

CLEARING

The declassification of industrial hemp as a Schedule I drug hasn't lessened legal complications but has created a surge in cannabidiol products and associated health claims.

By Esther L. Ellis, MS, RD, LDN

Since the signing of the Agriculture Improvement Act of 2018 — commonly known as the 2018 Farm Bill — cannabidiol, or CBD, has flooded the marketplace. CBD seemingly is everywhere and in everything, from health and beauty products including bath salts, mascara, lotions and lipsticks to food and beverage items such as sparkling water, ice cream, restaurant menu items and candy. CBD has become so popular that Nielsen predicts the U.S. hemp-derived CBD market could become a \$6 billion industry by 2025.

How It Started

Although a new farm bill is enacted approximately every five years, the 2018 Farm Bill was unlike its predecessors because it legalized the cultivation

of industrial hemp with a license or permit and declassified it as a Drug Enforcement Administration, or DEA, Schedule I controlled substance. This declassification transferred supervision of hemp from the DEA to the U.S. Department of Agriculture's Agricultural Marketing Service. Additionally, the bill expanded the possibilities for, and placed an increased emphasis on, industrial hemp research apart from standard market evaluations, which are done for business research purposes.

Defining the Substance

Hemp, marijuana, CBD and delta-9-tetrahydrocannabinol, or THC, all have had their share of the spotlight. While there is some relation between them, there are key differences.



THE *air*

In legislation, hemp is defined as the cannabis plant — the same cannabis plant that produces marijuana. However, it does not, and legally cannot, contain more than 0.3 percent THC. Before the 2018 Farm Bill, federal law did not differentiate hemp from other cannabis plants such as marijuana.

THC is the key psychoactive compound in marijuana that produces the sensation commonly referred to as being “high.” Marijuana plants contain higher concentrations of THC. CBD is found in both hemp and marijuana. But unlike THC, CBD is not a psychoactive compound and therefore does not provide the same “high” sensation as THC. Both CBD and THC have the same molecular structure, but one small difference in the arrangement of molecules is responsible for the big difference in their psychoactive or nonpsychoactive effects.

The human body produces its own cannabinoids, known as endocannabinoids, the endocannabinoid system (ECS) or endogenous cannabinoids. When THC is consumed, it interacts with endogenous cannabinoids to create the “high” sensations and effects. Researchers

still are unsure of how CBD interacts with the ECS.

CBD Research

Early evidence suggests there may be benefits from CBD. In 2018, the U.S. Food and Drug Administration approved the first CBD drug, Epidiolex, to treat seizures associated with Lennox-Gastaut syndrome and Dravet syndrome in patients age 2 and older. Children with these serious forms of epilepsy typically do not respond to traditional therapies and anti-seizure medications, but clinical trials showed Epidiolex, along with other medications, was effective in reducing the frequency of seizures compared to placebo.

Among the general public, pain reduction is perhaps a more widely associated and touted benefit of CBD. While CBD is frequently promoted as being able to reduce chronic pain, medical research exploring and confirming the mechanisms is limited to mostly animal models, meaning more human research is needed. Other possible yet unsubstantiated benefits include a reduction in anxiety, treating inflammation and promoting sleep. Current claims on the benefits of CBD mostly are anecdotal, and more research is needed to confirm and understand these statements.

The benefits of CBD may be promising, but there are potential side effects: Some human pre-clinical and clinical trials on CBD for epilepsy and psychiatric disorders reported adverse effects such as CBD-induced drug interactions, liver problems, diarrhea, fatigue, vomiting, mood changes and extreme sleepiness.

Legal Confusion

The 2018 Farm Bill may have declassified industrial hemp as an illegal substance, but it also ushered in a lot of confusion. Is CBD legal? In short, it depends.

In a statement released by the FDA immediately following the signing of the bill, then commissioner Scott Gottlieb, MD, emphasized that despite the declassification, the FDA maintains its authority to regulate products that contain cannabis or

cannabis-derived compounds under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and section 351 of the Public Health Service Act. These regulations create complications for food and beverage manufacturers that wish to incorporate CBD into their products.

Under the FD&C Act, it is unlawful to use any active ingredients that are already in FDA-approved drugs, or any ingredients that were studied in substantial clinical investigations, in foods or dietary supplements. This means both food and dietary supplements containing added CBD or THC is unlawful, regardless of whether the substance is hemp-derived or not.

The FDA can issue a regulation to allow the use of CBD and THC in a food or dietary supplement. And while it held a public

CBD IS FOUND IN BOTH HEMP AND MARIJUANA. BUT UNLIKE THC, CBD IS NOT A PSYCHOACTIVE COMPOUND AND THEREFORE DOES NOT PROVIDE THE SAME “HIGH” SENSATION AS THC.

hearing in May 2019, allowing stakeholders to share feedback and scientific data related to CBD, the FDA has not issued any new regulations and says it will continue to uphold current guidelines until it can obtain enough research, data and public health input to warrant a change.

Numerous warning letters have been sent by the FDA and the Federal Trade Commission to companies selling CBD products such as food items and dietary supplements and products meant for therapeutic use, mainly those claiming to cure diseases such as Alzheimer's, Parkinson's or cancer. It should be noted that there are three hemp-derived substances that have been approved by the FDA as Generally Recognized as Safe (GRAS) and are therefore lawful: hulled hemp seeds, hemp seed protein powder and hemp seed oil.

THE ACADEMY SUPPORTS
A "SCIENCE-BASED, PUBLIC
HEALTH-DRIVEN APPROACH TO
THE REGULATION OF PRODUCTS
CONTAINING CANNABIS OR
CANNABIS-DERIVED COMPOUNDS,
INCLUDING THC AND CBD."

The rules and regulations get even hazier considering various state laws; some states still consider CBD illegal despite the 2018 Farm Bill. There are some states where all marijuana and cannabis (medical or recreational) are illegal.

Laws fluctuate between all states, and CBD oil may be legal recreationally or medically depending on the location. Some states have been more adamant about enforcing these laws including

Texas, Ohio and Iowa, whose law enforcement has raided stores selling CBD products.

Implications for RDNs

Since CBD is gaining popularity, clients and patients likely will have questions about the compound. Because laws vary by state, registered dietitian nutritionists should stay abreast of their individual state laws as well as any progress in federal legislation. Keeping clients and patients aware of the legality of CBD in food and dietary supplements may be as important as educating them on the potential risks and benefits.

Many products containing CBD are being introduced without regard for the legal requirements that apply to dietary supplements, foods, drugs and cosmetics. The FDA sends warning letters after a product has been produced and sold — usually because it is either promoted as a cure for disease or due to an adverse reaction. This means some CBD products may have gone through little, insufficient or no testing before sale. Some products could contain more or less CBD or THC than advertised, which could have safety implications of a drug interaction, impairment or an occupational problem for those who are drug tested. Additionally, products could contain other harmful ingredients unknown to the buyer.

The Academy of Nutrition and Dietetics recommends consumers use caution when purchasing CBD products and food items and has taken a neutral stance regarding the use of CBD in food and beverage products. The Academy supports a "science-based, public health-driven approach to the regulation of products containing cannabis or cannabis-derived compounds, including THC and CBD."

RDNs should monitor developing research, laws and regulations concerning CBD to best counsel and educate clients and patients.

Esther is an associate editor
of *Food & Nutrition*.

