evidence-based peer-review literature, my experience in clinical practice, and proven protocols based on clinical studies. Practitioners enrolled in the certification course will also learn vital information that ensures patients do not overdose on CBD. Additionally, the modules will address other topics crucial to the proper prescribing of hemp oil as described below.

*The Entourage Effect of Hemp Oil.* The entourage effect is a concept originally proposed by Doctors Mechoulam and Ben-Shabat two decades ago. It originally referred to the ability of certain endocannabinoid system components to enhance the beneficial effects of the two most important actors in this system: anandamide and 2-arachidonylglycerol.<sup>3,4</sup> Since



## Hemp Oil Certification

then, the definition of the entourage effect evolved. It now can refer to the fact that components of cannabis or hemp oil other than THC and CBD – such as phytocannabinoids and terpenes – can actually act synergistically to THC, CBD, or each other. The ICCT certification online course will explain why the entourage effect is important in clinical practice.

*CBD Receptors and Pain Perception.* Hemp oil may be the answer to today's opioid and pain crisis. Opioid overdose is associated with more than 115 deaths per day in the United States.<sup>5</sup> Finding an alternative to their use is therefore critical.

The endocannabinoid system is closely associated with pain management. The receptors in this system including CB<sub>1</sub> and CB<sub>2</sub> are activated by endogenous endocannabinoids. However, CBD as a phytocannabinoid and other phytocannabinoids in hemp oil also affect receptors in this system as does THC, the psychoactive component of cannabis.<sup>6,7</sup>

The certification course will include an in-depth discussion of endocannabinoid receptors and their role in pain management.

*Hemp Oil and Neurodegenerative Conditions and Mood Disorders.* An abundance of evidence indicates hemp oil impacts the pathophysiology, progression, cause, and ecology of neurodegenerative conditions, mood disorders, and epilepsy. The certification program will help the busy healthcare provider digest this research and discover how it can be applied in clinical practice.

*The Gut-Brain Axis and Cannabinoids.* An increasing amount of evidence points to an interplay between intestinal and neurological systems and that this connection is modulated by the gut microbiota, the population of microorganisms found in the intestinal tract. This link between neurological and intestinal systems has become known as the gut-brain axis. Intriguing evidence has emerged that the endocannabinoid system is involved in this interaction.<sup>8,9</sup> The certification program will delve deeply into the role of the endocannabinoid system in the gut-brain axis and how this knowledge can be used to reduce inflammation and support the health of patients with anxiety and depression.

*Legal Considerations of Prescribing Hemp Oil.* Based on the expertise of a leading attorney in this field of practice,

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practitioners who receive their cannabinoid certification will move forward with confidence and reassurance on the clinical application of hemp thanks to information presented in a comfortable and simple manner. A number of questions about the legality of hemp oil often arise. These include: 1) What is the difference between federal and state law and the issues of intrastate commerce? 2) Is it true that hemp oil is legal in all 50 states? 3) Is it likely for a person who tests positive to THC, that it could be from hemp oil use alone? 4) Do I need to have special charting or record keeping if I sell hemp oil to patients? 5) If a product that I sell as hemp contains THC beyond the "Legal Limit" to be considered hemp, what is my risk? Hoban Law Group, the leading cannabis business law firm which has presented on behalf of the industry in front of the 9th circuit court, will answer these questions and discuss legal considerations of implementation of hemp oil therapy in practice.

"If you are carrying a hemp product or selling a product with more than 0.3 percent THC then you are dispensing marijuana," said Jason Searns counsel to Hoban Law Group. "It is legally essential to know without question what you are dispensing. With the legal system and U.S. government delineating the role of hemp oil, it is important for clinicians to adhere to a high standard of education as offered by organizations such as the international research and educational organization ICCT."

*The Endocannabinoid System and Immunity, Cancer, Senescence, and Healthy Aging.* The endocannabinoid system has been found to play an important role in diverse aspects of health. Hemp oil, through its modulation of this system, is a likely option for many health challenges faced by our patients. For example, endocannabinoids are synthesized by most immune cells and upregulate or downregulate a number of immune functions.<sup>10</sup> The CB<sub>2</sub> receptor is also involved in reducing oxidative stress associated with cellular senescence, indicating the endocannabinoid system is involved in healthy aging.<sup>11</sup> The certification program will help practitioners understand the myriad ways in which the endocannabinoid system is involved in health and how modulating that system through hemp oil can achieve beneficial results.

*Essential Facts Practitioners Must Know About Employing Hemp Oil in Clinical Practice.* The different delivery mechanisms of cannabis can influence how it affects the body. The certification program will allow healthcare providers to become proficient in understanding these delivery systems. For example, there is a next generation of CBD products moving into the American market. These products have efficient, transdermal properties so they bring the active substances deep into the tissue. It is also important when using hemp oil not to unduly disturb the endocannabinoid system and overwhelm natural production of the endocannabinoids or alter receptor activity. The certification program will help practitioners understand how to achieve the benefits of hemp oil without causing this undesirable effect. Processing and extraction processes commonly used and pharmacokinetics, pharmacodynamics will also be discussed.

**Anti-Inflammatory Properties.** CBD and other phytocannabinoids and constituents of hemp oil modulate inflammatory pathways. CBD reduces the inflammatory mediators interleukin-6 (IL-6) and TNF- $\alpha$  in rodent models.<sup>12-14</sup> The certification program will discuss in detail hemp oil's role in influencing inflammatory pathways in various disease states.

**Other Benefits of Certification.** ICCT's certification includes a marketing module conducted by Marketing Unlimited, a firm with 28 years' experience in the natural products industry. This lecture will provide recommendations for marketing the ICCT certification to patients and prospective patients in order to help build clinicians' practice.

### Raising the Bar on Hemp Oil Manufacturing and Prescribing

ICCT's ultimate mission in offering its certification programs is to bring European regulatory standards into the US cannabis market. The only type of products carrying ICCT certification will be those that incorporate the efficient use of cannabinoids in well-constructed products to maximize the medical benefit for patients. The ICCT anticipates that consumers will actually seek out doctors who have obtained its certification in cannabinoid therapy and products that have obtained ICCT's blessing as an assurance of quality and safety.

For more information about the ICCT certification programs, visit [www.icctcertification.com](http://www.icctcertification.com) and join the ICCT mission of education and empowerment.

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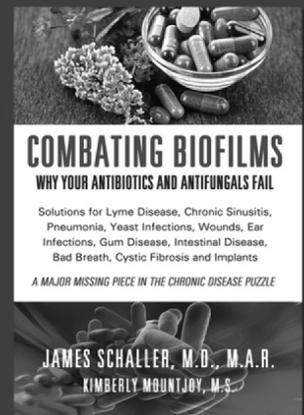
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