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FDA, Floral Hemp, and CBD—What a Mess!

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18-23 minutes

The history of Controlled Substances being allowed in foods, beverages and supplements is almost non-existent.

The mis-understanding of this history has harmed the entire American hemp economy: farmers, processors and sellers of hemp products.

Almost two years after the 2018 Farm Bill removed hemp (and cannabidiol) from the Controlled Substances Act, the DEA moved to de-schedule cannabidiol based Epidiolex from the CSA.

Once again, the “experts” have gotten it wrong: the FDA continues to question the safety of CBD, when almost two years ago (May 2018) they told the DEA it was safe. Finally, the DEA (March 2020) seems to agree.

What does this have to do with the hemp economy (farmers) and CBD?

Everything.

Turning good genetics, good farming practices, good manufacturing processes, and good formulations into products that customers want has positioned the modern American hemp economy for a constructive framework that links farmers to consumers in a virtuous economic vertical.

So why is the hemp industry still such a mess?

Legal and regulatory delays and general confusion, like the pointless 15 month delay in DEA’s descheduling of CBD, have delayed the inclusion of cannabinoids in mainstream consumer products.

What actions are needed to remedy this, quickly?

- 1. FDA must recognize the present status of hemp-derived cannabinoids, like CBD, as safe and without significant public health concern;*
- 2. The FDA must insist that all cannabinoid products be produced within the existing food, beverage and supplementary regulatory frameworks, as with any other consumer products;*
- 3. The FDA and the hemp industry must commit to auditing the entire hemp product supply chain, from farm to table.*

Read on, we’ll demonstrate.

The FDA already has the plan to introduce federally legal cannabinoids into foods, beverages, and supplements.

On the **day after the 2018 Farm Bill** was signed by President Trump, then **FDA Commissioner Scott Gottlieb** issued a **statement** that said precisely that the **path to inclusion of CBD in food** was contingent on meeting specific safety criteria:

“In addition, pathways remain available for the **FDA to consider whether there are circumstances in which certain cannabis-derived compounds might be permitted in a food or dietary supplement. Although such products are generally prohibited to be introduced in interstate commerce, the FDA has authority to issue a regulation allowing the use of a pharmaceutical ingredient in a food or dietary supplement.** We are taking new steps to evaluate whether we should pursue such a process. However, the FDA would only consider doing so if the agency were able to determine that all other

requirements in the FD&C Act are met, including those required for food additives or new dietary ingredients.”

Why was he so quickly able to comment and with authority? And now, DEA and FDA agree that CBD, or mixtures with CBD, are not Controlled Substances that most people expect in approved pharmaceuticals.

The FDA already knows that CBD is safe, and has for at least two, perhaps even five years. The evidence is there: it's in FDA's writings, and it's within FDA's warning letters to dozens of CBD companies. [Link to FDA warning letters.](#)

Earlier in 2018, The Department of Health and Human Services (HHS- the agency charged with oversight of FDA) [clearly told the DEA in the “Giroir Letter”](#) that Epidiolex¹ — containing only CBD as an “active” ingredient— should not be scheduled because it had no human abuse liability and did not meet the requirements for scheduling.

[1]Epidiolex is an FDA approved mixture of commonly available substances, and CBD sourced from marijuana in Great Britain; very similar in nature — except for FDA approval — to commonly available CBD oil drops. While undoubtedly legal, the sourcing of foreign marijuana for a compound readily available from US farmed hemp is a strange application of US regulatory “power” that truly harms US hemp farmers.

Because of timing (pre-2018 Farm Bill), DEA insisted (probably incorrectly, but that is a story for **later**) that CBD was a scheduled substance and therefore Epidiolex had to be scheduled. Because the FDA commented at length on the safety profile of CBD, the default scheduling was at the very lowest level possible, Schedule V. In the view of HHS (FDA), if CBD was not a controlled substance, then the scheduling would need revisiting.

This brings us back to 2020 and the recent news from the DEA about de-scheduling Epidiolex. The DEA finally got around to correcting its administrative error from 2018 and that's generally good news.

For the DEA, de-scheduling of any drug is a very rare event (only 3 times in the last 20 years) and the significance of the recent de-scheduling of Epidiolex has probably been lost due to a tumultuous (and unprecedented) news cycle.

If the DEA had not rushed (why?) and scheduled Epidiolex in a hurried manner in 2018, then the fears of CBD inclusion in foods, beverages and supplements would probably have been overcome by now. [Likely by simply following former FDA Commissioner Gottlieb's very public suggestions](#) in late-March and early-April 2019 for FDA's CBD working group and Congress “...[to consider whether there are legislative options](#) that might lead to more efficient and appropriate pathways than might be available under current law — again, with the same science-based, public health focus that the FDA endeavors to bring to all matters before it.”

Some of the legal “experts” around the industry suggest that because Epidiolex was the source of an IND — an Investigational New Drug — that CBD is not available for the use of consumers in the form of supplements or food/beverages. This is ridiculous, especially in the face of the simple suggestions put forward by the FDA's then Commissioner Gottlieb, as linked above.

Because HHS and FDA have done most of the work that shows CBD is safe. We have been waiting for almost two years since the “Giroir Letter” was publicized — well, not really, it was kind of buried, and we are grateful to [Hemp Industry Daily for hosting](#) it since publication — to tell the world what we know ([skip to pages 23/24 if the first part is too pedantic](#)) and many others already know: **that CBD, when produced with high quality standards and consistency, is safe, reliable, and ought not to be scheduled.**

In July of 2019, we provided comments on behalf of [GenCanna](#) to the U.S. Food and Drug Administration (FDA) as part of their request for *Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds* and larger post-2018 Farm Bill rulemaking process.

In our comments to the FDA (which can be accessed here), we suggested that any path forward for CBD should include:

1. Recognition that regulatory framework already exists and that it is a matter of understanding and implementation;

2. FDA recognition of the present status as safe and without significant public health concern; and
3. A plan to audit the industry supply chain from American source to American consumption.

At the time, and still to this day, we welcome the needed regulatory clarity for all cannabinoids, especially those most consumed by Americans (federally legal CBD and the state regulated THC). In the time since participating in the rulemaking process, there has been incremental evolution by the FDA as they unpack and understand the scientific data and information about the manufacturing, quality, marketing, labeling, sale and overall safety of products containing cannabis-derived compounds.

But let's be clear: they declared CBD safe for consumption almost two years ago because they had data and a 5+ year history of investigating CBD ([read FDA warning letters from 2015](#)).

We recommended that the FDA use its own internal criteria (and those laid out in section 201 of the Controlled Substances Act) to simply use the power that it already possesses to declare that hemp and hemp derived products — including hemp-derived cannabinoids — can lawfully enter the marketplace as food, beverage, or dietary supplement consistent with other laws such as the Food, Drug, and Cosmetic Act (FDCA).

As we've referenced previously, in early 2018 the U.S. Department of Health and Human Services (HHS) [sent the Girior Letter](#) to the U.S. Drug Enforcement Administration (DEA) that opines on the safety of a cannabidiol (CBD) based drug — Epidiolex — that was at the time under review. The study used eight factors laid out in Section 201 of the Controlled Substances Act (21 U.S.C. §811) to determine whether a substance should be scheduled — or in layman's terms, they sought to understand how dangerous it actually was.

HHS's findings from the Girior Letter are explained below:

In determining the public health needs surrounding CBD, the work already conducted by HHS and FDA confirms that CBD is safe. While there is work that is still ongoing to fully understand federally legal cannabinoids produced from hemp, early data clearly substantiates the safety profile for inclusion of CBD as food or dietary supplement.

Since we submitted this comment in July 2019, significant progress has been made on understanding the safety profile of CBD (*and what we've seen is promising — — data from GRAS studies is very positive for significant serving sizes, regulators in the UK are approving [unexpectedly large serving sizes](#), and developments in the EU using CBD from US farms as part of EU Novel Foods applications*). This provides positive momentum, although confusion remains throughout many segments of the industry because of FDA's lack of clarity. This has had a severely negative impact on the entire hemp economic value chain, and removes hope from rural America.

The FDA is at least two years behind, from a regulatory perspective, where it ought to be with regards to federally legal cannabinoids.

In late 2019, Congress passed legislation ("Appropriations") for the 2020 fiscal year. As part of these congressional appropriations, \$2 Million was allocated to the FDA for efforts to develop regulations for hemp-derived CBD and to submit a report to congress within 60 days "regarding the agency's progress toward obtaining and analyzing data to help determine a policy of enforcement discretion and the process in which CBD meeting the definition of hemp will be evaluated for use in products."

On Thursday March 5th 2020, [the U.S. Food and Drug Administration \(FDA\) issued an update to Congress on the status of rulemaking for CBD](#). While hemp and cannabinoids derived from hemp such as Cannabidiol (CBD) were legalized under the 2018 Farm Bill, FDA retained their authority to develop a regulatory framework for CBD products, just like any other food, beverage or supplement.

Strangely, the FDA seems to note no difference between cannabinoids derived from hemp and those from marijuana, even though the 2018 Farm Bill clearly differentiates the two and FDA acknowledges the same in the Executive Summary of the March 2020 report. **The FDA simply does not regard the efforts and products from American hemp farmers as any different than products from federally illegal marijuana.** This causes a real, negative effect on rural hemp economics and is inconsistent with federal law.

Although the regulation of CBD is currently a fluid situation that may involve congressional action, the report provides some valuable insight into the FDA's thinking and next steps for the industry.

- **FDA is actively evaluating a potential rulemaking to allow CBD in dietary supplements.** In the meantime, the agency is considering the issuance of a risk-based enforcement discretion policy to provide more transparency regarding its enforcement priorities.
- **The agency continues to block pathways for adding CBD to food and beverages.** FDA maintains that the data currently available raises safety concerns and encourages parties to share relevant information with the FDA.
- **FDA argues that those marketing cosmetics should ensure the safety of their products.** They note that there is limited data on topical use of CBD, and that topical products — including those with CBD — should not make structure/function or therapeutic (drug) claims.
- **FDA is re-opening the docket to obtain information** on “full spectrum” and “broad spectrum” hemp extracts, and how they compare to CBD isolate products.
- **The agency is also actively working to develop a sampling study** of the CBD marketplace to determine the extent to which products are adulterated or misbranded as mandated by Congress. This report to “perform a sampling study of the current marketplace for CBD to determine the extent to which products are mislabeled or adulterated” is due soon.

Many participants new to the issue of hemp and federally legal cannabinoids were pleased with this report. **We strongly believe that this report did nothing other than placate those who can settle for the FDA further pushing off its regulatory responsibility to meet the congressional intent of the 2018 Farm Bill.** FDA is slow-playing its ability to quickly recognize federally legal cannabinoids as foods, beverages, or supplements. While the report does give a slight positive indication that a path for cannabinoids as supplements might happen, the question of when remains unanswered.

Further, and far more importantly to hemp farmers seeking a market for their floral material, **the report provided no quick path to CBD’s inclusion in food and beverages, despite the clear market intentions — and consumer demand — for these products.**

The negative effects on America’s hemp farmers, including those still with a harvest from 2019, is devastating because the anticipated demand has been rejected by the FDA. **WHY?**

The net effect of FDA’s Congressional Report on CBD is to perpetuate the status quo, where products from uncertified producers, not meeting clear FDA production standards, fills a nebulous grey market because the larger food and beverage companies are fearful of FDA recriminations for advancing product development. **This is not sustainable.**

As above, we believe that the FDA is at least two years behind where it ought to be in regulatory development for federally legal cannabinoids.

While we cite the 2018 Farm Bill as the “federal legalization” moment, this actually happened with Section 7606 of the 2014 Farm Bill, and explains how and why FDA has been involved in warning letters since 2015. In fact, as evidenced from those 2015 warning letters, FDA has been studying CBD in consumer products since [at least the end of 2014](#).

Thus, FDA statements about needing more data/time seem unnecessarily bureaucratic and ignorant of the Congressional intent of the 2018 Farm Bill to promote hemp farming. The harmful effect of this slow-playing of federal regulatory development by FDA has cascading effects on the entire hemp economic value chain because it simply robs the industry of its biggest potential customer: American food product manufacturers.

Let’s be clear. **Although formal enforcement discretion has yet to be issued, the potential regulatory framework laid out in this nonbinding report would be devastating to the hemp industry:** A regulatory pathway that includes dietary supplements only would **eliminate the need for anything other than a few thousand acres of floral hemp to be cultivated in the future**. This notion is antithetical to the congressional intent of legalizing hemp in 2014 and 2018.

The lack of clarity from FDA has created an insurmountable bottleneck for the industry insofar that “pull through demand” from the farm to finished goods is effectively blocked until the FDA puts forth a regulatory framework addressing CBD products. Lack of clarity from the FDA negatively impacts farmers, processors, and mainstream food and beverage manufacturers that would normally see opportunity in this space.

Steve Bevan in a hemp field, 2019

More clearly, **consumers want products that contain federally legal cannabinoids**, and they want them to be from reliable, sustainable sources that meet modern product manufacturing standards. This

is all readily available as soon as FDA pushes the “GO” button by simply recognizing CBD as safe for foods, beverages and supplements and enforcing standard, modern production standards that it enforces on all all foods, beverages and supplements.

In this time of the global fear of pandemics, virus spread, and other negative health worries we have seen a quick response by governmental agencies, including FDA, to meet public needs based upon common sense and urgency. The standard, established bureaucratic timelines have been ignored, trumped by the public and political need to provide solutions for a safer and healthier population.

In over 5 years of monitoring, studying and regulating CBD, the FDA has never, once, pulled a CBD product from a store shelf, from online distribution, or fined or shuttered any producer of federally legal cannabinoid products. The **clear implication**, cast in the context of the FDA's own writings on CBD, is that **FDA views CBD as inherently safe for public consumption**. Further, we are unaware of any serious adverse effects from any federally legal CBD products. Massive amounts of CBD, contained within millions of oil drops, softgels, chewables, tablets, etc. have been consumed by Americans without report of harm. The absence of any comment on observed serious effects in the report demonstrates what the **FDA already knows: CBD is safe for consumption in food, beverages and supplements**.

In the last 5 months, there have been multiple legislative proposals in both the U.S. House of Representatives and U.S. Senate that would “force the FDA's hand” on the regulation of CBD, as opposed to leaving it up to their own, archaic devices. These legislative proposals have lacked the connection to agriculture to truly make an impact. This is not to say that there aren't proposals out in the world that could alleviate some of these issues, such as [H.R. 5587 introduced by House Agriculture Chairman Rep. Collin Peterson](#), but its passage is deemed unlikely.

Ironically, the legislative path to regulating CBD was initially [proposed by former FDA Commissioner Gottlieb after the Farm Bill was passed, and again in 2019](#).

This is why the decision to deschedule Epidiolex (cannabidiol) is promising, even if very late. It's also worth noting that this is the third time in 22 years that a substance has been *removed* from the CSA. Of course, this indicates a greater availability of Epidiolex, which is great news for those in need of its prescribed use case, but doesn't do much to alleviate the plight of American hemp farmers.

CBD is estimated to have been consumed by over 40 million Americans in the last few years, without negative effects. Archaic FDA policies are masquerading as benefiting the public health good — when the only true beneficiaries seem likely to be large global pharmaceutical purveyors. Meanwhile, American hemp farmers, and rural economies suffer because of FDA bureaucracy.

Current **FDA Commissioner Dr. Stephen Hahn** recently stated “**we're not going to be able to say you can't use these products....it would be a fool's game to stop it**”.

It's time the FDA moves their position forward and allow access to cannabinoids for the benefit of everyone including consumers and hemp farmers.