NAVIGATING THE FUTURE OF CANNABINOID REGULATION: BALANCING SAFETY, INNOVATION, AND CONSUMER ACCESS

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In recent years, the proliferation of products containing various cannabinoids has become commonplace. *Cannabis*, whether hemp or marijuana, contains well over 100 different cannabinoids with varying effects which requires nuanced and thoughtful policy considerations. This has become particularly apparent since the federal descheduling of hemp-derived cannabinoids (other than delta-9 tetrahydrocannabinol or THC) with the passage of the 2018 Farm Bill, which coincided with multiple states legalizing medical and adult-use marijuana across the country.

Much of the discussion surrounding cannabinoids has been about potentially intoxicating/psychotropic products versus those that are not, as well as *how* these cannabinoids are produced. Specifically, much of the discourse has turned on whether these cannabinoids are extracted directly from the hemp or marijuana plant, or are synthesized from other cannabinoids (such as cannabidiol (CBD)), certain chemical precursors to cannabinoids (olivetolic acid) and/or non-plant biomass (such as yeast, algae and other microorganisms).

Consumers spend billions of dollars annually on CBD alone, demonstrating the popularity and demand for cannabinoids, which are commonly incorporated into topical products (beauty creams, oils, balms, and sprays), ingested products (dietary supplements, beverages, edibles), and inhaled products (hemp pre-rolls and vaped goods). And while the permissibility of plant-extracted cannabinoids readily follows from a plain reading of the text of applicable federal and state laws, synthesized cannabinoids are still a gray area. What becomes clear from observing the market is that while plant-extraction will remain the most practical and cheapest means of producing enough THC and CBD to meet the needs of consumers, consumer demand for certain naturally-occurring rare and minor cannabinoids (prized for unique potential wellness benefits) cannot currently be met cost-effectively[1] without the production of synthesized nature-identical (bioidentical) cannabinoids.[2]

[1] Note that this may not hold over the longer term; with breeding, levels of minor and rare cannabinoids can be increased through future generations of plants, making plant extraction of these cannabinoids more cost-effective and competitive over time. That said, it's also worth noting that the range of "traditional" production methods varies materially; at times, certain existing extraction, distillation, and separation techniques using plant-derived material may not yield the levels of purity and consistency demanded certain use-cases, potentially making the synthesis of rare cannabinoids more advantageous in those instances.

[2] It's important to note hear that NCIA is not addressing the production of *novel* cannabinoids, which are unknown in nature; while we believe these cannabinoids are appropriate subjects for medical and scientific research as well as the development of FDA approved pharmaceutical drugs, their unknown safety profiles make them unsuitable for inclusion in consumer products currently on the market. Also, we are not including certain cannabimimetic substances (*e.g.*, "K2" and "spice," *see* https://www.dea.gov/sites/default/files/2020-06/K2-spice-2020.pdf) under the rubric of synthesized cannabinoids, because they are not true cannabinoids (much less naturally-occurring phytocannabinoids present in the cannabis plant) and have been shown to be potentially injurious to human life. Finally, we do not necessarily consider *all* chemically-converted cannabinoids (*see* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10369762/) under the umbrella of synthesized cannabinoids, as we would exclude any production methods that create cannabinoid analogues and byproducts with an unknown safety profile and which *cannot* be effectively purged from the final product.

NCIA's position is that it is crucial to contemplate the entire cannabinoid supply chain as it is expected to take shape (rather than turn a blind eye to reality), and prioritize the inclusion of safe, regulated plant-extracted *and* synthesized cannabinoids in all manufactured products sold to consumers.[3] The absence of federal standards for cannabinoid products continues to cause uncertainty in both the hemp and marijuana industries, leading to a patchwork of state regulations that may lead to both over and under regulation. NCIA has historically supported the adoption of a common sense federal regulatory framework that applies equally to all cannabis and cannabis-derived products based on their cannabinoid content and intended use, rather than whether the product is produced from "hemp" or "marijuana" as those terms are utilized under federal law to define the cannabis plant. NCIA further believes that cannabinoids the plant produces through its own synthesis or the result of natural degradation (e.g., CBDA to CBD, or THC to CBN), especially those that are not impairing, should be allowed regardless of the means of production—and regardless of whether cannabinoids are extracted or synthesized, they should be sensibly regulated with an emphasis on safety, consistency, and quality.

NCIA has long advocated for a bifurcated market in which cannabinoid-containing products with no more than a *de minimis* level of potentially intoxicating cannabinoids are regulated through one pathway akin to dietary supplements or cosmetics, while products with a greater prospect for intoxication be treated akin to alcohol. This approach should be applied to consumer products incorporating cannabinoids, whether plant-extracted or synthesized, equally.

As a consequence, this would mean establishing clear limits on the levels of intoxicating cannabinoids in *all* consumer products to align with the regulatory frameworks of state-regulated adult-use and medical cannabis, where higher potencies are permitted under strict controls. By imposing reasonable restrictions on the concentration of intoxicating compounds in products intended for food and dietary supplements, we aim to safeguard public health within a regulated framework, thereby mitigating the risks associated with an unregulated market. However, it is crucial to recognize that overly restrictive regulations could inadvertently sustain the unregulated market, depriving consumers of safe and regulated options. To address this, we propose that all products containing THC levels that could be reasonably anticipated to lead to impairment be regulated similarly to alcohol, ensuring they meet rigorous safety standards similar to those applied to state-licensed marijuana products. This approach not only protects consumers but also leverages the interstate commerce of hemp to bolster small businesses and retail food establishments. Through such balanced regulation, we can ensure consumer safety while supporting the economic potential of the hemp industry.

[3] While we are optimistic about the potential of rare and novel cannabinoids, we also understand that the safety of ingesting high levels of minor cannabinoids and terpenes have not been extensively studied and so we advocate for continued research to conclusively determine the safety profile of these compounds.

We acknowledge that the market for hemp-derived products is flourishing outside of state regulatory marijuana programs in part because those state regulatory marijuana systems are overly restrictive with onerous regulations and taxes, which make it nearly impossible to operate successfully. For that reason, NCIA advocates for sensible state regulations that protect public safety while ensuring that legal businesses can thrive and successfully replace the unregulated and untaxed underground markets. Additionally, states should not impose arbitrary limits on the number of licenses available to sell intoxicating products to adults over 21 or qualifying medical patients, whether that be at a dispensary or other licensed retail storefront.

Another opportunity for federal reform lies within the Farm Bill (which will continue to be negotiated for much of 2024). We continue to urge Congress to modify the statutory definition of hemp to protect both farmers and consumers, by increasing the allowance for **total** THC in hemp crops to 1%, while also adopting responsible potency caps for finished hemp products. The increased allowance for unprocessed hemp crops is necessary to allow for the hemp industry's continued growth and allow farmers and rural communities to benefit from growing and processing hemp. Under the current definition of hemp (which restricts THC to only 0.3% by weight of the plant), many farmers are exiting this industry out of fear that they may be forced to destroy their **entire** crop if they are above the 0.3% THC limit when harvesting. Conversely, applying the current definition and THC threshold to finished hemp products frequently results in per-serving THC dosages that far exceed what's permissible in state-regulated marijuana products.[4] As such, adopting a reasonable threshold for total THC content (not measured as a percentage of the weight of the finished product, but by milligrams per serving) is necessary to align federal law with the efforts of states (and their voters) to protect public health and sustain regulated marijuana markets.

Finally, NCIA cannot emphasize enough that current legal access to cannabis products under existing state laws and regulations must not be disrupted. It is also true that certain of these products (like cannabinoid health and wellness products) are produced from cannabis plant material (rather than isolated chemical constituents)--or "whole plant-based products," and could face byzantine obstacles traveling the existing Food, Drug, and Cosmetic Act (FDCA) pathways for conventional drugs as a result.

As such, the FDCA may not readily accommodate all whole plant-based products under existing "food," "dietary supplement," and "drug" pathways (including those for "botanical drugs"), most notably existing medical cannabis products relied on by countless Americans

[4] For example, applying the current 0.3% THC threshold to a can of hemp-infused soda that weighs ~355g would result in a product with over 1000 mgs of THC. The total milligrams of THC per-serving in regulated marijuana products are generally 10 mg or less across jurisdictions.

today. In order to provide continued, safe consumer access to cannabinoid products now and safeguard consumer access to medical cannabis products in advance of and after de-scheduling or rescheduling, Congress must carve out an alternate pathway for cannabinoids under the FDCA. Forcing any category of whole plant cannabis product into existing FDCA categories (especially the "drug" category) is at once an inappropriate and inadequate regulatory response.[5]

It is clear that Americans are finding access to all manner of cannabinoid products, and will continue to consume them even in the face of regulatory and legislative inaction. Cannabis products, whether plant extracted or synthesized will require fresh thinking, an affirmative carve-out from the application of the FDCA's "drug" paradigm, and creation of a new pathway for such products.

Thank You to Our Contributors:

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- NCIA's Hemp Committee

[5] Notwithstanding the forgoing, we also aren't advocating for completely recreating the wheel when the regulatory pathway for cannabinoids could very well leverage portions of existing frameworks–for instance, by facilitating FDA recognition of Generally Recognized As Safe (GRAS) designations for cannabinoid ingredients, as they currently do for food and drug ingredients.