Selling CBD in food is illegal, FDA says. So why are so many retailers selling it?

by Sam Wood, Updated: March 26, 2019- 11:42 AM



MICHAEL BRYANT / STAFF PHOTOGRAPHER

Step away from those gummy bears. Surrender the smoothie. Put down that ice cream and that hot sauce.

Under federal law, if those products contain CBD, they're illegal.

CBD, or cannabidiol, is derived from cannabis. It is a nonintoxicating compound reputed to have several health benefits. And this year, CBD's popularity has exploded.

It's added to skin creams, oils, and dietary supplements. Soon, those products will be for sale at CVS, the largest drug store chain in the United States. Anecdotal accounts have claimed CBD to be somewhat effective as an anti-psychotic, a calming agent, and a pain reliever.

CBD from hemp is also being added to foods. It's in the kombucha called Cannabliss at Weavers Way co-ops. It's in the muffins, coffee, and lollipops at the Hip Hemp Cafe in South Philadelphia. It turbocharges drinks at the Fuel lunch counter in Center City. Rocky's Hot Sauce, produced in Oreland, purports to pack 100 milligrams into tiny bottles of fiery elixer. Restaurants structure menus around it as an ingredient.

Though Pennsylvania and New Jersey regulators are turning a blind eye, it may become a source of serious agita for vendors who lace their edibles and drinks with it.

The U.S. Food and Drug Administration prohibits the addition of CBD to prepared foods. That's despite language in the 2018 Farm Bill that loosened restrictions on the interstate commerce of hemp — cannabis that contains less than 0.3 percent of THC — and its derivatives such as CBD. Even advocates and researchers advise caution before consuming it.

If you're confused, join the club.



RICHARD VOGEL / AP

FILE- In this Aug. 31, 2018, file photo CBD buds of chocolate by Chronic Candy are displayed at the Big Industry Show at the Los Angeles Convention Center. From skin-care lotions to bottled water, cannabis companies are rolling out a growing array of consumer products infused with a chemical found in marijuana called cannabidiol, or CBD. (AP Photo/Richard Vogel, File)

The federal stance has triggered crackdowns by a number of states and municipalities. The New York City Health Department sent letters last month warning that after Oct. 1, violators will face fines, "embargoes," and a slashing of their all-important health letter grades. Los Angeles will soon start penalizing companies that have "adulterated" foods with CBD (though a law pending in the California legislature could permit sales statewide). States banning CBD in food include Ohio, Maine, North Carolina, and South Carolina.

The Departments of Agriculture in Pennsylvania and New Jersey see wiggle room in the law and are taking a laissez-faire approach, declining to take action until the FDA gives more guidance. (The Pennsylvania Department of Health, which oversees the state medical marijuana program, tightly regulates CBD from marijuana that is sold in dispensaries.)

But major retailers such as Whole Foods are exercising caution. "Whole Foods Market will not sell products containing CBD (cannabidiol) until all issues regarding the regulatory status are completely resolved to our satisfaction," a spokesperson said.

So how did this happen?

Until last year, there was a federal ban on CBD, not that the FDA enforced it. Beyond firing off a few letters ordering manufacturers to stop making unproved health claims, the FDA made no efforts to stop commerce. After all, CBD has never killed anyone.

Because CBD is extracted from cannabis, it long has been considered a Schedule 1 substance, along with all other forms of the marijuana plant and its derivatives. But because CBD doesn't get anyone

high, it existed in a gray area. CBD oils and tinctures quietly were sold at health food stores and head shops.

Last summer, the FDA approved a highly purified form of CBD as a treatment for some rare forms of childhood epilepsy. The CBD drug, Epidiolex by GW Pharmaceuticals, may cost uninsured patients up to \$32,500 a year. The FDA's ruling initially was cheered by activists and advocates who assumed that all forms of CBD would now be legal. Not so.

"Once CBD was approved as a drug, it became prohibited to be included in a food or a nutraceutical supplement," said Joe Reardon, assistant commissioner for consumer safety for the North Carolina Department of Agriculture. "You can't add a drug to a food."

Before FDA Commissioner Scott Gottlieb abruptly resigned this month, he told Congress the agency would hold listening sessions to discuss hemp and its derivatives. A public meeting is scheduled in April to explore how CBD could be sold legally in food beverages and supplements. The FDA can listen. But it is bound by law.

The drug exclusion rule prevents any active substance in a pharmaceutical from being added to a food, pointed out Erika Lietzan, an associate professor at the University of Missouri School of Law. "It's not even ambiguous under the federal Food Drug and Cosmetic Act," said Lietzan, who has written extensively about the legality of CBD. "It's not controversial and not something that can be debated. The law isn't gray at all."

The FDA, however, could just ignore CBD. "I think that's what they've been doing," she said. "You look around and there's CBD everywhere." The agency can also choose to selectively enforce the statute. "There are plenty of examples of them doing that. For instance, you can bring a month supply of an unapproved drug into the country for personal use," she said. "But [selling food with CBD] is risky. The FDA could decide to make an example out of someone."



RICHARD SHOTWELL / RICHARD SHOTWELL/INVISION/AP

FILE - In this May 7, 2017 file photo, Snoop Dogg, left, and Martha Stewart pose in the press room at the MTV Movie and TV Awards in Los Angeles. The domestic diva who brought us hemp yarn is now partnering with Canada's Canopy Growth Corp. to develop new products containing CBD, a compound derived from hemp and marijuana that doesn't cause a high. Stewart's tie-up with Canopy may not be a surprise to her fans. In 2015, she baked brownies on "The Martha Stewart Show" with marijuana aficionado Snoop Dogg, and hinted that Snoop could add a little weed if he wanted to. (Photo by Richard Shotwell/Invision/AP, File)

Given the FDA's priorities, enforcement of the statute is likely to remain sporadic. And for most merchants, the rewards for selling the products outweigh the risk.

That's because there's something magical that happens when a few drops of CBD are added to food. The price of a fruit smoothie increases by \$2.95. The cost of a can of CBD-infused sparkling water can soar to \$3.99, \$8.99, or more. A CBD lollipop can run you \$5.

The wholesale price of a few milligrams of bulk CBD isolate is rarely more than a few pennies. "CBD is creating a lot of head-scratching," said attorney William Roark, who co-chairs the Pennsylvania Bar Association's Committee on Cannabis and Hemp. "But it's also creating a huge industry."

Analysts at Cowen Investment Management "conservatively" expect CBD products to reach \$16 billion in sales in the U.S. by 2025. Cowen estimated the CBD market launched in 2014 with a few million in sales. Four years later, in 2018, CBD generated revenues of between \$600 million and \$2 billion. Some analysts believe the CBD industry could overtake a legal recreational marijuana market.

Consumers should think twice before taking the substance, whether in food or as a nutritional supplement, researchers and advocates said.

"We don't yet know if it's safe to add cannabinoids to food and at what amounts," said Marcel Bonn-Miller, a scientist who investigates cannabinoids at the University of Pennsylvania. "We need proper studies to determine what amounts of each cannabinoid, or cannabinoid combination, is safe in foods. The good thing is that there are guidelines from the FDA and companies are working to figure out the answers."

Without regulation, consumers have no idea if what they're paying for is pure, potent, or free of toxic substances, or if it even contains the compound.

"It's a pity that the regulatory agencies aren't doing their job," said Martin A. Lee, the author of *Smoke Signals, a Social History of Marijuana* — *Medical, Recreational and Scientific* and the director of the California-based Project CBD, a nonprofit advocacy group promoting research into the substance.



FUEL CBD smoothies from Fuel.

"The idea of putting CBD in coffee or water or cupcakes is more a marketing gimmick. It's not an effective form of therapy," Lee said. "People are reaching for it because it's a fad."

Lee warns that CBD can interact with prescription drugs, at turns either magnifying or diminishing their effects. People with compromised immune systems, he said, should not use CBD without being assured that the product isn't tainted. "CBD is intrinsically safe," Lee said. "If you're using

THC or CBD for cancer, you may be able to reduce the dose of chemo. But if you don't adjust the level of chemo, it could build up to toxic levels."

CBD may also reduce blood pressure and, because it's an astringent, cause some users to become dehydrated. "These are serious issues," Lee said. "We're not hearing about this stuff."

Some marijuana advocates dismiss the marketing of all CBD products as bogus. "It's a way to make money out of nothing," said Chris Goldstein, a New Jersey-based organizer for NORML, the National Organization for Reform of Marijuana Laws. "It's like a Pet Rock. CBD should stand for 'Caucasian Bulls— Drops.'"

Vendors said that if the FDA or local regulatory agencies decide to clamp down, they'll comply. "We're not worried," said Helen Webster, director of Wellness at Weavers Way. "If Pennsylvania decides to do that, we'd have to strategize. The food aspect might change, but as far as CBD supplements, I still think we could sell those."

CBD fruit smoothies are a popular item at the Fuel Recharge Yourself Restaurant in Center City, said the chain's CEO, Rocco Cima.

"We haven't heard anything negative," Cima said. "But at the end of the day, if the FDA comes down, we'll abide by the rules."



Posted: March 26, 2019 - 11:42 AM
Sam Wood | @samwoodiii | samwood@phillynews.com

Reproduced with the expressed, written consent of Sam Wood.

 $\frac{https://www.philly.com/business/weed/cbd-legal-cannabis-weavers-way-fda-lietzan-health-food-fuel-kombucha-ice-cream-20190326.html$