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ADAPTING A REGULATORY FRAMEWORK FOR THE EMERGING CANNABIS INDUSTRY





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Executive Summary

For almost a century, the United States government has criminalized the production, distribution, and sale of cannabis. However, this era of prohibition has been crumbling in the face of voter and, increasingly, legislative revolt. Even as these federal laws remain unchanged, most states have legalized some form of medical cannabis, and eleven states and the District of Columbia have changed their laws to regulate adult-use cannabis in a manner similar to alcohol. Moreover, Congress recently removed hemp (and any cannabinoids derived therefrom) from the Controlled Substances Act (CSA), legalizing a subset of cannabis plants and derivatives that contain less than 0.3% THC. With momentum building and public support ever-increasing, the critical question has shifted from “Should cannabis be legalized?” to “How will we regulate the commercial cannabis market at the federal level?”



As the leading policy voice for the state-regulated cannabis industry, the National Cannabis Industry Association (NCIA) herein offers reasoned and responsible approaches that the federal government could adopt to regulate cannabis products after the last vestiges of federal prohibition are removed.

The diversity of products that contain cannabis means that a “one-size-fits-all” regulatory framework would be ineffective. Under such a framework, some products would be overregulated, while others might be underregulated. Instead, different regulatory structures, or “lanes,” could be utilized based on the characteristics and intended uses of the products to leverage existing federal regulatory expertise. This will lead to an effective and efficient review process for existing government agencies that avoids unnecessary bureaucracy, costs, and delays for cannabis companies. Indeed, because human consumables are already regulated by the federal government through a variety of regulatory lanes designed for these purposes, most cannabis products could simply follow analogous products already being sold legally through these lanes. By



building off existing systems and making modifications where necessary, all cannabis products could be properly regulated by existing federal agencies without reinventing the wheel.

Currently, because of marijuana’s status as a Schedule I drug under the CSA, the Drug Enforcement Administration (DEA) is the primary federal regulator of cannabis, with criminal enforcement serving as the sole regulatory tool for the law enforcement agency. The first and most important step of a comprehensive regulatory system for cannabis would be for Congress to remove marijuana and its derivatives, including delta-9 tetrahydrocannabinol (THC), from the CSA, otherwise known as “descheduling.”¹ Descheduling is the only way for cannabis to be regulated in the manner proposed herein, and it is the only way to truly reform federal cannabis policy in a sensible manner. Our proposal calls for cannabis products, like other highly regulated consumables, to be regulated by the government agencies that currently regulate most food and drugs, primarily the Food and Drug Administration (FDA) and the Alcohol and Tobacco Tax and Trade Bureau (TTB) within the U.S. Department of the Treasury.

Under our plan, cannabis products would be divided into four categories, based on chemical components, safety, intended use, and consumption method. Each of these groups would be regulated through a separate regulatory “lane” tailored to the public policy issues raised by that particular classification. The four lanes are: (1) Pharmaceutical drugs; (2) Ingested, inhaled, or topically applied products with more than de minimis amounts of THC; (3) Ingested and inhaled products with de minimis amounts of THC; and (4) Topically applied products with de minimis amounts of THC.

**Lane #1 — Pharmaceutical drugs (e.g., Epidiolex; Marinol)
(Regulated Like Prescription/OTC Drugs; Lead Federal Regulator:
FDA)**

Lane #1 includes all products approved as pharmaceutical drugs, over which FDA currently exercises jurisdiction under the authority of the Federal Food, Drug, and Cosmetic Act. This category currently includes approved drugs such as Epidiolex and Marinol and would include any cannabis derivative (whether extracted or synthetic) that is approved as

¹ Some politicians advocate moving marijuana to a different/lower schedule (rescheduling within the CSA). However, rescheduling would limit most cannabis products to sales only through the current pharmaceutical drug system (Lane #1).



Lane #1 — continued

a new drug or authorized for use as an active pharmaceutical ingredient under a tentative or final over-the-counter (OTC) monograph. Products in Lane #1 are subject to FDA's existing rigorous drug approval process. Once the products have been approved by FDA, substantiated disease claims could be made about them, consistent with the terms of the FDA's approval and existing limitations governing off-label uses. These products would be sold alongside prescription or OTC drugs, depending on whether they are approved for use by prescription or OTC.

Necessary Legislation: Lane #1 requires no legislative modifications, other than “descheduling” cannabis to facilitate further drug research and vest FDA with sole regulatory authority.

Lane #2 — Ingested, inhaled, or topically applied products with more than de minimis amounts of THC (+0.3%) (Regulated Like Alcohol; Lead Federal Regulator: TTB)

Lane #2 includes edible, inhalable, and topically applied cannabis products that are not approved as pharmaceutical drugs by FDA under Lane #1 but that contain more than a de minimis amount of THC (greater than 0.3% by dry weight). The intoxicating properties of these cannabis products raise public policy and safety concerns that are not present for the low-THC products in Lanes #3 and #4. Accordingly, these products would be sold through a network of state-licensed retail stores to individuals meeting state age requirements and/or qualifying medical condition requirements, as appropriate. Here, the states would assume the primary regulatory responsibility for these products, with TTB playing a significant oversight role at the federal level. Of course, thirty-three states already have regulations in place for the sale of medical marijuana through state-licensed dispensaries, and eleven states have legalized recreational sales through state-licensed retail facilities.



Lane #2 — continued

Necessary Legislation: Congressional action would be needed to deschedule marijuana and THC (above 0.3%). Legislation would also be needed to grant authority to TTB to regulate these substances (similar to the regulation of alcohol) and to facilitate interstate shipment of the products, as the 2018 Farm Bill did for hemp. Consistent with the model for alcohol, FDA and the states would retain important regulatory roles. Congressional action would be needed to authorize FDA to establish manufacturing requirements for inhalable products. Most cannabis products currently being sold through state adult-use or medical cannabis programs would be regulated through this lane.

Lane #3 — Ingested and inhaled products with de minimis amounts of THC (<0.3% THC) (e.g., CBD, CBN, and CBG) (Regulated Like Food/Dietary Supplements; Lead Regulator: FDA)

Lanes #3 and #4 are the least restrictive lanes and cover products containing no more than de minimis amounts of THC. Currently, federal law provides for the inclusion only of hemp and hemp derivatives with a THC concentration below 0.3%.

Numerous non-intoxicating cannabinoids such as CBD, CBN, THC-A, and THC-V may be derived from either the marijuana plant or the hemp plant. The 2018 Farm Bill created an arbitrary dividing line between marijuana and hemp plants, based entirely on their THC concentration. This has resulted in an overregulation of popular non-intoxicating products based on the THC level of the plant source material instead of the THC level of the finished product (e.g., CBD derived from the marijuana plant). We propose remedying this problem by classifying any final product containing less than 0.3% THC within Lane #3, rather than focusing on the THC content of the plant source material or of any intermediate product.

Based on existing research, these low-THC products carry relatively attenuated public safety risks (see below). Products in Lane #3 would be regulated by FDA to protect the public health and ensure accurate labeling,



Lane #3 — continued

with regulatory oversight varying based on the products' intended use and any health-related claims made. Sales would be allowed anywhere food or dietary supplements are currently available, without a special retail license requirement. Products with more than the statutorily allowable THC level (currently 0.3%) would be considered adulterated and prohibited from being sold through this lane.

Necessary Legislation: Congressional action is necessary to clarify that non-intoxicating products derived from the marijuana plant should be treated the same as non-intoxicating products derived from the hemp plant, so long as the final product contains no more than 0.3% THC. To expedite the ongoing FDA review process and to meet the significant public demand for these products, congressional action would also make explicit that low-THC products are allowed in food and dietary supplements. Congressional action would also be needed to: (1) authorize FDA to regulate inhalable products, and (2) establish parameters for permissible claims for such products. Congress should also make clear that FDA is the primary regulatory body for this lane.

Lane #4 — Topically applied products with de minimis amounts of THC (<0.3% THC) (e.g., CBD, CBN, and CBG topicals) (Regulated Like Cosmetics; Lead Federal Regulator: FDA)

Lane #4 includes products with low levels of THC that are not consumed orally or inhaled (e.g., topical lotions, creams, balms, etc.). Like products in Lane #3, these products would be regulated by FDA to protect the public health and ensure accurate labeling. Sales would be allowed where other cosmetics are sold without any special retail license. Products with more than the statutorily allowable THC level (currently 0.3%) would be considered adulterated and prohibited from being sold through this lane.

Necessary Legislation: To expedite the ongoing FDA review process related to CBD and to meet the significant public demand for these products, congressional action is needed to make explicit that low-THC products



Lane #4 — continued

are permitted in topically applied products. This legislation would also set maximum allowable THC levels for products sold through this lane.

Next Steps

It is clear that the era of prohibition is coming to a close. It is now incumbent on the federal government to devise an efficient and effective regulatory system for cannabis products. By leveraging the existing infrastructure and expertise of federal regulators already engaged in analogous tasks, Congress can act to create a system for ensuring a safe product supply chain (as demanded by voter-consumers) without reinventing the wheel or adding layers of unnecessary bureaucratic red tape. This approach is tailored by product category to avoid underregulation and overregulation, both of which advance only the interests of the cartels supplying the illicit market with untested, unregulated, and potentially unsafe products. After a failed century of prohibition, the public deserves and demands safe access to appropriately regulated cannabis products.



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Introduction

For much of the last century, with few exceptions, the U.S. government misguidedly deemed the cannabis plant too dangerous to possess. During this time, millions of people were arrested and billions of dollars were spent on enforcement. Nonetheless, cannabis consumption continued unabated.

However, over the past few decades, a grassroots coalition of Americans across the nation and political spectrum has started chipping away at this near-total prohibition. States, often through ballot initiatives responding to the will of the electorate, have begun to liberalize their cannabis laws. To date, thirty-three states and the District of Columbia have legalized medical cannabis, and eleven states and the District of Columbia have legalized cannabis for adult use.² The Agriculture Improvement Act of 2018 (2018 Farm Bill) removed hemp, defined as cannabis and its derivatives, extracts, and cannabinoids with no more than 0.3% THC, from the CSA.³

Demand for products containing the cannabinoid cannabidiol (CBD) has exploded recently, with the global CBD product market potentially reaching \$22 billion by 2022.⁴ Polls consistently show that a clear majority of the public now supports cannabis legalization. For example, 65% of respondents in an April 2019 CBS News poll supported marijuana legalization, with clear majorities of Republicans, Democrats, and Independents favoring the end of prohibition.⁵

A great deal of work nevertheless remains before we see the end of prohibition. While NCIA continues to endorse incremental legislation that achieves piecemeal progress, only descheduling and a new robust federal regulatory framework will ultimately suffice. Part of our ongoing work is envisioning how the cannabis plant should be regulated after it is descheduled. We need to start focusing on the regulatory structure now so that we are not caught flat-footed once descheduling legislation passes both chambers of Congress and is signed by the President.

² Jeremy Berke and Skye Gould, *Illinois just became the first state to legalize marijuana sales through the legislature — here are all the states where marijuana is legal*, Business Insider (June 25, 2019), <https://www.businessinsider.com/legal-marijuana-states-2018-1>.

³ 2018 Farm Bill, Pub. L. No.115-334, 132 Stat. 5018.

⁴ *CBD Market Insights*, Brightfield Group, <https://www.brightfieldgroup.com/products/cbd-market-research> (last visited Sept. 5, 2019).

⁵ Jennifer De Pinto, *Support for Marijuana Legalization Hits New High*, CBS News (April 19, 2019), <https://www.cbsnews.com/news/support-for-marijuana-legalization-hits-new-high-cbs-news-poll-finds/>.



Non-cannabis consumables for humans and animals are regulated differently depending on ingredients, safety concerns, intended use, and consumption method. Below, we propose appropriate regulatory schemes for each different lane, based on the characteristics of the products, using the regulatory model of similar products as a guide for cannabis regulation.

The first and most important step of this new regulatory process involves removing marijuana and THC from the CSA (descheduling). Proposals to reschedule (as opposed to deschedule) marijuana and THC have been made in the past, but rescheduling would actually create more problems than it would solve. Specifically, moving marijuana and THC to another schedule (below Schedule 1) would still require companies to go through the FDA drug approval process. Merely rescheduling would cause an irreconcilable conflict with the adult-use and medical cannabis systems that have been broadly supported by the public. It would also keep the DEA as a regulator and delay sales while pharmaceutical companies performed the expensive and lengthy clinical drug studies required for FDA drug approval. In short, rescheduling is not just suboptimal—it is simply incompatible with state cannabis laws and runs counter to the will of the voters. Rescheduling is plainly bad public policy.

Removing marijuana and THC from the CSA entirely (“descheduling”) is also by itself an inadequate solution without a comprehensive regulatory system in place at the federal level. In the absence of a consistent national regulatory structure, cannabis products will struggle to enter the legal marketplace, and either such products will continue to be sold in the illicit market or legitimate sales will be hampered by ongoing legal uncertainty.⁶

One (suboptimal) option would be to create a new federal agency to regulate the large variety of cannabis products that have market demand. However, creating a new agency is time-consuming, expensive, and unnecessary. The best path forward is to design a regulatory scheme that leverages existing government agencies’ expertise and the lessons learned from the many states that have legalized cannabis, while making the necessary legal adjustments to smooth the transition into a post-prohibition world where cannabis products are treated similarly to non-cannabis products. This involves tailoring the regulatory framework of each group of products to address relevant public policy concerns.

⁶ For example, without further guidance from Congress, FDA could consider cannabis extracts “adulterants” and keep them out of consumable products. Similarly, a comprehensive regulatory system would facilitate interstate commerce in these products.



The regulatory system proposed here begins by embracing the current methods through which human consumables are regulated, leveraging existing systems and agencies with relevant institutional knowledge to group cannabis products into different regulatory lanes. This approach allows these products to have tailored regulatory structures that address product-specific concerns without applying unnecessary regulatory burdens. By leveraging existing agencies, our proposal can increase efficiency and reduce cost and regulatory uncertainty. For example, both FDA and TTB have significant experience regulating similar products and have previously implemented successful regulatory schemes. Given this available expertise, reinventing the regulatory wheel makes little sense.

“The first and most important step of this new regulatory process involves removing marijuana and THC from the CSA (descheduling).”

Indeed, almost all cannabis product types have comparable offerings currently available through existing regulatory schemes. The proposals outlined below would allow for all cannabis products to be safely produced, sold, and consumed in any state that chooses to permit their sale, ending a lost century where millions of lives were ruined in a misguided attempt to prevent reasonable access to the cannabis plant.



Legal Status of Cannabis in the United States

For much of modern history, cannabis existed with very little regulatory oversight and was widely grown as a cash crop. The plant was used for many industrial products like rope, textiles, and building materials. The effects of consuming cannabis were widely known, and cannabis was used for both medical and recreational purposes. It was not until the end of the nineteenth century and the beginning of the twentieth century that the push to restrict and regulate cannabis gained momentum. This movement to regulate was part of a larger push to improve public health and regulate human consumables. Alcohol prohibition and the first food and drug safety statutes were implemented at around the same time. It should be noted that scholars of this effort to regulate cannabis have identified race as an important impetus, given that



government officials and the public portrayed “marihuana” as a dangerous drug brought to the United States by Mexican immigrants.⁷ The restriction and criminalization of cannabis continued to accelerate over the next few decades until the passage of the CSA, which essentially created the criminal cannabis regulatory system we have today.

Under the CSA, cannabis (other than hemp and pharmaceutical drugs approved by FDA) is classified as a Schedule I drug, meaning that the substance is considered to have a high potential for abuse, it has no accepted medical use, and there is a lack of accepted safety for the use of the substance under medical supervision.⁸ Of course, that classification is fundamentally irreconcilable with reality. There is no serious debate that numerous cannabinoids have accepted medical use. One blatant example of this dichotomy is the patent in the hands of the federal government. In 2003, the United States Department of Health and Human Services was awarded a patent entitled “Cannabinoids as Antioxidants and Neuroprotectants.”⁹ So the

⁷ Olivia B. Waxman, *The Surprising Link Between U.S. Marijuana Law and the History of Immigration*, Time (Apr. 20, 2019), <https://time.com/5572691/420-marijuana-mexican-immigration/>.

⁸ *Drug Scheduling*, DEA, <https://www.dea.gov/drug-scheduling>.

⁹ U.S. Patent No. 6,630,507 (filed Apr. 21, 1999).



fact is that despite cannabis having been classified as having no medicinal use, the United States government itself has a patent on its medicinal use. Meanwhile, there is no consensus in the scientific community that cannabis has a high potential for abuse. Non-scheduled substances such as alcohol and tobacco are widely considered to have a much higher potential for abuse than cannabis.

Commercial production and sale is currently prohibited at the federal level for all Schedule I substances, and this prohibition is enforced with severe federal criminal penalties. Not only are nearly all cannabis-related activities criminalized at the federal level, but an individual may be punished as a principal for aiding, abetting, counseling, commanding, inducing, or procuring another person to engage in a cannabis-related transaction that violates the CSA.¹⁰ Further, monetary transactions involving a violation of the CSA are separately criminalized under federal money-laundering statutes.¹¹ In short, the federal scheduling of cannabis results in possible federal criminal liability for all those who work to produce or sell cannabis products, who provide services related to cannabis products, or who handle funds from the production or sale of cannabis products, regardless of state law. This has created an unsustainable federalism clash, with the states operating in direct contravention of federal criminal law.

There has been significant movement cutting against this full federal prohibition. First, numerous states (thirty-three at the time of this writing), in direct conflict with federal law, have licensed cannabis sales and consumption. Second, the federal government began to protect some of these state regimes through guidance memos and language included in appropriation bills.¹² Third, Congress, first as a pilot program in the 2014 Farm Bill, and then permanently in the 2018 Farm Bill, bifurcated the legal status of cannabis, allowing for legal production and sale of products containing less than 0.3% THC (hemp) while keeping products with THC levels above 0.3% (marijuana) federally criminalized and classified as a Schedule I drug.¹³

These efforts have left cannabis in a unique and unsustainable legal status. Products containing THC are sold both for adult use and medical purposes

¹⁰ 18 U.S.C. § 2.

¹¹ 18 U.S.C. § 1956.

¹² Memorandum from James M. Cole, Deputy Attorney General, Guidance Regarding Marijuana Enforcement, (Aug. 29, 2013), <https://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf>.

¹³ 2018 Farm Bill, Pub. L. No. 115-334.



by state-licensed facilities, but they remain criminalized at the federal level. The federal government (through FDA) has approved the use of some drugs that contain cannabis derivatives or their synthetic equivalents (e.g., Marinol, Epidiolex), while regulatory restrictions on wide-scale cannabis research prevents many other potentially beneficial drugs from being developed. The 2018 Farm Bill descheduled a vast number of hemp-derived products, but regulations have not yet been completed by the U.S. Department of Agriculture (USDA) to govern hemp cultivation or by FDA to permit the production and sale of CBD products as foods or dietary supplements. And CBD derived from the marijuana plant (as opposed to the hemp plant) remains federally illegal, regardless of THC content, and notwithstanding the identical chemical composition derived from either source. FDA has been internally evaluating how to allow popular, widely consumed CBD products to be lawfully marketed, particularly for use in ingestible form. Comprehensive reform is needed to address all these issues and the many more that will arise during the transition from prohibition. The piecemeal approach that some in Congress are supporting will not solve the federalism problems and will not serve to support this burgeoning industry that has proven to be an essential revenue driver for the states that have allowed it to flourish.

Current Legislative Efforts

There have been scores of legislative efforts in Congress to change the current regulatory system for cannabis. Although none of them are as comprehensive as the plan we present here, they all continue the piecemeal process of liberalizing the cannabis laws of the country. Legislative proposals include highly publicized efforts like the Strengthening the Tenth Amendment Through Entrusting States Act (STATES Act), which would allow each state to determine how it wants to regulate adult-use and medical cannabis within its borders, and the Secure and Fair Enforcement Banking Act of 2019 (SAFE Banking Act), which would clarify that banks and financial institutions can provide services to the cannabis industry. There are also efforts to fully deschedule cannabis, such as the Marijuana Opportunity Reinvestment and Expungement Act (MORE Act) or the Marijuana Justice Act. State governments also continue to push efforts to legalize cannabis forward, with Illinois recently becoming the first state to allow for adult-use cannabis sales through legislative action, as opposed to ballot initiative.



NCIA supports all of these efforts as an intermediate step. However, merely rescheduling, providing access to banking, providing for state autonomy, or even removing criminal penalties at the federal level will continue to leave the industry in a precarious gray area. We need a plan to actively regulate production and sales of cannabis. NCIA therefore calls upon Congress, and the federal agencies referenced herein, to work to implement a comprehensive federal regulatory system that begins with descheduling cannabis.

Cannabis Products

Few plants have as many possible applications as cannabis. It is consumed and used for industrial purposes. It can be intoxicating. It can be medicinally therapeutic. It can be inhaled, ingested, and applied topically. But there are a few distinctions between these products that are important to note. Most importantly, we must differentiate between products consumed or otherwise ingested (hereinafter “consumable” products) and those that are not. These consumable products will be the focus of our proposal, given that our aim is to design a regulatory scheme for such products. While there are innumerable uses for industrial hemp fibers and other cannabis products, those uses fall beyond the scope of this regulatory plan.

Within the segment of consumable products, there are still important distinctions that should form the basis for different product regulatory frameworks. Cannabis products can be classified based on whether or not they are intoxicating, whether they are intended for a medical or therapeutic purpose, their cannabinoid concentration levels, consumption method, and myriad other ways. These distinctions are important in determining how each product should be regulated. Inhaling an intoxicating product raises much different policy concerns and requires a different regulatory system than applying a non-intoxicating infused lotion. In general, however, the level of regulation should be proportionate to the potential harm the product can cause and be adequately tailored to that product’s intended use.

Below, we present a proposed regulatory structure that encompasses consumable and non-consumable products, including:

- combustible/vaporizable products, like flower, trim, concentrates, and “vape pens”



- orally consumed products, like food or drinks infused with cannabis, pills and capsules, and concentrates intended for oral consumption
- skin and body products, like topicals and patches

Removing the Outdated Regulatory Structure

Cannabis is currently regulated under the CSA, which classifies drugs into five schedules depending on factors such as medical usage, potential for abuse, safety, and potential for forming dependence. Schedule I drugs are those with a high potential for abuse, no currently accepted medical use, and no accepted safe usage under medical supervision. Schedule II drugs are those that have a high potential for abuse and whose abuse may lead to severe psychological or physical dependence but that have a currently accepted medical use. Schedule III drugs are those that have less abuse potential than Schedule I or II drugs, whose abuse may lead to moderate or low physical dependence or high psychological dependence, and that have a currently accepted medical use. Schedule IV drugs have a lower abuse potential, have more limited dependence issues than Schedule III drugs, and have a currently accepted medical use. Schedule V drugs are those that have low abuse potential, have more limited dependence issues than Schedule IV drugs, and have a currently accepted medical use.¹⁴

Remarkably, marijuana and THC, except in low concentrations in hemp, are currently both classified as Schedule I drugs. This classification is plainly contrary to the facts. For instance, FDA has approved multiple cannabis-related therapeutic drugs, there is a lack of evidence linking cannabis to dependence, and there are no documented cases of overdose. The most direct path to resolve this misclassification is for Congress to act by descheduling cannabis and establishing a comprehensive regulatory framework.

While some politicians have called for rescheduling, that will create far-reaching problems and is unworkable as a solution. Removing all products derived from the cannabis plant from the CSA will lead to fairer outcomes and mirrors how similar products are currently being regulated. There are clear precedents as well: Most recently, the 2018 Farm Bill used this method when creating a regulatory structure for hemp. Similarly, alcohol and tobacco

¹⁴ See *supra* note 8.



have long been exempted from the CSA. This is because these products are not well-suited to regulation through the CSA model, notwithstanding their addictive properties and potential for harm.

Keeping marijuana and THC scheduled (even at a lower schedule) would only allow for the sale of any non-hemp-derived cannabis product through the current FDA-approved drug model. It would have dramatic negative consequences for the popular legal medical cannabis systems in thirty-three states. The practical result would be the destruction of the current medicinal and recreational cannabis industry and the resurgence of the illicit marijuana market.

Accordingly, the most efficient blueprint for cannabis regulation begins with descheduling, followed by the implementation of a series of product category-specific regulatory frameworks to deal with the unique policy concerns raised by each product category. In short, cannabis products have too many practical and medicinal uses to be regulated within the limited structure of the CSA and to face the continued specter of criminal enforcement by the DEA.

“Remarkably, marijuana and THC, except in low concentrations in hemp, are currently both classified as Schedule I drugs. This classification is plainly contrary to the facts.”

Removing marijuana from the CSA also solves many of the related issues plaguing the industry. It would remove restrictions under section 280E of the Internal Revenue Code, facilitate badly needed research into the medical benefits of cannabis, permit full access to banking and payment processing, end criminal sanctions to cannabis-related activities, and facilitate interstate commerce. Descheduling is therefore the most important first step and is a necessary precondition to any effective federal regulatory system.

Establishing a New Regulatory Framework

Americans enjoy the benefits of a broad federal regulatory system designed to promote public health and safety. Consumers benefit every time they take



a new prescription drug that FDA has approved or safely consume food that has passed through the USDA inspection process. To date, Americans who purchase cannabis products from state-regulated markets have not been able to enjoy those same benefits. Fortunately, however, this existing federal regulatory system encompasses enough diversity to sufficiently and adequately regulate all cannabis products, provided that certain regulatory and statutory adjustments are made.

Our proposed regulatory system involves existing agencies that will regulate different aspects of the process, ranging from cultivation to retail sales. Under this approach, cannabis products would be grouped into different regulatory lanes, each subject to targeted regulation to address the specific public policy issues raised by that particular group. The four proposed lanes are as follows:

- Lane #1 — Pharmaceutical drugs
- Lane #2 — Ingested, inhaled, and topically applied THC products (+0.3%)
- Lane #3 — Ingested and inhaled cannabinoid products with low/no THC
- Lane #4 — Topically applied cannabinoid products with low/no THC

Further, the proposed system would strive to maximize regulatory certainty and protect orderly markets. This includes creating baseline regulations to facilitate interstate commerce. Recognizing that the well-entrenched (and untaxed) illicit market is unlikely to disappear overnight with the creation of a legal market, regulators must be mindful of overregulation that undermines the efforts of participants in these regulated (and taxed) markets to produce safe products while competing against their unlicensed rivals. Efficiently regulating cannabis products, like similarly situated products, in a safe and consistent manner promises to hasten the demise of the illicit market supplying Americans with unregulated, untested products.

Lane #1 would include all products approved as pharmaceutical drugs by FDA. Products in Lane #1 would be regulated by FDA, and sales would take place through the existing pharmaceutical model, both by prescription and over the counter.



Lane #2 would include all products that are not regulated through Lane #1 and contain more than a de minimis amount of THC. These products would be regulated in a manner similar to alcohol, with TTB, FDA, and the states all having regulatory roles to play. Most products currently being sold through state adult-use or medical cannabis programs would be regulated through this lane.

Lane #3 would include orally consumed and inhaled cannabinoid products with minimal THC concentration. These products would be regulated by FDA in a manner similar to food and dietary supplements. Sales would be allowed anywhere food or dietary supplements are currently available without a special retail license requirement but subject to specific label requirements.

Lane #4 would include topically applied cannabinoid products with minimal THC concentration (e.g., topical lotions, creams, and balms). Like the products in Lane #3, these products would be regulated by FDA, and sales would be allowed where other cosmetics are sold without any special retail license.

This four-lane structure would allow for adequate controls and retail restrictions over products that have intoxicating effects, while allowing greater consumer access to non-intoxicating cannabinoid products. The two primary agencies recommended to regulate cannabis are FDA, which is part of the U.S. Department of Health and Human Services, and TTB, which is part of the U.S. Department of the Treasury. These agencies have extensive experience creating safe and predictable markets for regulated consumer products and are best suited for regulating cannabis.

FDA is the primary federal regulatory agency that oversees food (including food additives and dietary supplements) and drugs (both prescription and OTC). TTB regulates alcohol and tobacco, although FDA retains certain regulatory responsibilities for both products. While most consumable products fall under these agencies' jurisdiction, the agencies have different regulatory mandates. FDA ensures that food products are safe to consume and are properly labeled, and it verifies that drugs are adequately tested to ensure that they are safe and effective for their intended use. To that end, FDA works to prevent or stop the marketing of adulterated or misbranded foods and drugs. By contrast, TTB collects taxes on alcohol, protects consumers, combats the illicit alcohol market, and enforces liquor laws. It is worth noting that these regulators are



highly trusted by the public, which generally has high confidence in the quality of the American food and drug supply, and has little concern with bootleggers that sell illicit alcohol. Cannabis deserves the same level of effective regulation. And again, there is no reason to reinvent the wheel.

An illustrative example of the unique charges of the two agencies is the differences in their labeling requirements. FDA requires a declaration of ingredients on food products as well as a nutritional facts panel that consumers can use to understand the relevant nutritional value of the products, with information on such aspects as serving size, calories, fat content, and percentage of daily vitamins. TTB requires different label information on alcoholic beverages, including specific mandated warning language. Both labeling regimes inform the public about important attributes of a product based on the product's contents and intended use, but the form and content are tailored to the product category.

Social Equity

There are other regulatory goals that policymakers should incorporate into any new regulatory framework. Most notably, the federal government must prioritize opportunities for people of color in this developing industry. NCIA's Policy Council recently published a white paper entitled "Increasing Equity in the Cannabis Industry: Six Achievable Goals for Policy Makers."¹⁵ All of the goals from that paper are compatible with the regulatory framework presented here. We urge policymakers to heed the message of our paper and incorporate social equity priorities into any new regulatory framework.

¹⁵ *Increasing Equity in the Cannabis Industry: Six Achievable Goals for Policy Makers*, NCIA (Mar. 2019), <https://thecannabisindustry.org/reports/increasing-equity-in-the-cannabis-industry-six-achievable-goals-for-policy-makers/>.



LANE #1: Pharmaceutical Drugs

- Products: Products approved as pharmaceutical drugs by FDA
- Regulator: FDA
- Model: Pharmaceutical drugs
- Policy goal priorities: Public health; consumer protection
- Retail locations: Drugstores—by prescription or over the counter
- Health-related claims: Detailed disease claims allowed

Lane #1 would require no modification to existing law other than descheduling marijuana and THC to allow for robust research and development and to decriminalize possession of the plant. The sole federal regulator for this lane would be FDA.



In fact, there is already a regulatory path that enables cannabis products to legally make it to market in this lane. But at present, that regulatory path is hindered by restrictions on research due to the current scheduling of cannabis. Though FDA has approved a handful of cannabis-derived products or their synthetic equivalents

as drugs, including Epidiolex, Marinol, and Cesamet, the research to secure approval was unnecessarily challenging because of cannabis's current CSA schedule. That said, this cannot be the sole lane for cannabis products to reach the market, particularly given that the drug approval process is expensive and complex. In 2016, the Journal of Health Economics estimated the average cost per approved drug at well over \$1 billion.

Products in Lane #1

If a cannabis product is approved by FDA as a drug, it would be sold through this lane in a manner that is consistent with any other FDA-approved drug. Lane #1, like the regulatory lanes governing other pharmacologically active compounds and concentrations that have received FDA approval, would supersede all other regulatory lanes for cannabis-derived products that are



intended to treat, cure, prevent, mitigate, or diagnose a disease. Because product approval through this lane is a function of well-established medical and scientific principles, there are no additional content or concentration restrictions in Lane #1 beyond those specified as a condition of approval.

Policy Areas Implicated in Lane #1

FDA is best situated to promote the primary policy goals of this lane: promoting public health by unleashing the potential of the cannabis plant through research and protecting the health and safety of consumers.

This lane provides an opportunity to market cannabis products that, having been approved through a rigorous scientific process, can make disease claims. Once approved, cannabis products can be marketed, sold, and consumed to address specific diseases or ailments consistent with the terms of FDA's approval and current restrictions governing off-label use. Because of the rigorous approval process, this system protects public health by preventing businesses from making false or unsubstantiated disease claims. As a result of the need to achieve these important policy goals and protect consumers, this lane is heavily regulated and requires significant cost outlays for companies trying to bring a product to market that wish to make disease claims. We nevertheless recommend adopting this process for Lane #1 because the FDA approval process facilitates public trust that a cannabis product marketed as a drug has been approved as safe and effective for its intended use.

“Regulation of cannabis products under Lane #1 would be no different than the current FDA drug approval process for non-cannabis products.”

An important benefit of proceeding entirely within the current regulatory structure is that these products would go to market under an orderly system that operators and consumers understand. The market is stable, companies understand how to operate within the system, and customers are familiar with purchasing FDA-approved drugs. Moreover, this lane offers access to consumers for these cannabis drug products. Consumers will be able to access these drugs through their existing local pharmacy network and can obtain coverage for them alongside other comparable FDA-approved drugs through their health insurance plan.



What Regulation Would Look Like Under Lane #1

Regulation of cannabis products under Lane #1 would be no different than the current FDA drug approval process for non-cannabis products. FDA regulates the safety and efficacy of drugs. This includes premarket review and approval and postmarket monitoring to ensure that a drug is safe. FDA exercises ongoing jurisdiction while the drug is sold.

The FDA approval process normally begins with testing in the laboratory setting. A prototype is developed and the pharmaceutical or biotechnology company submits an Investigational New Drug (IND) application. If this is authorized, the company can then begin testing the product on humans through a series of clinical trials. Three phases of clinical trials are required, with increasing numbers of patients in each subsequent phase. Information collected through the trials is submitted to FDA as a New Drug Application (NDA).

The NDA is reviewed by FDA with a focus on (1) the safety and efficacy of the drug's proposed use; (2) the appropriateness of the proposed labeling; and (3) the adequacy of manufacturing methods to assure the drug's identity, strength, quality, and purity. There are certain limited pathways for some drugs to be approved faster, but generally the process from initial research through final approval is difficult, time-consuming, and expensive.

After approval, the drug may be sold in the United States, but it remains subject to heavy oversight by FDA. The sale of many FDA-approved drugs requires a prescription from a doctor, but some drugs are approved for OTC sales. Whether prescription drugs or OTC drugs are at issue, FDA retains and exercises its authority to oversee product integrity, labeling, adverse event reporting, and advertising through product and facility registrations, inspections, chain-of-custody documentation, mandatory reporting requirements for adverse events, updates to labels and product inserts, and other post-approval monitoring and enforcement efforts.

As noted above, some cannabis-derived products and their synthetic analogues have received approval under this system. We expect that many more pharmaceutical products will be developed after cannabis is descheduled. The main barrier to cannabis products through the pharmaceutical lane so far has been cannabis's Schedule I status. The Schedule I classification has



prevented the research and development necessary at the early stages to lead to IND applications, which in turn lead to NDAs. Removing these restrictions will allow research and development that will directly lead to new approved drugs containing THC, CBD, and other compounds found in the cannabis plant.

OTC monographs offer an alternate path for the marketing of cannabis drug products. An OTC monograph sets out standards for the marketing of an OTC drug that is not covered by a new drug application and specifies the permissible active ingredients and labeling (including indications for use). Through the submission of a petition, FDA can be asked to amend a monograph to add ingredients and new indications for use.

LANE #2: Ingested, Inhaled, or Topically Applied THC Products

- Products: All ingested, inhaled, or topically applied products with THC levels above the federally allowable hemp limit that are not otherwise approved as drugs by FDA through Lane #1
- Regulators: TTB, FDA, and state regulatory authorities
- Model: Alcohol
- Policy goal priorities: Public health; public safety; eliminating the illicit market; regulatory certainty and efficiency; and revenue and tax generation
- Retail locations: Allowed only in state-licensed locations
- Health-related claims: State lists of qualifying conditions remain in place; structure/function claims and general wellness claims are allowed under state law for medical cannabis products sold through state-licensed dispensaries

Cannabis products containing more than de minimis levels of THC have stood at the center of debate around reform. It is clear that access to safe and regulated products containing THC has served as an important driver of the cannabis reform movement sweeping the nation. Given the potential for intoxication from use of products that contain THC, the regulatory structure for these products would largely follow the alcohol model. That system also was designed to transition a widely consumed intoxicating product from a robust illicit market to a legal marketplace while protecting public health. And that system succeeded by any measure: today, bootlegging and concerns over the source of alcohol products have largely been consigned to the dustbin of history.



Of course, ending cannabis prohibition is not identical to ending alcohol prohibition, and certain necessary modifications are addressed below. However, many of the larger regulatory concepts would remain the same. Producers, processors, and wholesalers would be regulated at the federal level by TTB. FDA would have a secondary role in Lane #2 regulation (as it does with alcohol), exclusively focused on public health. Age restrictions and retail sales location restrictions would be imposed and enforced by state and local governments.

Products in Lane #2

Lane #2 would encompass all of the products that contain THC at a concentration above that of “hemp” (as defined in the 2018 Farm Bill) and that are not otherwise approved as drugs by FDA through Lane #1. These would include inhalables (flowers, concentrates, etc.), edibles, other ingestible products, and topically applied products with elevated concentrations of THC. Congress has already defined a THC concentration dividing line in the 2018 Farm Bill between hemp and cannabis: hemp is defined as the cannabis plant or any parts or extracts thereof with a THC concentration of “not more than 0.3 percent on a dry weight basis.”¹⁶ This lane would contain all products with more than a de minimis level of THC.



As a result, this lane would contain most of the products sold under the state adult-use and medical cannabis systems. Under this regulatory structure, what today exists as adult-use and medical products would be treated the same through the cultivation, processing, and wholesale phases. These products would be produced, tested, and labeled in a manner similar to that currently allowed under state regulations, and medical cannabis could be prescribed consistent with existing lists of qualifying conditions maintained by the states. Where distinctions remain between these state adult-use and medical cannabis systems, namely tax rates and permissible claims, they are addressed below.

¹⁶ 2018 Farm Bill, Pub. L. No. 115-334, 132 Stat. 4908.



Policy Areas Implicated in Lane #2

The century-long prohibition on cannabis has created a major competitor: the illicit market. The illicit market will not evaporate merely because the government deschedules cannabis. The legal market needs to compete with this market on price and access. A legal cannabis market that is properly regulated with sufficient product quality, access, and price will keep cannabis consumers out of the criminal justice system and put illicit cannabis sellers out of business. The regulatory structure should be set up to continue to protect public safety by emphasizing policies that will reduce ancillary criminal activity. Likewise, by reducing consumption of untested, unregulated products from the illicit market, public health is simultaneously promoted.

Successful development of a regulatory lane for these products is essential to achieving key policy goals: promoting public health, improving public safety, eliminating the illicit market, creating regulatory certainty and efficiency in the legal market, and generating public revenues, both direct and indirect.

To promote public health, the system should be designed to keep adulterants and harmful substances out of consumable products. Notably, unlike in Lanes #3 and #4, THC above 0.3% would not be a prohibited adulterant in Lane #2. As with other products with potentially intoxicating properties, appropriate warning labels should be developed and retail locations should be licensed by the state.

This well-regulated, efficient regulatory lane will also promote interstate commerce by developing certain universal standards applicable to the production and sale of cannabis. Through Lane #2, policymakers can impose labeling restrictions, age restrictions, and other reasonable limits on consumption. Consumers will soon familiarize themselves with standard warnings, symbols, and instructions so they can properly identify products and understand the effects and the potential dangers of consumption. To be explicit, state control over the retail tier will permit each state to restrict sales in ways that reflect the wishes of the local community. National standards nevertheless play an important role in facilitating interstate commerce.

Finally, this lane should allow for revenue collection to fund this regulatory system and other important public policy goals, including social equity. We



recognize that the other non-cannabis products regulated in this manner are subject to an excise tax. While we do not attempt to determine an appropriate level of taxation, the amount set should account for the following realities. First, the level of taxation should be sufficient to cover the costs of a new federal regulatory system. Second, unlike many other industries, legal cannabis sales are competing directly with an entrenched illicit market in which participants do not pay any taxes—they avoid paying not merely excise taxes but also taxes on corporate profits and taxes on employee wages. Taxes imposed therefore should be calibrated so that legal cannabis is cost-competitive with the illicit market, including existing state-specific cannabis taxes. None of these public policy goals can be accomplished if the illicit market is not displaced, and that will not happen if consumers do not transition to the legal market because prices are too high. One important caveat to this revenue-generating system is that we recommend that products intended for state-medical cannabis systems should be excluded from this excise tax at the federal level.

Importantly, this model has a clear precedent for success. As with alcohol regulation, which successfully transitioned most illicit alcohol commerce to the legal market, this model will help consumers, operators, and law enforcement agencies better navigate the new regulatory landscape.

What Lane #2 Regulation Would Look Like

Lane #2 would use alcohol as a regulatory model and leverage the state regulatory systems that already exist.¹⁷ State officials would still have an important role in regulating cannabis. Here, Congress would provide TTB with the authority to regulate products containing more than de minimis levels of THC that are not included in the Lane #1 approval process. TTB has the expertise to hit the ground running here. TTB already enforces the Federal Alcohol Administration Act (FAA Act), which involves permitting certain businesses in the alcohol industry, collecting taxes, approving truthful labels, performing inspections and audits, regulating imports, and ensuring that only “qualified persons” work in the industry. As with cannabis, this system was designed to

¹⁷ While we recognize that FDA has the authority under the Family Smoking Prevention and Tobacco Control Act (“Tobacco Control Act”) (Pub. L. 111-31) to regulate products made or derived from tobacco and intended for human consumption, we do not believe that cannabis-derived products in any of the categories outlined in this paper should be regulated akin to tobacco-derived products for numerous reasons. By way of example, the findings made by Congress in Section 2 of the Tobacco Control Act (which provides the rationale for granting FDA the authority to regulate tobacco products and serves as the basis for the Act’s ensuing requirements) are specific to tobacco use (and the tobacco industry generally) and are inapplicable to the cannabis-derived product space. Moreover, tobacco-derived products are highly addictive because of the drug substance nicotine naturally found in the tobacco plant. Cannabis and cannabis-derived products, on the other hand, do not contain nicotine and are generally non-addictive. Third, cannabis and cannabis-derived products have the potential to produce intoxicating effects, depending on the presence and level of THC found within the product. Whereas, these intoxicating effects are generally not associated with tobacco-derived products. For these reasons, we believe that cannabis-derived products warrant different regulatory treatment than products made or derived from tobacco, and that any additional authority granted to FDA to regulate cannabis-derived products acknowledges these distinctions.



regulate a product emerging from prohibition, with a particular emphasis on shifting sales from a robust illicit market to a legal but regulated market. Many of the methods used by TTB to regulate alcohol would be applicable to the regulation of intoxicating cannabis products and should be adopted.

In this proposal, TTB would be supported by FDA in a manner similar to the alcohol model. The two agencies have previously entered into memoranda of understanding delineating their relationship for regulating alcohol, and we recommend that Congress direct them to enter into a similar agreement for cannabis regulation. For cannabis products in Lane #2, FDA would play the same role that it performs in alcohol regulation: protecting public health by registering production facilities, performing inspections in accord with standards most directly applicable to the product, evaluating the safety of non-cannabis-derived ingredients, and monitoring for adulterants. States would continue to regulate the composition and potency of cannabis-derived ingredients.

Licensing: All producers, manufacturers, and wholesalers of products regulated under this lane would have to receive a permit from TTB. Producers and manufacturers would also have to register with FDA. Retail facilities would not have to register with the federal government and would be regulated solely at the state and local level.

The permitting systems for cannabis products and for alcohol products under TTB would be very similar. In both cases, the state would set minimum conditions for persons eligible to hold these permits. There would be no limit on how many permits could be issued. Facilities would then be subject to safety inspections.

All facilities producing or manufacturing cannabis products would also be required to register with FDA. This allows FDA to know where human consumables are being produced. FDA would have the authority to inspect these facilities for compliance with the most directly applicable manufacturing requirements and to monitor products for harmful adulterants. The law would clarify that no substance derived from the cannabis plant could be considered an adulterant for products sold through Lane #2.



Retail Sales: Intentionally absent from the proposed federal permitting system are retail locations. In this system, the federal government would not issue permits for retail locations. Instead, each state that chooses to permit product sales through Lane #2 would develop a permitting structure for retail sales. This is consistent with how alcohol is regulated and allows each state flexibility and autonomy. States would have the ability to develop regulations to limit sales, make decisions about the location of sales establishments, impose purchase limits, etc. This split system, with the states regulating retail and the federal government and the states regulating all of the upstream commerce, strikes an important balance between providing clarity for businesses while respecting state laws and local political conditions.

Labeling: Label regulation for alcohol is one of the primary functions of TTB, and it would fulfill that role for cannabis as well. Here, TTB would ensure that labels are accurate, do not mislead the public, provide adequate information about the contents and quality of the product, and are regulated for other qualities determined by policymakers (e.g., prohibiting obscenity).

In addition to the standardized labels, TTB would have authority to create a standardized warning label and universal THC symbol to affix to all products. This standardization is of great importance for interstate commerce because it enables companies to move products from state to state without having to comply with fifty distinct labeling requirements.

We propose one major change from the alcohol labeling system, however. The current alcohol labeling system requires preapproval of all labels before a product can be sent to market. This system was designed for a different technological era and a different industry. With today's rapid communication networks and the diversity of cannabis products that will be entering the market, a preapproval process would unnecessarily overburden regulators without providing any additional benefit to consumers. Rather, we propose a system in which the agency issues detailed guidance on labeling as well as a standardized warning label, a universal symbol, and a standard template for information on ingredients and potency. Then the producer or manufacturer can release the products to market without preapproval but must submit a copy of the label to TTB. Businesses can then begin selling the product into the market, but if TTB finds that the label violates agency guidance, it may require the company to revise the label and, for egregious violations or



potentially harmful misrepresentations, may order an immediate recall of all products bearing that label. TTB may also conduct periodic audits to ensure accuracy.

Taxation: Under this proposal, a federal excise tax could be imposed at the retail level on all nonmedical products. While we remain silent on the level of taxation, we again emphasize that the legal cannabis market is directly competing with an unregulated and untaxed illicit market. While taxes should be sufficient to cover the necessary regulatory structure, the rate should be kept reasonable to allow legal cannabis to compete against the illicit market. We further propose that products sold through this lane’s state-regulated medical retail outlets be exempt from federal tax.

Product Safety: Under our proposal, TTB and FDA would work in tandem to protect public health. FDA currently oversees a wide range of ingested and inhaled products that could be infused with cannabis. While TTB would have authority over the “cannabis” side of these products, FDA would have shared regulatory authority over product safety. TTB would consult with FDA regarding the safety of non-cannabis ingredients. FDA would be responsible for inspecting production facilities to ensure that they follow the most directly applicable standards, including but not limited to Good Agricultural Practices (GAPs), Good Manufacturing Practices (GMPs), and/or preventive controls.¹⁸ Further, FDA would supervise recalls of products that pose a health risk; however, any recall would be made in concert with TTB given TTB’s primary enforcement powers.

Health-Related Statements: Most products regulated by TTB are not permitted to make health-related claims. However, the unique status of cannabis makes this default position untenable, and certain health-related claims should be allowed for a limited subset of Lane #2 products as permitted under state law. These claims would also be strictly limited to avoid consumer confusion with products sold through Lane #1 and would mirror the health-related claims that makers of dietary supplements can make regarding their products.

We recommend this regulatory carve-out because, as mentioned earlier, thirty-three states and the District of Columbia have adopted medical cannabis programs. Countless patient testimonials and doctor recommendations credit

¹⁸ Federal legislation would be needed to authorize FDA to establish GMPs for inhalable products. As an alternative, industry could develop and implement model GMPs, ideally in consultation with FDA and its state counterparts.



cannabis with health benefits. Today, millions of patients rely on cannabis for health purposes, but because of federal prohibition, this medical cannabis system grew independently from the traditional FDA-regulated drug system. When dismantling the prohibition-era policies, care should be taken to avoid destroying the systems that have flourished in the majority of the states.

Cannabis products regulated in Lane #2 would continue to be prescribed in accord with lists of qualifying conditions maintained by the states. In addition, manufacturers could make certain limited health-related claims if permitted under state law, provided those products are sold through a state-licensed medical cannabis dispensary. The claims allowed, like those for dietary supplements, would be structure/function claims and general wellness claims. As with dietary supplements, these products would include a disclaimer on their labels stating that FDA has not evaluated the accuracy of the claim. To be clear, no products could claim that they could diagnose, cure, mitigate, treat, or prevent a specific disease, and products would be misbranded if they made any such claims. Such claims could only be made for products approved through Lane #1.

“Today, millions of patients rely on cannabis for health purposes, but because of federal prohibition, this medical cannabis system grew independently from the traditional FDA-regulated drug system.”

Inapplicable Alcohol Regulations: There are provisions of TTB’s alcohol regulations designed to target particular issues facing the alcohol industry. Those should not be applied reflexively to the cannabis industry. One such regulation is the mandatory “three-tiered system.” The federal government requires, in most cases, that alcohol producers sell their products to wholesale distributors, who then sell to retailers. This requirement emerged from circumstances unique to alcohol prohibition, and imposing it upon cannabis businesses would not further the public policy goals summarized here. Today, states have engaged in a broad federalist experiment to determine the optimal tiered structure for cannabis regulation. Many states have adopted a distribution tier, and many have not. Accordingly, wholesale distributors should be allowed and permitted, but they should not be required.



Another issue that TTB addresses in the alcohol context (that should not be imposed on the cannabis industry) is the “tied house” prohibition. Tied house rules prohibit breweries from having exclusivity contracts with drinking establishments, effectively prohibiting vertical integration. These rules were imposed in an effort to stop aggressive practices of certain large breweries that are not applicable to the cannabis context. In fact, many states have required cannabis companies to be vertically integrated. With a recognition that Congress and TTB could revisit these issues in the future if necessary, we recommend that tied house rules not be adopted at present.

LANE #3: Ingested and Inhaled Cannabinoid Products with Low/No THC

- Products: Cannabis products with de minimis THC sold as food and food ingredients (including dietary supplements and dietary ingredients) in various forms (including tinctures and capsules), as well as non-intoxicating (e.g., CBD) inhaled products
- Regulator: FDA
- Model: Food and dietary supplements
- Policy goal priorities: Public health; regulatory certainty and efficiency; consumer protection
- Retail locations: Wherever food and dietary supplements are sold; no further restrictions
- Health-related claims: Health claims and structure/function claims for dietary supplements and foods, consistent with existing requirements

Lane #3 would govern the large number of ingested and inhaled products that are hitting shelves around the country containing CBD, hemp extract, and other low-THC cannabis compounds. Since the passage of the 2018 Farm Bill, FDA has begun working to identify how to properly regulate these products. Due to various restrictions (discussed below), many of these products are not currently able to flow smoothly through this lane and to market. Statutory changes should be made to help allow these products, which are non-intoxicating and provide myriad nutritional and health benefits, to safely reach the public.

Numerous non-intoxicating cannabinoids such as CBD, CBN, THC-A, and THC-V may be derived from either the marijuana plant or the hemp plant. The 2018 Farm Bill created an arbitrary dividing line between marijuana and hemp based entirely on THC concentration. This has resulted in an overregulation



of popular non-intoxicating products based on the THC level of the plant source material instead of the THC level of the finished product. We propose remedying this problem by classifying any final product containing less than 0.3% THC within Lane #3, rather than focusing on the THC content of the plant source material or any intermediate product.

This lane encompasses products that would be regulated as food for humans (including dietary supplements), food for animals, and products that are inhaled. The regulatory scheme should reflect the low risk associated with these products.



The exact regulatory requirements would depend on the intended use and whether any health-related claims are made. FDA would serve as the federal regulator for this lane.

Products in Lane #3

Many of the products included in this lane are already governed by the current federal definitions of the terms “food” at 21 U.S.C. § 321(f), “food additive” at 21 U.S.C. § 321(s), and “dietary supplement” at 21 U.S.C. § 321(ff).¹⁹ Though FDA does not currently regulate non-nicotine vaporized products as such, those products would also fall into this category of relatively benign products.

The federally mandated Current Good Manufacturing Practice (cGMP) rules for both foods and supplements already require goods in these categories to take measures to prevent hazards or contamination that may adulterate a product, through the implementation of preventive controls and good manufacturing practices, as applicable. Testing is an important means of ensuring that specifications are met and that hazards are controlled, and it will help ensure that these products are not intoxicating. All of the regulating responsibilities under this lane with respect to ingested products fall under the purview of FDA and existing state agencies that ensure food safety. Federal legislation would be needed to (1) grant FDA authority over inhalable products, and (2) establish parameters for permissible claims for such products.

¹⁹ Lane #3 includes food products for humans and animals. The definition of food, pursuant to 21 U.S.C. § 321(f), includes food for humans and “other animals.”



Under certain circumstances, existing law prohibits the use in foods and supplements of approved drugs or investigational drugs that are undergoing clinical trials. FDA’s interpretation of this law has created a regulatory barrier for products in Lane #3 that contain CBD because CBD is the active pharmaceutical ingredient in an approved drug (Epidiolex). Although FDA has recognized that certain hemp-derived ingredients can be added to food, none of those ingredients contain more than trace levels of CBD. FDA has expressed its intention to consider creating a regulatory “pathway” for the use of CBD in foods and supplements but has also recognized that congressional action could resolve this issue. Similar regulatory or statutory pathways should also be facilitated for other non-intoxicating cannabinoids such as CBN and CBG. Once these issues are addressed, this lane will require the fewest modifications to the existing structure for regulation of ingested products.

In the interim, responsible marketers of non-intoxicating products that contain hemp and hemp-derived ingredients, including CBD, should operate as if the existing regulatory structure governed their operations. For example, each such company should be registered with FDA as a food facility; its manufacturing operations must comply with the relevant cGMP rule(s); product labels must refrain from making any disease claims, conform to the relevant nutrition labeling regulation (i.e., with Nutrition Facts for foods and Supplement Facts for supplements), and disclose major food allergens, if present; safety obligations must be met for any substance in a food (through food additive or “generally recognized as safe” (GRAS) provisions) or for any new dietary ingredient in a supplement (through the “new dietary ingredient” (NDI) notification process, if applicable); and supplement marketers must submit to FDA required information about any serious adverse event report they receive in association with their products.

Under this proposal, any product in this lane would be considered adulterated if it contains a THC concentration greater than 0.3%. There are already cannabis products regulated through this lane, including hemp seed and hemp seed oil.

Policy Areas Implicated in Lane #3

Public health is the primary policy concern for products in Lane #3, as it is for all the other lanes. This lane includes products ingested for nutritional purposes, to supplement a person’s diet, and to promote general wellness.



The regulations adopted by FDA should facilitate these products entering the market without bureaucratic hurdles, and an emphasis should be placed on allowing members of the public to make informed decisions about the products that they consume. Thus, a well-functioning regulatory system that provides clear guidance for appropriate claims provides an important benefit for producers and consumers alike.

There is no justifiable public health policy reason to continue restricting access to these products beyond the standard restrictions for food and dietary supplements. Moreover, foods and dietary supplements have a long-standing regulatory system built upon best practices that consumers know and trust to keep them safe. Given the limited public safety concerns regarding these products and the absence of an entrenched illicit market, it is critical to narrowly tailor regulations to legitimate public health concerns and avoid overly burdensome regulations that would prevent the United States from being competitive in the emerging global market for these popular products.

With respect to inhalable products, standards would have to be developed to make sure that such products do not contain toxic substances at levels that could pose a health hazard and that they are manufactured in such a way as to help ensure product safety and quality.

“There is no justifiable public health policy reason to continue restricting access to these products beyond the standard restrictions for food and dietary supplements.”

What Lane #3 Regulation Would Look Like

Ingested Products

FDA ensures the safety of food through enforcement of the Federal Food, Drug, and Cosmetic Act (FFDCA). This enforcement is designed to protect public health and involves regulating the products and ingredients that enter the food supply, including dietary supplements, which are subject to some additional requirements.



Before substances can enter the food supply, the FFDCRA requires that they be demonstrably safe. In general, there are two ways in which a substance can be lawfully used in conventional food (as opposed to dietary supplements): (1) its use is determined to be GRAS by virtue of common use in food prior to 1958 or through scientific procedures, or (2) its use is approved as a food additive by FDA before it goes to market.²⁰

Dietary supplements have a related but slightly different regulatory system. A dietary supplement is a product that contains one or more dietary ingredients such as a vitamin, mineral, or botanical and that is used to supplement the diet. If a dietary supplement includes a “new dietary ingredient” (NDI), which is defined as a dietary ingredient not marketed in the United States before October 15, 1994, that NDI must be present in the food supply as an article used for food in a form in which the food was not chemically altered, or it must be the subject of a notification submitted to FDA at least 75 days prior to marketing a dietary supplement containing the NDI. The notification must provide the basis for the manufacturer’s conclusion that the NDI will reasonably be expected to be safe when used under the conditions recommended or suggested in the labeling of the dietary supplement.

The current FDA position is that many cannabis products cannot be sold as food or dietary supplements due to statutory restrictions. A substance cannot be added to food or marketed as a dietary supplement if the substance is already an active ingredient in an approved drug or if it has been authorized for investigation as a new drug, substantial clinical investigations have been instituted, and the existence of those investigations has been made public (the “drug exclusion rule”).²¹ Because cannabis products are already being sold through Lane #1, FDA has interpreted the drug exclusion rule to prohibit CBD products from being marketed as food or dietary supplements.²² There is an exception to this rule for products with a prior history of marketing as food or supplements (the “prior use exception”), but FDA has stated that CBD does not currently meet that exception without additional substantiation.

FDA does have the authority, upon notice and public comment, to promulgate a regulation allowing CBD products to be marketed as food or dietary supplements. Indeed, FDA Principal Deputy Commissioner Amy Abernethy,

²⁰ Overview of Food Ingredients, Additives & Colors, IFIC and FDA (Apr. 2010), <https://www.fda.gov/food/food-ingredients-packaging/overview-food-ingredients-additives-colors>.

²¹ 21 U.S. Code § 331.

²²*Id.*



M.D., Ph.D., clarified in a July 2019 letter that the agency is committed to evaluating the regulatory framework for non-drug uses of CBD, including products marketed as foods and dietary supplements. Dr. Abernethy acknowledged that the statutory provisions behind the drug exclusion rule “allow the FDA to issue a regulation creating an exception, and some stakeholders have asked that the FDA consider issuing such a regulation to allow for the marketing of CBD in conventional foods or as a dietary supplement, or both.”²³ She further acknowledged that this process would likely involve determination of a threshold CBD level that could appropriately be considered safe for foods and dietary supplements.

“In the absence of prompt action by FDA, we recommend that Congress act to clarify the status of these products.”

Former FDA Commissioner Scott Gottlieb, M.D., previously expressed similar opinions. He testified in February 2019 before the U.S. House Appropriations Committee that CBD could potentially exist “in a high concentration, pure formulation as a pharmaceutical product” while also existing at lower concentrations in products that could be sold as foods and dietary supplements.²⁴ More recently, in an article published in The Washington Post on July 30, 2019, former Commissioner Gottlieb also acknowledged the ability of FDA to “approve the sale of some CBD products immediately, while effecting a framework for their safe and proper regulation and a pathway for an enforceable market for these goods.”²⁵ This would involve a combination of manufacturers providing new ingredient submissions and FDA exercising enforcement discretion to allow CBD to be marketed in food and supplements so long as the products meet certain conditions. Former Commissioner Gottlieb further acknowledged that “Congress can help by passing language saying that the FDA doesn’t need to issue a broad regulation on CBD and can instead rely on petitions filed by individual, prospective producers.”²⁶

In the absence of prompt action by FDA, we recommend that Congress act to clarify the status of these products. There is immense public desire for these

²³ Amy Abernethy & Lowell Schiller, *FDA is Committed to Sound, Science-based Policy on CBD*, FDA (July 17, 2019), <https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/fda-committed-sound-science-based-policy-cbd>.

²⁴ Kyle Jaeger, *FDA Head Reveals New Details About Agency’s CBD Regulation Plans*, Marijuana Moment (Feb. 27, 2019), <https://www.marijuanamoment.net/fda-head-reveals-new-details-about-agencys-cbd-regulation-plans/>.

²⁵ Scott Gottlieb, *The CBD craze is getting out of hand. The FDA needs to act.*, Washington Post (July 30 2019), https://www.washingtonpost.com/opinions/the-cbd-craze-is-getting-out-of-hand-the-fda-needs-to-act/2019/07/30/94c8024c-b211-11e9-8f6c-7828e68cb15f_story.html?noredirect=on.

²⁶*Id.*



products, and numerous clinical studies have shown that CBD is safe and well-tolerated in humans, even at very high (> 30 mg/kg/day) doses. This dose is approximately equivalent to 2,800 mg per day for the average adult male, 2,000 mg per day for the average adult female, and 550 mg per day for the average child. In humans, CBD exhibits no effects indicative of any abuse or dependence potential.^{27, 28, 29, 30}

It is important to recognize that, but for federal prohibition, many of these products would very likely have proceeded to market many years ago and thereby qualified for the prior use exception. Accordingly, congressional action should be taken to accomplish the following:

- Clarify that non-intoxicating products derived from the marijuana plant should be treated the same way as non-intoxicating products derived from the hemp plant, so long as the final product contains no more than 0.3% THC;
- Clarify that CBD and other non-intoxicating cannabinoids are not prohibited from being marketed in or as dietary supplements solely because they are the subject of clinical trials conducted under an IND or have been approved for use as new drugs;
- Clarify that CBD and other non-intoxicating cannabinoids are not prohibited from being added to food solely because they are drugs that have been the subject of clinical trials or have been approved for use as new drugs; and
- Require periodic audits of cannabis products sold through this lane for label accuracy.

After Congress takes this action, these cannabis products would be regulated like any other food or dietary ingredient, which would require the following:

Registration and Inspection: All food facilities must register with FDA. This would include all facilities that manufacture, process, pack, or hold Lane #3 products products destined to enter the food supply. These facilities would

²⁷ Orrin Devinsky, et al., *Randomized, dose-ranging safety trial of cannabidiol in Dravet syndrome*, 90 *Neurology* e1204 (Apr. 3, 2018).

²⁸ Kerstin Iffland & Franjo Grotenhermen, *An Update on Safety and Side Effects of Cannabidiol: A Review of Clinical Data and Relevant Animal Studies*, 2.1 *Cannabis Cannabinoid Research* 139 (2017).

²⁹ Mateus Machado Bergamaschi, et al., *Safety and Side Effects of Cannabidiol, A Cannabis sativa Constituent*, 6 *Current Drug Safety* 237 (2011).

³⁰ Linda C. Laux, et al., *Long-term safety and efficacy of cannabidiol in children and adults with treatment resistant Lennox-Gastaut syndrome or Dravet syndrome: Expanded access program results*, *Epilepsy Research*, Aug. 2019, at 13.



then be subject to inspection by FDA and all of the current food quality and safety regulations.

Product Approval: For a substance to enter the food supply, its use must be (1) determined to be GRAS; or (2) allowed pursuant to a food additive regulation promulgated by FDA. Most substances that enter the food supply go through a GRAS determination. Some cannabis products like hemp seed, hemp seed oil, and hulled hemp seed have already been determined to be GRAS with no objection from FDA. That pathway should be available for these products as well.³¹

A GRAS determination is typically made by a company, sometimes with the help of outside consultants or organizations. That determination can then be voluntarily communicated to FDA. In response, the agency can issue a “letter of no objection” or a letter that raises questions about the determination. The congressional action recommended above would enable such notifications to be voluntarily submitted to and considered by FDA, because they would not be rejected solely because of the ingredient’s presence in an investigational or approved drug. This approach will allow research to continue without foreclosing the possibility that these hemp derivatives could be used in or as food. Similar congressional action could also enable NDI notifications to be submitted to and considered by FDA, notwithstanding an ingredient’s presence in an investigational or approved drug.

Product Safety: FDA requires all facilities to follow certain manufacturing standards intended to ensure safety and quality. These standards would apply to all Lane #3 products. There are different GMP standards for food and dietary supplements. Applicable standards would depend on the nature, type, components, marketing, and intended use of the product. These GMP standards ensure that final products do not include the wrong ingredients or contaminants, bear improper labeling, etc.

³¹ Currently, most GRAS determinations are based on scientific procedures (as opposed to experience based on common use in food prior to 1958). Scientific procedures include the application of scientific data (including, as appropriate, data from human, animal, analytical, or other scientific studies), information, and methods, whether published or unpublished, as well as the application of scientific principles, appropriate to establish the safety of a substance under the conditions of its intended use. Note that general recognition of safety may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food. General recognition of safety requires common knowledge throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food that there is reasonable certainty that the substance is not harmful under the conditions of its intended use. General recognition of safety based upon scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of a food additive. Further, it must be based upon the application of generally available and accepted scientific data, information, or methods, which ordinarily are published, as well as the application of scientific principles. See 21 C.F.R. §§ 170.3(h), 170.30(a-b).



Labeling: Food and dietary supplements are both subject to detailed labeling requirements. Product labels must include a statement of identity, state the net quantity of contents, provide nutrition information (i.e., with Nutrition Facts for foods and Supplement Facts for supplements), declare ingredients, and disclose major food allergens. A cannabinoid or other cannabis-derived substance included in a product would be listed as an ingredient. Products marketed as dietary supplements are subject to additional requirements. These include the provision of a standard disclaimer coupled to structure/function claims.

Health Claims: There are similarities and differences between food products and dietary supplements with regard to the distinct types of health-related claims that can be made about each product. Neither type of product can bear a claim to diagnose, cure, mitigate, treat, or prevent a specific disease. However, both products can bear a health claim (meaning a claim that characterizes the relationship between a nutrient and a disease or health-related condition), provided that the claim has been approved by FDA or FDA has been notified of it. More specifically, health claims are allowed if FDA “determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.”³² Health claims are also allowed based on statements from federal scientific bodies. Qualified health claims may be allowed based on lesser scientific evidence if authorized by FDA.

In addition, both types of products can bear a structure/function claim (meaning a claim of an effect on a structure or function of the body). In the case of dietary supplements, such a claim must be submitted to FDA within thirty days of the product being marketed and must be coupled to a disclaimer stating that the claim has not been evaluated by FDA and that the product is not intended to diagnose, treat, cure, or prevent any disease. In the case of conventional foods, there is no requirement for notification or the use of a disclaimer; however, FDA’s position is that any claimed effect on a structure or function of the body must derive from nutritive value.

³² 21 U.S.C. § 343 (r)(3)(B)(i).



Retail Sales: Assuming no contrary state regulations, these hemp and cannabinoid products would be permitted for sale in all retail outlets that are able to sell food or dietary supplements now, with no age restrictions or additional regulatory barriers.

Inhalable Products

Currently FDA does not regulate inhalable products, unless such a product makes a claim that renders the product a drug (i.e., a disease claim or a structure/function claim) or the product qualifies as a tobacco product. Therefore, congressional action would be needed to grant FDA authority to regulate cannabis-derived inhalable products and to secure a pathway for marketing of inhalable products that make structure/function claims or other appropriate non-disease claims. Enabling legislation could specify the safety standard applicable to such products, designate substances that are prohibited for use, and establish GMPs, mandatory labeling elements, parameters for permissible claims, and restrictions on retail sales. Pending enactment and implementation, the cannabis industry could voluntarily develop and implement guidelines to address these issues so as to help ensure the safety and quality of these products.

LANE #4: Topically Applied Low THC Products

- Products: Low-THC cannabis products that are topically applied
- Regulator: FDA
- Model: Cosmetics
- Policy goal priorities: Public health; regulatory certainty and efficiency; consumer protection
- Retail locations: No restrictions
- Health-related claims: Not allowed

Topically applied products, both those that contain cannabis and those that do not, are generally believed to pose more limited public health concerns than orally consumed products. FDA, which regulates cosmetics, recognizes this and applies a less comprehensive regulatory system to these products than it does to food or drugs.

The existing regulatory structure for cosmetics should be used for clarity and consistency, with hemp derivatives being just one of the many allowed ingredients in cosmetics. This system would provide appropriate oversight



while ensuring that customers can access cannabis cosmetic products in all stores that sell cosmetics.

Products in Lane #4

Lane #4 will contain all cannabis products that do not contain more than a de minimis level of THC and are “intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body . . . for cleansing, beautifying, promoting attractiveness, or altering the appearance,” consistent with the current statutory definition



of “cosmetic.”³³ Such products can come in various forms, such as lotions, creams, and balms. This lane is very similar to Lane #3, again involving the introduction of non-intoxicating, safe cannabis products into an already existing regulatory framework. But because topical products generally pose more attenuated potential health risks than food products, they should follow the federal regulatory framework of other cosmetic products.

Policy Areas Implicated by Lane #4

Cosmetics are not orally consumed, reducing the public health risk. Moreover, cosmetics are not marketed with health-related claims or nutrition claims.³⁴ The goal of this regulatory system should be to protect the public from dangerous products and misleading claims, while not imposing unnecessary burdens on businesses or consumers.

The current cosmetic regulatory system does exactly that and should be applied to products that contain cannabis. Cosmetics crossing the THC threshold would be considered adulterated and subject to FDA enforcement actions. Cosmetics making disease or structure/function claims would be considered misbranded. This ensures that consumers have ready access

³³ *Cosmetics & U.S. Law*, FDA (Nov. 3, 2017), <https://www.fda.gov/cosmetics/cosmetics-laws-regulations/cosmetics-us-law>.

³⁴ Although a cosmetic product might have a structure/function effect, that effect cannot be the subject of a labeling claim, because such a claim would render a cosmetic a drug.



to low-THC products that raise few policy concerns, while creating a path for products with higher levels of THC through Lane #1. Although the mere presence of a cannabis derivative is not sufficient to render a cosmetic a “drug,” we recommend that this be made clear in any enabling legislation.

What Lane #4 Regulation Would Look Like

FDA has the authority to regulate cosmetics under the FFDCAs. The FFDCAs, the Fair Packaging and Labeling Act, the Color Additive Amendments Act of 1960, the Poison Prevention Packaging Act, and related regulations constitute the law governing cosmetics.

In many ways, FDA’s regulation of cosmetics is a less burdensome version of Lane #3. Given that some of the public health concerns are inapplicable to cosmetics due to the nature of these products, the more onerous regulatory requirements have been deemed unnecessary. The focus remains on adulterated and misbranded products. FDA may still seize products in violation of the FFDCAs, may issue injunctions, and may enforce the law with criminal penalties in some instances. It also may conduct inspections. However, much of the rest of the regulatory environment for cosmetics takes the form of guidelines and self-regulation. Registration of manufacturers is voluntary. There is no requirement to use GMPs, although FDA has set out recommended GMPs in a draft guidance. There are no premarket notification requirements except those involving color additives.



Conclusion

With the prohibition era nearing its end, it is imperative to begin discussing how to shape an effective, comprehensive cannabis regulatory framework. The system proposed here would allow all cannabis products to flow to the market through a regulatory scheme designed to best advance the policy goals raised by these products. It builds off the existing expertise of federal agencies and the developing state-level industry. Potentially intoxicating products and those making medical claims will be sold through controlled systems that limit their availability, while non-intoxicating products will not be hampered by those same restrictions. The system proposed here would end prohibition in a thoughtful and comprehensive manner, ensuring that the mistakes of the previous era do not negatively affect the opportunities that are at our doorstep.



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