

What the Hemp? Regarding the FDA and CBD

WRITTEN BY REALM OF CARING ([HTTPS://WWW.THEROC.US/WHATTHEHEMP/ITEMLIST/USER/408-](https://www.theroc.us/whatthehemp/itemlist/user/408-)

REALMOFCARING)



JORDAN STANLEY WATERS CW HEMP PLANTS / JOE AMON, THE DENVER POST

Perhaps you've read an online article saying the FDA has outlawed CBD⁵. I am not here to ease your responsibility to act. By the end of this post you will see how you can help alleviate the confusion. However, I think if you are using a hemp based CBD product like we are, you can be assured you have many safety nets in place for your protection.

1. This is old news. The FDA has sent out warning letters for over a year now. Good! Some of the companies whose products earned them a FDA warning letter were knowingly mislabeled, some products were making unapproved claims, and some were doing both. This is why the FDA exists. Snake oil salesmen need not apply. The week after the first CNN special "WEED with Sanjay Gupta," there were an abundance of CBD products on Amazon. The manufacturers of these products couldn't even pronounce the word cannabidiol prior to WEED.

2. If you are accessing hemp-derived high-CBD products from companies that are connected to their state agricultural department, or an institution of higher learning, you are protected by the Agricultural Act of 2014¹. (All of the products that Realm supports comply. I have inspected all of those grows, as well as their labs, to ensure proper adherence to quality control. I use a 14 page quality checklist that I borrowed from a pharmaceutical company.) You can also engage in research through Realm’s observational research registries with Johns Hopkins University.

BUT BEWARE—there are companies that have not filed an application to grow hemp under their state regulations. In fact they are not even growing cannabis legally at all. You need to take responsibility for yourself in this area. I will also mention the Agricultural Act of 2014 changed the definition of hemp². It was widely accepted that hemp was defined as stalk and seed but not the flower. This is no longer the case; flower is now considered an acceptable source for extraction. And thank God since the flower is where the majority of the CBD milligrams are held.

3. The Omnibus Appropriations Act of 2016³, signed 12/18/2015 by President Obama further clarified section 7606 of the Agricultural Act. It favorably addressed processing, sale, and transportation of hemp products produced by agricultural departments and institutions of higher learning. (For all of those concerned about interstate commerce.) This means that all of the federally compliant hemp products that Realm supports are allowed to be sold and transported across state lines. Hemp products that are imported from outside of the United States are “GRAS” (Generally Recognized As Safe). They are no more illegal than the hemp milk in your grocery store. Your health food store is full of these imported products. There are many high quality, even organic hemp based products. However, they contain little to no CBD in them (hemp seeds, hemp oil, hemp milk). These products may be great for overall nutrition, but you will not find symptom relief for you or your loved ones from them. Some of the hemp based CBD products that RoC supports are now being carried in local health food stores as well.

4. The DEA released an official position in October 2001, which stated any hemp product made for human consumption containing any level of THC is a controlled substance. Fortunately, DEA official positions are subject to US statute (actual laws). This position was ultimately found inconsistent with the Controlled Substances Act (CSA) and, therefore, deemed unenforceable by a federal court in 2004 (HIA v. DEA⁴).

5. Contrary to some popular opinions, CBD is not a controlled substance. You will not find CBD on the controlled substances list or anywhere in US statute. It is generally believed to be a controlled substance, but it is not; I have looked. In 2011, the DEA attempted to add a new controlled substance code, which would have included the term cannabidiol to the CSA. This recommended addition has not received all necessary approvals to be added to the CSA. As affirmed in 2004 by HIA v DEA, such additions to the CSA require proof that a substance is harmful and of no medical value. As we all know, no one will be able to prove this.

6. Some states that passed high CBD legislation included decriminalization. This is another layer of protection.

7. Although many have interpreted recent FDA statements to block CBD as a dietary supplement, this is not the case exactly. The FDA allows for the possibility that CBD was marketed as a supplement prior to CBD having “been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public”. CBD in a botanical extract was being used long before GW Pharmaceuticals received their IND (Investigational New Drug status) and substantial clinical investigations were instituted or made public . It was on the market before they popped on

the scene. My son was seizure free using Charlotte's Web almost a year before GW even received their IND. Therefore, the assumptions that CBD may only exist as a drug are fallacious according to the hemp industry.

8. CBD based hemp and cannabis products also existed long before the Dietary Supplement Health and Education Act (DSHEA) became law in 1994. In fact, CBD exists in unknown and un-regulated quantities in all hemp foods that have existed in our grocery stores for decades.
9. This article linked above mentions Vitamin C. This is a good example. Big Pharma tried to shut that out of the dietary supplement marketplace. They lost. Just because a compound provides a medical benefit, does not make it a drug only. In fact, the only factor that makes any product a drug according to the FDA is how that product is marketed. For example, if a company claims that their bottled water can cure or treat a specific disease, then that bottled water must go through the FDA drug approval processes.
10. I also think there is plenty of space for both pharmaceuticals and natural supplements to exist. For instance, I am vitamin D deficient. I can pay over the counter for a supplement, or I can get it by prescription. We are on a highway, and as long as the pharmaceutical industry stays in their lane and is not permitted to take the whole road, I think we will be fine. There will be some that will want to access it through the prescription model. Not I. I believe it is a broken, isolated, and expensive model. But I know some will prefer it, and that is OK.

I want to say "in conclusion," but this is far from over. You can see there are many different conflicting opinions and even regulations. It may take a battle between the Hemp Industry and the FDA/cannabis based pharmaceuticals to make lasting change. If that is the case, be confident that the Hemp Industry will win. I am.

There is a SOLUTION to the confusion. (http://www.coalitionforaccessnow.org/take_action) You can take action federally to remove the ambiguity and update antiquated laws, regulations, and opinions. CBD should clearly be de-scheduled. It is not toxic and not addictive. The director of the US National Institute on Drug Abuse (NIDA), Nora Volkow, believes that cannabidiol (CBD) – a nonpsychotropic cannabinoid – is "safe with no addictive effects." Volkow further acknowledged, "Preliminary data suggest that it may have therapeutic value for a number of medical conditions."

Our society often makes things much more difficult than necessary. You should feel comfortable to access this option for yourself and your loved one as it sits today. Know that there are people who are fighting on your behalf to remove the confusion in this space. You should join them. Nothing feels better than ending the day leaving no doubt that you have done everything you can to leave the world in a better place than you found it. You can be a part of the solution. In fact, you MUST be part of the solution. Sorry people, that's what you get for being a pioneer!

Onward,



Heather Jackson
CEO / Co-Founder Realm of Caring Foundation
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¹AGRICULTURAL ACT OF 2014 - President Obama signed the Agricultural Act of 2014 on February 7, 2014 including Section 7606 known as "Legitimacy of Industrial Hemp Research." (http://www.votehemp.com/2014_farm_bill_section_7606.html) Section 7606 defines industrial hemp (0.3% or less THC) & authorizes institutions of higher education or state department's of agriculture in states that legalized hemp cultivation to conduct research and pilot programs.

²Section 7606 of the Farm Bill defines industrial hemp as "the plant *Cannabis sativa* L. and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis."

³Key Hemp Provision Added to the Omnibus Appropriations Act of 2016- Protects the transportation, processing and sale of hemp from Farm Bill compliant pilot programs. Sen. McConnell was successful in adding this provision to the Omnibus Appropriations Act of 2016 and it reads:

SEC. 763. None of the funds made available by this Act or any other Act may be used-
(1) in contravention of section 7606 of the Agricultural Act of 2014 (7 U.S.C. 5940); or
(2) to prohibit the transportation, processing, sale, or use of industrial hemp that is grown or cultivated in accordance with subsection section 7606 of the Agricultural Act of 2014, within or outside the State in which the industrial hemp is grown or cultivated.

⁴https://www.votehemp.com/PDF/HIAvDEA_9th_final_decision.pdf (https://www.votehemp.com/PDF/HIAvDEA_9th_final_decision.pdf)

⁵ *Here is one of the most recent articles causing unnecessary alarm.* (http://www.naturalnews.com/053369_CBD_hemp_oil_extract_FDA_regulations.html)

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