

WHITE PAPER

PANDORA'S BOX

The Dangers of a National, Unregulated, Hemp-Derived Intoxicating Cannabinoid Market

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Executive Summary

While cannabis and its derivatives remain federally illegal, massive loopholes in the federal definition of hemp are being exploited by "hemp" product manufacturers to sell extremely potent, often chemically synthesized intoxicants that are more powerful than anything available in licensed cannabis dispensaries.

- 1. "Hemp" product manufacturers are exploiting legal loopholes to sell unregulated, highly intoxicating cannabinoid products without regard for public health and safety.
- 2. "Hemp" manufacturers are producing novel synthetic cannabinoids that are many times stronger than traditional THC with little to no safety testing.
- 3. Intoxicating, unregulated hemp products are all too often rife with contaminants, inaccurately labeled, and brazenly marketed to children.
- 4. While industry stakeholders assumed that the 2018 Farm Bill intended to legalize nonintoxicating hemp products like CBD, a recent Ninth Circuit decision unleashed a Wild West of intoxicants when it ruled that products containing delta-8 THC meet the statutory definition of industrial hemp.
- 5. The Ninth Circuit ruling is at odds with other federal statutes such as the Federal Analogue Act, which explicitly prohibits THC analogs.
- **6.** Approval of novel cannabinoids, like THC-O, THC-P, HHC and others, rightfully falls under the purview of the U.S. Food and Drug Administration.
- California prohibits intoxicating cannabinoids in hemp products, whether
 naturally derived or synthetic. These laws must be enforced to protect the
 immediate threat to the health and safety of consumers.
- **8.** All plants grown for cannabinoid content should be subject to a similar set of regulations rather than an arbitrary, unworkable THC threshold.
- 9. Absent a single federally regulated cannabinoid market that oversees both hemp and cannabis, the Farm Bill urgently needs to be amended to close the loophole allowing the unregulated sale of concentrated, intoxicating, and/or synthesized cannabinoids.

Introduction

While cannabis and hemp are the same plant, legislators and regulators have created a broad, artificial distinction that separates the two based on the quantity of delta-9 tetrahydrocannabinol, the psychotropic compound commonly known as THC.

Cannabis and its derivatives remain federally illegal and are legally available only in highly regulated state markets. But massive loopholes in the federal definition of hemp are being exploited by "hemp" product manufacturers to sell extremely potent, often chemically synthesized intoxicants that are more powerful than anything available in licensed cannabis dispensaries.

Rife with contaminants and chemical byproducts,^{1,2} many of these so-called hemp THC and THC-like products are sold online and in convenience stores, gas stations, and smoke shops without age-gates, testing standards, packaging and labeling requirements, marketing limitations, or even a proper understanding of their potential effects on consumers. It's a public health disaster.

The ultimate solution is a single, federally regulatory framework that oversees both hemp- and cannabis-derived cannabinoid products for human consumption.

Short of a significant regulatory overhaul along these lines, interim steps must be taken to protect consumers nationwide. One action would be revising the U.S. Farm Bill to close loopholes that, intentionally or not, have encouraged a proliferation of tainted, synthetic intoxicants and mega-dose THC products in unregulated markets. Another step – aimed at protecting Californians right now – would be for the state to immediately enforce prohibitions against selling intoxicating cannabinoids (whether "hemp-" or cannabis-derived) outside the regulated cannabis market where extensive consumer protections already exist.³

Cannabis and Hemp: What's the Difference?

Cannabis and hemp have a long and storied history that is, by nature, intertwined and somewhat confusing. The bottom line is that they are the same plant species, known as *Cannabis Sativa L*. Historically, hemp has referred to low-resin *Cannabis Sativa L* that's bred for maximum fiber or seed oil content and grown for industrial purposes. Cannabis has referred to plants bred and grown for maximum resin content – in other words "drug" plants high in naturally occurring THC and other cannabinoids consumed for recreational and medicinal purposes.

The Controlled Substances Act of 1970 formalized this colloquial distinction. It defined cannabis (or "marihuana") as "all parts of the plant *Cannabis sativa L....* the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or

preparation of such plant, its seeds or resin" while excluding mature stalks, fiber, sterilized seeds, and products made from the non-resinous parts of the plant.⁴

Today, however, federal law has a blunter definition. It officially characterizes industrial hemp as having no more than 0.3 percent THC by dry weight – irrespective of its overall resin content. In other words, the Farm Bill of 2018 codified the 0.3 percent THC limit for hemp and the quantity of THC displaced resin content as the key factor distinguishing hemp from non-industrial cannabis.

Blurring the Lines

Rather than clarifying the difference between hemp and cannabis, the Farm Bill has inadvertently muddied the waters. The arbitrary distinction between the two classifications has become even less clear with increased interest in CBD, which, like THC, is concentrated in the resinous trichomes of the plant. Huge consumer demand for therapeutic CBD products has catalyzed the emergence of high resin "hemp," cultivated for drug rather than industrial purposes. Unsurprisingly, a 2021 genomics study by the University of Minnesota found that most of today's high CBD "hemp" actually gets 90 percent of its genetics from high resin cannabis.⁵

Having eroded the line between traditional hemp and cannabis – and seeking opportunities beyond the highly-regulated state cannabis markets – "hemp" product manufacturers are pushing the boundaries and exploiting legal loopholes created by the Farm Bill. Many of today's "hemp" products, which are sold online, in convenience stores, and in smoke shops and gas stations, are as intoxicating as regulated cannabis products, <u>if not more so</u>.

A Giant Loophole for Intoxicating Hemp

A closer look at the language of the Farm Bill pinpoints the problem:

The term "hemp" means the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and **all derivatives**, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, **whether growing or not**, with a delta-9 tetrahydrocannabinol concentration of **not more than 0.3 percent on a dry weight** basis. [Emphasis added]

Three phrases are critical: "all derivatives," "whether growing or not," and "not more than 0.3% [delta-9 THC] on a dry weight basis." This language has unintentionally given rise to the Wild West of hemp-derived intoxicating products we see for sale today.

Too Much THC

The phrase "whether growing or not" has been loosely interpreted to mean that hemp-derived products with less than 0.3 percent delta-9 THC in their final form are legal. If one measures THC on a percentage basis, one need only make a larger or heavier product to come up with an intoxicating dose.

Keep in mind that THC is a potent compound – a dose is typically measured in milligrams (thousandths of a gram), not grams. In the regulated California cannabis market, a single serving of an infused edible is capped at 10mg of THC per serving (and 100mg per package). If, as loosely interpreted, the Farm Bill allows for 0.3 percent THC in the final product and there is no cap on THC per package for "hemp-derived" products, here's how much "hemp-derived" THC you could see in a single infused gummy, cookie, brownie, or 12-ounce beverage:

PRODUCT TYPE	2 GUMMIES	1 Соокіе	1 Brownie	1 BEVERAGE
UNIT WEIGHT (GRAMS)	5.8g	16g	70g	340g
0.3% THC (MILLIGRAMS)	17.4mg	48mg	210mg	1020mg

Those are astonishingly high doses and mean we could have unregulated, hemp-infused edibles and beverages with up to 100 times the THC allowed in the regulated California cannabis market.

Chemically Synthesized Derivatives

Additionally, we're not just talking about traditional delta-9 THC here. "Hemp" manufacturers are producing compounds not native to the plant – or not present in meaningful quantities – by extracting and concentrating CBD and then modifying it to produce new synthetic and semi-synthetic cannabinoids. Typically, this process involves the use of toxic and corrosive solvents and heavy metal catalysts, remnants of which can sometimes be found in the final product. The result is novel compounds that are often many times stronger than traditional THC.

The recent proliferation of chemically synthesized, intoxicating cannabinoids includes:

- **THC-P:** Also known as THC-Heptyl or trans-delta-9-tetrahydrocannabiphorol, THC-P is structurally similar to traditional THC but includes two additional carbon atoms on the side chain (for a total of seven). A 2019 study published in *Scientific Reports* found it has a binding affinity for human receptors that's 30 times greater than THC, making it far more intoxicating.
- THCjd: Also known as tetrahydrocannabioctyl, THCjd is a recently discovered cannabinoid with an eight-carbon side chain. It's being hailed by "hemp" product

- makers for its "unique psychedelic effect" and is reportedly 19 times more intoxicating than THC.¹⁰
- THC-H: Also known as tetrahydrocannabihexol or THC-H hexyl, THC-H is a homologue of THC with six carbon atoms on the side chain. It's reported to be 10 to 15 times stronger than regular THC.¹¹
- **THC-O:** Also known as THC-O-acetate, ¹² THC-O is delta-8 THC (see below) that's been further modified. According to Leafly, a leading industry media company, THC-O "can be three times stronger than its more mainstream cousin" and borders on "hallucinogenic." ¹³
- HHC: Also known as HXC, or hexahydrocannabinol, HHC is THC with extra hydrogen atoms. In other words, it's partially hydrogenated THC and is reportedly more potent than delta-8 THC and delta-10 THC and similar in effect to traditional THC.
- **Delta-8 THC:** A chemical variant of delta-9 THC, delta-8 is typically synthesized from CBD and is somewhat less intoxicating than traditional THC.
- **Delta-10 THC:** Delta-10 THC, which is not native to the plant, is similar to delta-8.¹⁴

These intoxicating cannabinoids add up. Delta Extrax, for example, sells a gummy that includes a psychoactive stew of synthetics for a whopping 125mg of intoxicating cannabinoids per piece¹⁵ – over ten times the limit allowed in the California cannabis market. And mind you, many of those synthetics are more powerful than ordinary THC.

Questionable Safety

With few exceptions, these intoxicating compounds are created through chemical synthesis. **They are** *not* **the same as delta-9 THC.** Attesting to this, a growing number of "hemp" manufacturers advertise their wares as more potent than traditional THC. Others suggest that THC-like compounds like HHC may allow people to circumvent drug tests. ¹⁷

Cannabinoid researchers note that "synthetic cannabinoids (sCB) have been reported to cause various health problems and are potentially deadly. Diffuse alveolar hemorrhage, acute respiratory failure, heart attack, stroke, seizures, and kidney damage are all possible consequences of sCB use." Other studies suggest that sCB compounds may be linked to an increased risk of psychosis. A July 2022 study by scientists at Portland State University documented that THC-O-acetate, like Vitamin E-acetate, can yield ketene gas in concentrations that can be harmful when heated in a commercial vape device. Ketene gas is potentially lethal at five parts per million. Its production in vape devices is strongly suspected to have been partially responsible for the deaths and permanent lung injuries seen during the height of the EVALI "vaping crisis." And, at least one "hemp" product-maker selling THC-O vape carts online lists "seizures" as a "common side effect."

We cannot assume then that, in meaningful quantities, these novel compounds have the same safety profiles as cannabinoids that are native to and abundant in the plant. The Farm

Bill's definition of hemp, based solely on THC levels, overlooks a wide array of possible intoxicating derivations, some with known potential side effects and others dangerously unstudied.

It's also worth noting that, insofar as cannabis is highly taxed and hemp is not, consumers are incentivized to choose these unregulated products.

Mislabeled and Appealing to Children

We are now in a situation where intoxicating hemp and cannabis products are both readily accessible in California and nationwide – with one key difference: So-called hemp products are unregulated. A quick survey of the "hemp-derived" THC market reveals significant mislabeling, ²² brazen marketing to children, ²³ and levels of THC and/or other intoxicating cannabinoids that exceed the allowable limits in the regulated cannabis marketplace.

By contrast, cannabis companies in California and elsewhere are subject to THC potency caps, age restrictions, rigorous testing standards, stringent labeling requirements, child-resistant packaging, and advertising restrictions. The regulated cannabis industry is prohibited from mimicking conventional snack food, marketing products as candy, or making products that appeal to children. Hemp products are not abiding by any such restrictions, as shown below. It is easier for a kid to get their hands on these products than a six-pack of beer.



AGRODINE24

"THC Hot Cheetos are infused with **600MG** of Delta 8 THC in a single bag and can easily be finished in one sitting."*



CANNA KINGS²⁵

"...unleash your inner delta 8 'cookie monster'... amazing, wholesome taste...you can get a solid delta 8 high with only half of a cookie..."



BARELY LEGAL²⁶

"Around 3% of people, THCO produces very powerful, almost psychedelic effects. For the rest of the 90%, it's ...very strong and potent...."



TOP 5 WHOLESALE²⁷

"Offering the nostalgic flavor and texture of your childhood breakfast with an added adults-only buzz...each treat contains 500mg of Delta-8."

^{*} Quoted from product marketing materials.

Is It Legal?

Industry stakeholders widely assumed that the 2018 Farm Bill intended to legalize nonintoxicating hemp products, such as CBD. However, a recent court decision affirmed that, intentionally or not, Congress left the barn door open. On May 19, 2022, the Ninth Circuit Court of Appeal issued its ruling in *AK Futures*, *LLC v. Boyd Street Distro*, *LLC*, 35 F4th 682 (9th. Cir. 2022), affirming a District Court's decision that products containing delta-8 THC are lawful under the Farm Bill because they meet the statutory definition of industrial hemp – even though they can get consumers high.

AK Futures is significant because it is the first time a federal court has ruled that a psychoactive cannabinoid derived from industrial hemp is lawful under the Farm Bill. Since that decision, various state courts and legislatures have affirmed the "legality" of intoxicating hemp-derived products. A Kentucky court referenced the Ninth Circuit's decision when it recently rejected an argument that delta-8 is a derivative of a derivative and is, therefore, synthetic and illegal under the Farm Bill. A Georgia state court²⁸ and the Minnesota legislature²⁹ enacted similar positions.

It's important to note that the Ninth Circuit ruling contradicts the Federal Analogue Act (FAA), 21 U.S.C. § 813, which states that any substance that "has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II" must be treated like a Schedule I substance.³⁰

With companies overtly marketing cannabinoids like THC-O and HHC as "THC analogues,"³¹ "THC," and "synthetic cannabinoids,"³² it seems self-evident that these compounds are, for all intents and purposes, analogues – especially after the Drug Enforcement Administration (DEA) issued an interim rule reiterating that "all synthetically derived tetrahydrocannabinols remain Schedule I controlled substances."³³ Regardless, hemp purveyors claim that the Ninth Circuit opinion supersedes the FAA, rendering the latter moot on this point.

There is also a solid argument that the novel cannabinoids currently being marketed under the guise of legal hemp fall squarely under the purview of the U.S. Food and Drug Administration (FDA), which oversees new drug development. These are new compounds; if they exist in the plant at all, it's only in minute quantities. While cannabis has been safety tested on a massive scale over hundreds if not thousands of years, these new THC-like compounds have not.

Several states, including Colorado³⁴ and Vermont³⁵ have issued rules excluding chemically synthesized cannabinoids from their state markets. Here in California, intoxicating synthetic cannabinoids and intoxicating hemp products are emphatically illegal. **Enacted in 2021**, California Assembly Bill 45 (Aguiar-Curry) included comprehensive language to ensure that any intoxicating cannabinoids, whether naturally derived or synthetic, are prohibited in all hemp products.³⁶

But ignoring state and federal laws to the contrary,³⁷ hemp companies are building a robust intoxicating cannabinoid market on the disputed legal foundation of the 2018 Farm Bill and the recent Ninth Circuit decision.

Conclusions and Recommendations

The notion of legalizing intoxicating cannabinoids simply because they are derived or synthesized from hemp is ludicrous. A comparable scenario would be deregulating wine on the grounds that it derives from grape juice. An intoxicant is an intoxicant. Both common sense and public safety dictate that these substances must be handled with care. The proliferation of untested and unregulated synthetic and semi-synthetic intoxicating cannabinoids is a public health disaster. Action must be taken immediately to protect public safety. Specifically:

- 1. We Need a Unified Federal Framework for Intoxicating Cannabinoids.

 Fundamentally, the regulation of hemp and cannabis must catch up with the latest science and strike an appropriate balance between access and consumer safety.

 Concerning cannabinoids, the cannabis-hemp distinction is no longer meaningful.

 Cannabis needs to be legalized and regulated at a federal level, and all plants grown for cannabinoid content should be subject to a similar set of regulations rather than an arbitrary, unworkable THC threshold.
- 2. Congress Needs to Close Loopholes in the Farm Bill That Are Being Exploited. Absent a federally regulated cannabinoid market that oversees both hemp and cannabis, the Farm Bill urgently needs to be amended to close the loophole being exploited to sell intoxicating and/or synthesized cannabinoids outside of regulated markets.
- 3. The FDA Needs to Exercise Oversight Over Novel Cannabinoid Compounds. The FDA must exercise its authority to approve or disapprove of novel or synthesized cannabinoids not found in the plant in commercial quantities. These are new compounds and safety testing is necessary.
- 4. California Needs to Enforce Existing Laws Prohibiting Intoxicants in Hemp. California must take immediate action to protect consumers from potentially unsafe products by enforcing existing laws. Currently, efforts to curtail the sale of these products are woefully lacking.

Given the lack of federal leadership on cannabis policy, California has an opportunity to set an example for other states by crafting and implementing a coherent regulatory framework that encompasses all plants grown for cannabinoid content rather than industrial purposes.

Now is the time to do that.

End Notes

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