The One-plant Solution

Recommendations for advancing a national unified cannabis policy and federal regulatory framework

STRATEGIES 64

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About

The One-plant Solution: Recommendations for advancing a national unified cannabis regulatory framework was produced by Strategies 64, a national firm specializing in cannabis policy and the development of responsible legal markets. For over a decade, it has been shaping laws and regulations, informing public opinion, and guiding governments, industries, and other stakeholders through the transition from prohibition to regulation.

The analysis, conclusions, and policy recommendations in this paper were informed by extensive stakeholder input and feedback gathered from across the marijuana and hemp spaces. Over the course of three months, Strategies 64 conducted more than 80 interviews with federal officials, state regulators, policy experts, advocates, trade association leaders, and cannabis business operators, including cultivators, manufacturers, retailers, and testing facility operators, to collect and contemplate their perspectives and gain insight into the on-the-ground realities of governments and businesses.

Acknowledgments

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Disclosure

Strategies 64 is a policy advisory firm whose current and former clients include governmental bodies, cannabis businesses, trade associations, and other organizations engaged in cannabis policy, regulation, and public education. While the authors' professional work involves advising a wide range of stakeholders, the analysis, conclusions, and recommendations presented in this paper reflect the authors' own judgment and expertise and were produced with full editorial autonomy.

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Introduction

A Critical Need

The United States has outgrown the artificial legal divide between "hemp" and "marijuana." The federal government's longstanding prohibition on cannabis, its descheduling of "hemp" in 2018, and the pending recriminalization of most consumable hemp products have resulted in a fragmented and unstable cannabis policy landscape—within federal law, between federal and state systems, and across states themselves. The result is a market that rewards loophole engineering, delivers uneven consumer protections, complicates enforcement and youth safeguards, and undermines public health research and data collection.

Absent federal regulatory support, state governments have done their best to meet their constituents' demand for regulated cannabis markets. While they have generally succeeded and demonstrated that regulating cannabis works, they have also encountered limitations and challenges that reveal a clear and critical need for federal reform.

A Simple Plan

This paper proposes a pragmatic solution:

- Remove botanical cannabis from the federal drug schedules of the Controlled Substances Act and regulate it as one plant through existing federal channels.
- Preserve state autonomy, allowing states to continue setting their own policies on commercial and noncommercial cannabis activities and serving as the primary regulatory authority.
- Support states' regulatory efforts by establishing national guidelines and standards for product safety, youth access prevention, marketing, taxation, and product authentication.

This solution is not presented as an idealized endpoint, but as a realistic and achievable path forward—one that works within existing federal authorities, leverages well-established regulatory infrastructure, and aligns with the political constraints Congress and federal agencies currently face. By fitting cannabis into familiar federal regulatory channels while preserving state autonomy, this proposal prioritizes durability, enforceability, and public health outcomes over theoretical elegance, offering the most viable route to national coherence under present conditions.

A Timely and Unique Opportunity

These recommended reforms are particularly timely, as Congress just acted in November 2025 to recriminalize most hemp-derived products in November 2026. Many businesses and government officials around the country are bracing for the economic fallout, while many others are breathing sighs of relief, underscoring a sentiment shared by stakeholders across the spectrum: dividing cannabis into two legal categories is confusing, unstable, and unworkable.

Rather than continuing to oscillate between permissive gaps and abrupt crackdowns, federal policymakers should seize this unique opportunity to reset the system. Deschedule cannabis, regulate it as one plant, and establish rules across all cannabinoids and product types that are consistent, enforceable, and grounded in risk. By doing so, they can craft a durable U.S. cannabis policy suited to the realities of today's market and deliver the clarity that consumers, businesses, public health officials, and state and local governments have been asking for.

The one-plant solution would create a durable U.S. cannabis policy suited to the realities of today's market and deliver the clarity that consumers, businesses, public health officials, and state and local governments need to move forward responsibly

Current Policy Landscape

Federal Policy

The federal government statutorily prohibited "marihuana" (or "marijuana") under the Controlled Substances Act (CSA) in the early 1970s.[1] It defined marijuana as all parts of the cannabis plant and classified it under Schedule I of the CSA drug schedules. Schedule I is reserved for controlled substances with no currently accepted medical use and high potential for abuse.[2, 3]

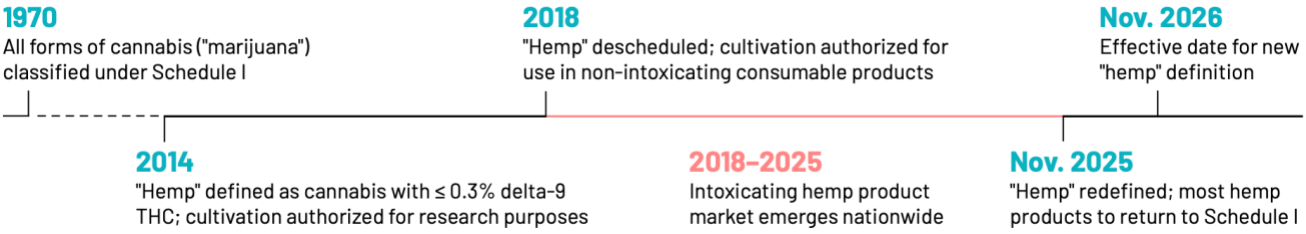
In 2018, Congress enacted a farm bill with provisions intended to remove federal restrictions on the cultivation of non-intoxicating cannabis, or "hemp," for agricultural use, industrial use, and use in consumer products like foods, dietary supplements, and cosmetics.[4] It defined "hemp" as any part of the cannabis plant with a delta-9 tetrahydrocannabinol (THC) concentration of no more than 0.3% on a dry weight basis.[5] THC is the compound (or "cannabinoid") in cannabis that is primarily responsible for its intoxicating effect.

The 2018 farm bill removed "hemp" from the definition of "marijuana" in the CSA, effectively removing it from the CSA drug schedules (or "descheduling" it). All other parts of the cannabis plant remained under Schedule I. Congress's intent was to allow hemp cultivation for use in non-intoxicating products, but the law was interpreted and applied in a manner that has allowed for the commercial production and sale of hemp-derived consumer products with intoxicating levels of THC and other natural, synthetic, and synthetically derived cannabinoids. This led to the rapid emergence of a largely unregulated interstate market. It also sparked innovation in synthetic cannabinoid development and cannabinoid conversion processes.[6]

The proliferation of intoxicating consumable hemp products created confusion and raised concerns among consumers, public health experts, and state governments. It also raised the ire of many federal policymakers, inspiring Congress to close the intoxicating hemp "loophole" in federal law.

The continuing resolution that ended the historic 43-day federal government shutdown in November 2025 included provisions to prohibit most consumable hemp-derived products.[7] Specifically, the legislation redefines "hemp" as cannabis with a concentration of not more than 0.3% *total* THC (rather than just delta-9 THC), excluding synthetic cannabinoids and any products with more than 0.4 milligrams of total THC per container.

The new federal definition of "hemp" is scheduled to take effect in November 2026, at which time most consumable hemp products will once again be defined as "marijuana" and classified under Schedule I of the CSA.[8]



[1] Controlled Substances Act, Pub. L. 91-513, tit. II, 84 Stat. 1242 (1970) (codified as amended at 21 U.S.C. §§ 801–904).

[2] The CSA defines "marihuana" and "marijuana" as "all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin."

[3] In October 2022, President Joe Biden directed the Department of Justice and the Department of Health and Human Services (HHS) to review marijuana's Schedule I classification. In August 2023, HHS recommended marijuana be reclassified under Schedule III, and in May 2024, the DEA proposed a rule to transfer marijuana to Schedule III. In December 2025, following several delays in the rulemaking process, President Donald Trump issued an executive order directing federal agencies to complete the process of moving marijuana to Schedule III. Marijuana was still classified under Schedule I at the time this paper was published.

[4] Agriculture Improvement Act of 2018, H.R.2, 115th Cong. (2018).

[5] Hemp was first defined as cannabis with less than 0.3% THC in the 2014 farm bill (H.R.2642), which authorized state departments of agriculture and institutions of higher education to cultivate hemp for state-run research pilot programs.

[6] Cannabinoid conversion is the chemical or biological transformation of non-psychoactive cannabinoids, such as THCA or CBD, into psychoactive cannabinoids like delta-8 THC and delta-9 THC.

[7] Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, H.R.5371, 119th Cong. (2025).

[8] If marijuana is reclassified from Schedule I to Schedule III, as discussed in Footnote 3, most consumable hemp products will be classified under Schedule III rather than Schedule I when the new definition of "hemp" takes effect. In either case, these products will be prohibited under federal law.

State Policy

Cannabis was generally prohibited in every U.S. jurisdiction until 1996, when California became the first state to legalize it for medical use. As of December 1, 2025, 40 states, four U.S. territories, and the District of Columbia have enacted legislation to legalize and regulate marijuana for medical use, and nearly half of U.S. states have legalized and regulated marijuana for use by adults 21 and older. States with regulated marijuana markets have each enacted relatively similar but markedly unique laws and regulations governing cannabis-related activity within their borders.

Since the federal descheduling of hemp in 2018, states have also taken a wide range of approaches to intoxicating hemp-derived products. Several states have prohibited or significantly restricted them, while others have integrated them into their marijuana regulatory systems or established parallel hemp-specific regulatory systems. Some states have taken no action, leaving intoxicating hemp-derived products generally unregulated. At the time this report was published, it was unclear how states may react to the forthcoming federal ban on most hemp-derived consumable products.

Divergence in U.S. Cannabis Policy

The U.S. cannabis policy landscape is defined by divergence at three levels: (1) within federal law (between marijuana and hemp), (2) between federal and state laws, and (3) among state laws and regulatory regimes. Each has produced some near-term benefits—especially as policymakers and markets have needed to adapt to rapid change—but they have also contributed to challenges related to public health, enforcement, and the development of a stable national industry.

Divergence Within Federal Law

Federal law currently treats cannabis differently depending on whether it meets the statutory definition of "marijuana" or "hemp." This has created two parallel federal regimes governing the same plant and overlapping products. For example, hemp-derived products with 100 milligrams of THC are legal, while marijuana products with just 10 milligrams of THC are illegal. As a result, intoxicating products are being distinguished by technicalities rather than consumer impact. The federal policy gap between "hemp" and "marijuana" is on track to narrow significantly in 2026, when legislation redefining hemp takes effect, but some hemp stakeholders and members of Congress have announced their intent to pursue legislation that would allow for the existing hemp product market to continue. In other words, the current marijuana-hemp divide within federal law should not be dismissed as moot.

Divergence Between Federal Law and State Laws

Most states permit some form of regulated marijuana commerce, while federal law continues to prohibit it. On the positive side, this has allowed states to serve as laboratories of democracy and tailor policies to their unique circumstances and preferences. However, absent federal standards and oversight, states are left to set their own public health regulations, which may not align with best practices. It also makes consumer safety dependent on geography, particularly when it comes to intoxicating hemp products, as some states have adopted rigorous health and safety rules while others have none. Conflicting federal and state laws also create an unstable operating environment in which state-legal businesses face barriers to standard banking and financial services, disparate tax treatment, investment risk, and the persistent threat of federal prosecution.

Divergence Among State Laws

Laws and regulatory regimes vary from state to state, with notable divergence in licensing structures; manufacturing, testing, and labeling standards; standard serving sizes; THC limits; marketing and advertising restrictions; and legality of hemp-derived products. This has allowed states to learn from one another's successes and failures, leading to iterative improvements and the spread of best practices. On the flip side, it makes regulatory compliance a particularly complex and costly endeavor for multistate operators. It can also create confusion for consumers, who may encounter different rules or product safety measures on vacation than they do at home. Data is also fragmented, making it harder to identify public health trends, evaluate safeguards, and forecast market behavior because each state collects different metrics on different schedules using different methodologies.

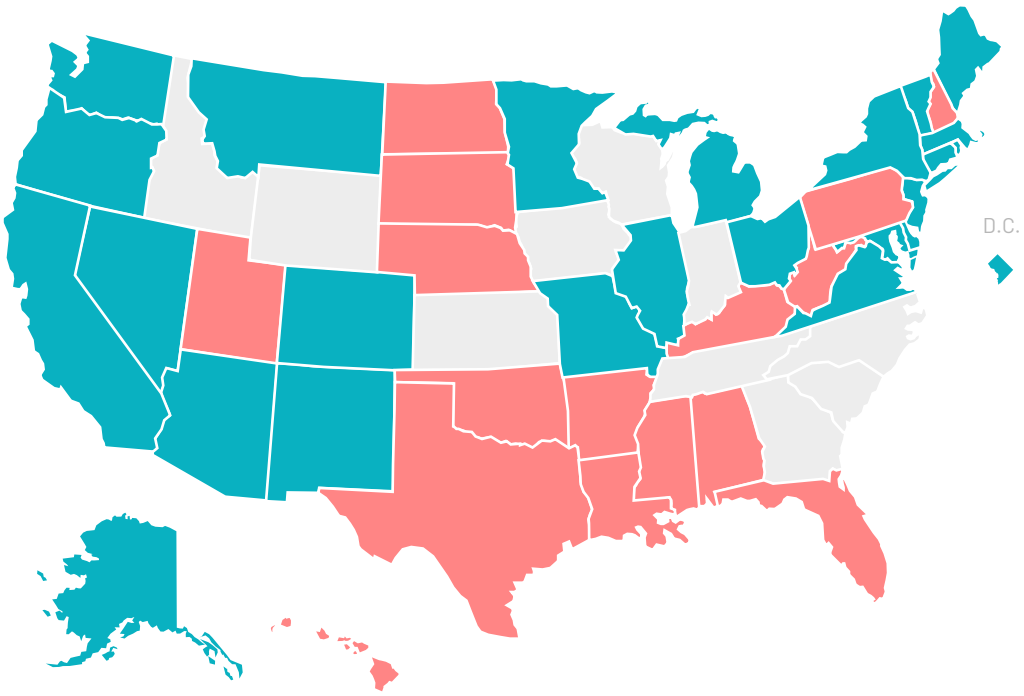
Taking the Next Step

Cannabis policy divergence in the U.S. was inevitable. With prohibition deeply ingrained in federal law, and a growing body of scientific and medical evidence, undeniable economic prospects, and shifting public attitudes around cannabis, it was just a matter of time before states would begin experimenting with new policies and testing the federal government's will and ability to intervene. It also came as little surprise that Americans would eventually demand federal law acknowledge the difference between cannabis that is intoxicating and cannabis that is not. In many ways, divergence in American cannabis policy is a manifestation of American political ideals—self-governance, federalism, liberty, free enterprise, common sense. It was a vital and necessary step for progress, and now the country must take the next one.

U.S. "Marijuana" Policy Landscape

As of December 1, 2025

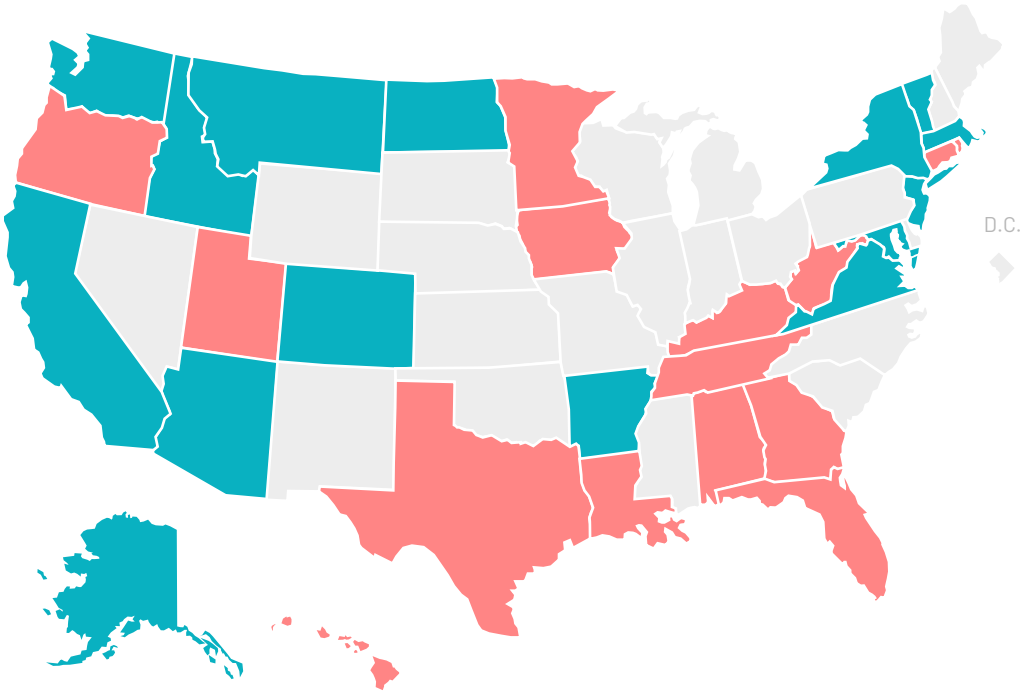
- Legalized marijuana for adult use (21+) and medical use
- Legalized marijuana for medical use only
- Has not legalized marijuana for adult use or medical use



U.S. "Hemp" Policy Landscape

As of December 1, 2025

- Prohibited or significantly restricted intoxicating hemp products
- Created a regulated market for intoxicating hemp products
- Has not enacted statutes or regulations governing intoxicating hemp products



The One-plant Solution

As cannabis markets have scaled and the "marijuana" and "hemp" channels have converged, the costs of the federal government's bifurcated cannabis policy are beginning to outweigh many of the benefits. Most notably, it:

- rewards loophole engineering over compliance,
- produces uneven consumer protections,
- complicates enforcement and youth protection,
- fragments data and undermines research, and
- hinders the development of stable national and state cannabis economies.

Cannabis science and product development are advancing at tremendous rates. More than 100 distinct cannabinoids have been identified, and significant progress continues to be made in cannabis medicine, technology, and research methods. In addition to being exciting, these advancements are making traditional policy divisions around the plant obsolete.

The time has come for a harmonized federal approach that regulates cannabis as a single plant, while maintaining state autonomy and establishing clear division of responsibilities between federal and state authorities. The one-plant solution proposed in this paper offers the most sensible path to preserving the upside of innovation while eliminating the risks associated with continued legal divergence.

The Same Plant

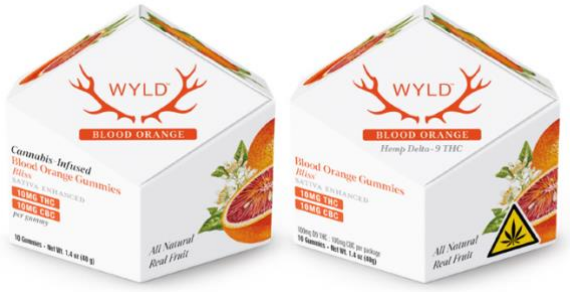
Whether it is medical or adult-use marijuana, industrial hemp, or hemp used in consumable products, it is all one plant: cannabis.

Until recently, "marijuana" was commonly thought of as a plant people consume for recreational or medical purposes, while "hemp" typically referred to a plant used for industrial or agricultural purposes. These terms were never based on genetic distinctions. They are legal fictions used to differentiate between two varieties of the same genetic species based on their concentrations of THC. Now that a significant amount of commercial hemp activity in the U.S. involves products with intoxicating levels of THC, it is no longer accurate or prudent to continue treating them like different substances.

The Same Potential for Intoxicating Products

All cannabinoids found in the cannabis plant (THC, CBD, etc.) are present in hemp, just in different concentrations. Technology is now available to isolate and extract these cannabinoids, even if there are only trace amounts. Also, some of these natural cannabinoids can be converted into new synthetic or semi-synthetic cannabinoids.

Extracted cannabinoids can be infused into foods ("edibles") and beverages or used to create other consumable products. Virtually all consumable cannabis products, including those that are intoxicating, can now be made from "marijuana" or "hemp;" it just requires more hemp biomass than it would marijuana.



"Marijuana" products (left) and "hemp" products (right) can be virtually identical, with the same cannabis-derived ingredients, in the same amounts, with the same serving sizes and potential for intoxication

These developments and others have rendered the old distinction between hemp and marijuana obsolete. Policies aimed at governing commercial cannabis activity and protecting public health and safety should differentiate consumable cannabis products based on their cannabinoid concentration, safety profile, and potential for intoxication, not on the THC concentration of the plants it was made from.

The time has come for a harmonized federal approach that regulates cannabis as a single plant, while maintaining state autonomy and establishing clear division of responsibilities between federal and state authorities

Descheduling and One-plant Regulation

The initial and most critical step the federal government must take is descheduling botanical cannabis and removing it from the federal drug schedules.

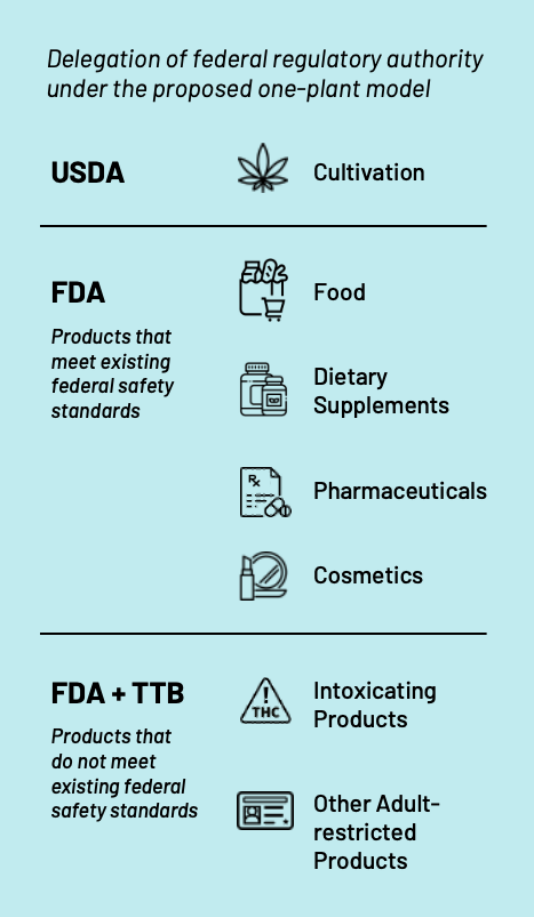
Like alcohol, cannabis should be excluded from the CSA and regulated through a separate framework that accounts for unique cultural and economic factors, including (1) its broad social acceptance and wide availability in the U.S., and (2) the substantial amount of jobs and tax revenue state and local economies have come to rely on.[9, 10]

Descheduling would also reflect the U.S. Department of Health and Human Services' 2023 determination that (1) cannabis has accepted medical use in treatment in the U.S., and (2) the rate and severity of negative outcomes associated with the nonmedical use of cannabis are relatively lower than those associated with alcohol and other substances on the federal drug schedules.[11]

Descheduling cannabis would effectively eliminate the federal government's current legal distinction between "hemp" and "marihuana" so that cannabis can be regulated as one plant with traditional federal oversight via existing regulatory channels:

- The U.S. Department of Agriculture would regulate cultivation in a manner consistent with other agricultural products.
- The Food and Drug Administration (FDA) would regulate consumable products and ingredients that meet existing product safety standards for food, dietary supplements, cosmetics, and pharmaceuticals.
- Consumable products and ingredients that do not meet existing safety standards, which includes any that are intoxicating, would be restricted to a new adults-only classification ("adult-restricted cannabis products") under a new product safety standard or exemption like those created for alcohol or tobacco. Such products and ingredients would be jointly regulated by the FDA and the Alcohol and Tobacco Tax and Trade Bureau.

Cannabis regulation can otherwise be largely left to state and local governments, like alcohol and tobacco, with the federal government's role focused on creating guidelines, setting standards, and providing enforcement support to ensure critical federal public health and safety priorities are addressed.



[9] An annual Gallup poll conducted in October 2025 found nearly two-thirds of U.S. adults think the use of marijuana should be legal, and at least 64% have expressed this sentiment since 2017. National surveys conducted by other polling companies, academic institutions, and media outlets have found consistent majority approval of legal marijuana over the past decade.

[10] As of May 2025, the state-regulated cannabis industry supported approximately 425,000 full-time equivalent jobs in the U.S., according to the 2025 Vangst Jobs Report. State governments in the U.S. have reported collection of more than $24.7 billion in adult-use cannabis tax revenue since January 2014, according to a May 2025 analysis by the Marijuana Policy Project. This does not include state tax revenue collected on medical cannabis sales, local cannabis tax revenue collected by municipal governments, taxes paid to the federal government, or income taxes generated by workers in the regulated cannabis industry. The National Conference on State Legislatures reports multiple states generate more cannabis tax revenue than alcohol tax revenue on an annual basis.

[11] Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44,597 (May 21, 2024).

The Case for a Federalist Approach

States with regulated cannabis markets have each enacted their own unique laws and regulations, which can vary significantly from one state to the next. They have different licensing frameworks, retail options, product safety measures, security requirements, and tax rates, among other distinctions.

Despite their policy differences, these states have experienced broadly similar public health and economic outcomes. For example, youth cannabis usage rates have remained relatively stable, while rates of adult use have moderately increased and then leveled off. They all collect more in annual cannabis tax revenue than they spend on administering their cannabis regulatory systems, and they have all seen reductions in the size of their illegal cannabis markets.

While the *extent* of specific effects may differ, the overall *direction* of these outcomes is nearly identical. These trends point to a clear conclusion: cannabis legalization itself, rather than individual regulatory choices, has played the dominant role in shaping public health and economic trajectories.

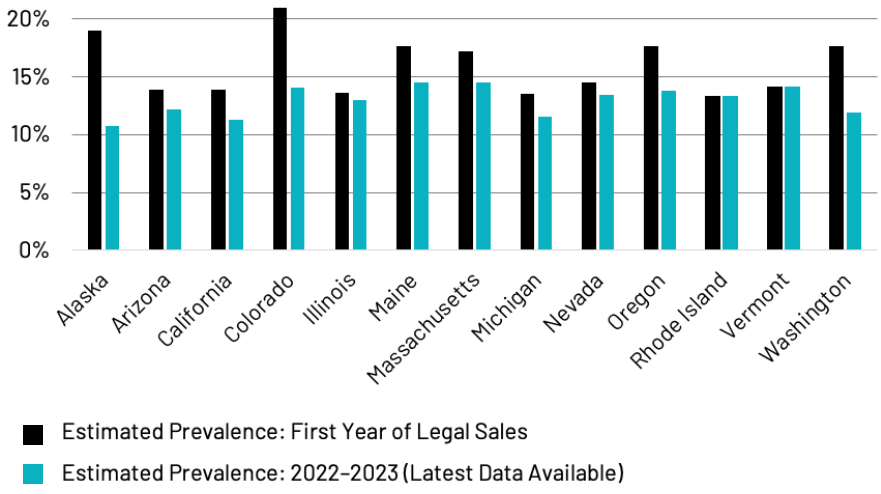
This should not be taken to mean that regulatory design is inconsequential, and leading scholars have argued that regulatory frameworks should be systematically categorized and studied to understand their effects more precisely.[12] However, most research continues to compare states with legal access to those maintaining prohibition. The limited number of studies that do disaggregate legal states often find that differences in regulatory structure have not led to substantially different trends. This consistency implies that while regulations can certainly alter the scale or magnitude of certain effects, they have not generated fundamentally divergent public health patterns.

These conclusions suggest the federal government need not choose the "best" state regulatory framework. Rather, it can focus on establishing a general federal framework and standards that ensure critical public health and safety priorities are being addressed, and it can leave most of the details to the states, similarly to how it treats alcohol and other regulated products.

Rates of youth cannabis use have remained relatively stable or slightly declined across all states with regulated adult-use marijuana markets, despite significant differences in regulations

Past-year Cannabis Use Among Youth Ages 12–17

Source: Substance Abuse and Mental Health Services Administration, National Survey on Drug Use and Health



[12] Pacula RL, Smart R. *How will cannabis legalization affect health, safety, and social equity outcomes? It largely depends on the 14 Ps*. American Journal of Public Health. 2024 Nov, 114(S8): S661–S664.

Maintaining State Autonomy

Federal descheduling would not automatically legalize cannabis at the state level and should not be coupled with any actions that force states to legalize. Such a requirement would be an inappropriate overreach of federal authority, impinging on states' capacity to adopt their own public health and safety laws, as well as their traditional role in regulating the time, place, and manner of activities occurring within their borders.[13]

States would be able to continue adopting their own policies on adult-restricted cannabis products, and they could retain existing criminal penalties and market regulations. The federal government should only seek to prevent states from prohibiting the transportation of cannabis through their borders, provided the transportation occurs within the federally regulated system.

The proposed one-plant policy also would not require states to cease their own distinctions between "hemp" and other forms of cannabis. For example, Kentucky has separate regulatory systems for medical marijuana and for intoxicating hemp products. While these legal distinctions are unnecessary, they do not undermine federal public health and safety priorities and there is no reason to force states to abandon them. Such bifurcation can continue if the federal government considers it all commercial cannabis activity subject to the limited federal guidelines outlined in this proposal. Eventually, states will likely opt to end these distinctions and regulate cannabis activity generally.

Familiar State and Federal Roles

This type of state-led, federally guided system is consistent with the U.S. approach to similar consumer goods like food and alcohol, in which:

- State governments, along with local governments, manage day-to-day administration and oversight of the industry. Many state governments are already serving this role for cannabis, and they are running into challenges that could be resolved through the type of federal engagement found in other industries.
- The federal government serves as the standard-setting body, applying its subject matter expertise and institutional memory to the development and general oversight of technical standards, especially in areas where states may lack specialization, experience, or resources. It also supports enforcement on regulatory issues that are complex, large-scale, or interstate.

Key areas in which federal involvement is needed are identified and discussed in detail in the "Recommendations for Federal Regulation" beginning on page 13.

Cannabis would not automatically be legalized at the state level, and states can continue to adopt their own policies on adult-restricted cannabis products

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Licensing

Under the proposed system, states would have the authority to establish licensing systems for commercial cannabis activities, just as they do for alcohol. Primary licensing functions would be handled by state governments, which can:

- adopt suitability requirements and limit or empower cannabis businesses in a manner that reflects local norms and constituent preferences,
- decide the types and quantities of licenses to issue and choose who to license, and
- set the time, place, and manner in which licensed cannabis facilities can operate.

The federal government's role would be limited to registering cannabis businesses, which will allow it to intercede where necessary. Federal tax registration is addressed in greater detail on page 24.

[13] Some exemptions may exist but would be relatively limited. For example, the federal government may be able to compel states to permit federally approved cannabis-based pharmaceuticals. However, such products currently account for a small amount of commercial cannabis activity, and current levels of public support for medical cannabis access make it unlikely states would prohibit cannabis-based medications that have been subject to the extensive approval process and controls associated with pharmaceuticals.

Cultivation

Many decisions relating to the regulation of cannabis cultivation are best addressed at the state and local levels.

In states with regulated cannabis markets, state and local governments have demonstrated the ability to effectively regulate the time, place, and manner of cannabis cultivation. This includes identifying appropriate zoning and setback requirements, developing minimum security standards, and addressing odor mitigation, among other things. In many cases, general regulatory expectations are set at the state level, with local governments either following the state's lead or building upon it.

There has proven to be little need for federal intervention in these areas, and states and localities have benefited from having the latitude to tailor their rules to the unique needs and circumstances of their communities. For example, states where cultivation occurs primarily indoors and in urban or suburban areas typically mandate costly alarm systems, video surveillance, and fencing. Vermont, on the other hand, recently removed many of these security requirements for outdoor cultivators in rural areas, easing the regulatory burden on farmers without increasing the incidence of theft or jeopardizing public safety.

Rather than addressing regulatory minutiae, the federal government should assume a role like the one it has traditionally filled in other areas of agriculture, focusing primarily on setting standards and managing interstate matters.

Notably, every state cannabis regulator interviewed for this paper stressed the need for federal support in setting agricultural safety standards, such as identifying pesticides that should be allowed in commercial cannabis cultivation. State departments of agriculture can then take the lead in monitoring compliance and enforcing the laws.

Many decisions relating to the regulation of cannabis business licensing, cultivation, and sales are best addressed at the state and local levels, where rules can be tailored to community norms, needs, and preferences

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Retail Sales

All decisions relating to cannabis retail sales would generally be left to the states, except for prohibiting underage sales and meeting age verification standards, which would be federally mandated, as discussed on page 18. Federal law should expressly grant states control over consumer access and clearly delegate to them the authority to permit, prohibit, or regulate where, when, and how cannabis products can be sold.

States should also have clear authority to address complex issues relating to delivery and direct-to-consumer sales. With cannabis, like with alcohol, these types of decisions should be made by state and local policymakers, who are best positioned to craft policies that align with local norms and constituent preferences.

This is consistent with federal alcohol regulation, which allows state and local governments to permit sales in a manner that best suits their communities. For example, some states allow all alcoholic beverages to be sold in privately owned businesses, while others allow private businesses to sell beer and wine but only permit the sale of distilled spirits in government-operated stores or privately owned liquor stores. State and local governments have also traditionally decided how many liquor licenses to issue and where and when sales can occur.

Recommendations for Federal Regulation

The federal government serves a vital role in the regulation of adult-restricted products, such as alcohol and tobacco. Traditionally, it has been characterized by relatively limited direct, on-the-ground regulation, with greater focus on setting national standards and providing enforcement support to bolster state and local regulatory efforts. By extending this role to cannabis, the federal government can meaningfully advance federal priorities like consumer safety, protecting youth, and reducing illicit market activity.

With states shouldering the bulk of the regulatory workload, the federal government can focus on four critical areas:

- Product safety
- Preventing youth access
- Marketing and advertising
- Taxation and product authentication

Product Safety

Product safety standards have historically been one of the greatest challenges for state-regulated cannabis markets. Every current and former state regulator interviewed for this paper specifically highlighted the need for national product safety standards developed by subject matter experts at the federal government.

Traditionally, product safety for consumable goods is overseen by a partnership between federal and state agencies, with support from local governments. Without federal partners, state regulators around the nation have done their best to adopt cultivation, manufacturing, testing, and labeling requirements, but this patchwork approach is papering over the underlying problem—the need for the federal government to assume its traditional role as a standard-setter and enforcement buttress.

To best protect public health and safety, the existing paradigm must be aligned with the nation's typical approach to product safety for food, dietary supplements, cosmetics, pharmaceuticals, and adult-restricted products. These existing systems are well-suited to incorporate cannabis-based products, and the relevant agencies should be empowered to assume their traditional roles with little modification.

Once this occurs, consumers will have access to final goods that are produced under quality control systems and subject to uniform standards designed by appropriate subject matter experts. State regulators can then partner with their federal counterparts, as they do for all other consumables, to address recalls and address other enforcement issues related to product contamination.[14]

Federal engagement is particularly critical in two areas:

- Safety standards, product classification, and ingredient assessment
- Manufacturing processes, contaminants, and recalls

Safety Standards, Product Classification, and Ingredient Assessment

The FDA governs consumable product safety through a product classification system based on safety standards. Products and their individual ingredients are evaluated against different safety standards and then classified as a food, dietary supplement, cosmetic, or pharmaceutical. Each standard and classification pairing has its own set of regulations that cover critical safety risk points, such as pre-commercialization research requirements, manufacturing and labeling standards, and restrictions on the types of claims that can be made.

Every current and former state cannabis regulator interviewed for this paper highlighted the need for national product safety standards developed by subject matter experts at the federal government

[14] The need for this state-federal partnership was highlighted by the e-cigarette/vaping-associated lung injury (EVALI) crisis, in which several deaths were attributed to cannabis vaping products in 2019–2020. State reactions varied widely, with some focusing on state-legal products rather than the unregulated products that turned out to be the primary culprit. In Massachusetts, for example, the governor ordered a quarantine of all cannabis vaping products from state-regulated cannabis retailers. An investigation of those products determined the source of the crisis was vitamin E acetate, which was not detected in state-regulated products. In effect, the quarantine may have increased consumer demand for unregulated products that were more likely to contain vitamin E acetate. Federal regulators could have helped facilitate a more uniform and effective response that may have led to better public health outcomes.

Adult-restricted Products

In limited circumstances, exemptions to these safety standards are created for unique products, such as alcohol, which is permitted despite its health and safety risks due to high consumer demand and the opportunity to positively impact public health through regulation. This system can easily be applied to cannabis products, where some consumables will meet safety standards for existing classifications—food, dietary supplement, cosmetic, pharmaceutical—and others will fall under an alcohol-like exemption, with a new safety standard and classification for "adult-restricted cannabis products."

Through this exemption, cannabis products and ingredients that present unique risks can be segregated and subjected to additional appropriate restrictions, such as age-gating, marketing limitations, taxation, and product authentication.

Cannabis's Unique Ingredients

Cannabis, and especially cannabinoid-based ingredients, present unique regulatory challenges that will require some modifications to traditional federal product safety standards. Fortunately, the existing federal regulatory framework provides a clean way to incorporate them into the system through the creation of an adult-restricted cannabis product classification and permitting the sale of products containing cannabinoids only after evaluation by the FDA.

Aside from cannabis flower, all cannabis products use part of the plant as an ingredient, similarly to how parts of the cocoa plant are combined with other ingredients to produce chocolate products. Some of these ingredients exhibit characteristics that conform to existing federal safety standards and their associated product classifications. For example, hemp seeds conform to the food standard Generally Recognized as Safe (GRAS) and, therefore, are already permitted to be sold as food. Cannabinoids, however, are active ingredients that produce specific effects in the body, so they would fall more in line with safety standards for dietary supplements, pharmaceuticals, or the new standard for adult-restricted cannabis products.

Although federal law permits self-certification against safety standards, the unique nature of cannabinoids warrants greater product safety oversight, and commercialization should not be permitted until a full review is performed by the FDA. This process already exists for pharmaceuticals, so only explicit pre-commercialization approval requirements would need to be established to determine whether a cannabinoid ingredient meets the product safety standard for a cosmetic, food dietary supplement, or the new standard for adult-restricted cannabis products.

The safety standard for the new classification of adult-restricted cannabis products should be set by subject matter experts. It should incorporate cannabinoids that are intoxicating (e.g., THC) and cannabinoids with profiles that do not meet dietary supplement safety standards and do not present an immediate acute risk to healthy adults (e.g., CBD). Using this standard, the FDA can authorize cannabinoids with appropriate safety profiles and adopt appropriate product safety restrictions, warnings, and labeling requirements for products that contain them.

Once the safety standard is formalized, businesses can use the existing FDA processes for approving new food and dietary supplement ingredients, GRAS and New Dietary Ingredient (NDI), to submit requests for FDA approval, and appropriate classification against safety standards can be made prior to commercial distribution.

The Drug Preclusion Clause

The Drug Preclusion Clause of the FFDCA will be a significant but not insurmountable hurdle to transitioning cannabis into the existing federal regulatory framework. It prevents substances from being marketed as a food or dietary supplement if they were previously approved as a drug or have already been the subject of drug research and development for which substantial clinical investigations have been made public.[15]

The FDA has approved pharmaceutical drugs containing cannabinoids, including the two most popular cannabinoids, CBD and THC, therefore they would be precluded from being sold in food and dietary supplements. However, there are large markets and great public demand for these compounds from non-pharmaceutical sources, and limiting access to that channel would drive consumers away from the regulated market. A solution is needed that strikes a balance between pharmaceutical development and the need for a regulated supply to meet consumer demand.

One potential solution would be to exempt from the Drug Preclusion Clause any cannabinoids that are naturally occurring and derived directly from the plant. Such an exemption would be unique and a significant departure from existing policy, but it is justified since there is evidence that cannabis has been used as a medicine for

[15] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(ff)(3)(B) (1994).

thousands of years.[16] Under this approach, there would still be significant incentives for pharmaceutical manufacturers, such as coverage by insurance and exclusivity over synthetics.

If stakeholders believe a narrower exemption is necessary to promote continued research and drug development, use of the exempted cannabinoids could be limited to adult-restricted cannabis products. This would limit the exemption to only a single product category, increasing incentives for pharmaceutical manufacturers without undermining the public health and safety benefits of establishing a federally regulated cannabis market.

Trace or Small Amounts of Intoxicating Cannabinoids

While many cannabis products that contain THC are designed to be intoxicants, some products do not have enough THC to be intoxicating, or their form factor does not lend itself to such use. Under current safety standards, THC does not exhibit the characteristics of an ingredient that would be eligible for use in food or dietary supplements.

In theory, federal law could create an exemption to existing safety standards for specific products that contain very low levels of THC and allow them to be sold as a food or dietary supplement. This would be in line with current federal treatment of kombucha, a fermented tea that contains alcohol but in quantities deemed low enough that it does not necessitate treatment as an intoxicant.

However, federal descheduling and state-level medical cannabis patient exemptions should allow broad continuing access to products with trace or very small amounts of THC. Therefore, we recommend products containing any amount of THC or other intoxicating cannabinoids only be permitted in the adult-restricted tier rather than modifying existing federal safety standards.

Inhalable Products

Inhalable products, including cannabis flowers and vaporizers, do not fit within existing FDA product categories under the FDCA. Most inhalable products are intoxicating and should be authorized as adult-restricted cannabis products. While a small market exists for non-intoxicating inhalable products, these products do not meet any safety standard and pose enhanced health risks to consumers. Therefore, we recommend all inhalable products be treated as adult-restricted cannabis products, reflecting their tolerable risk for adults and unsuitability for minors.[17]

Synthetic, converted, and minor cannabinoids

While there may be vast commercial and therapeutic potential for synthetic, converted, and minor cannabinoids, a federal cannabis regulatory system should initially focus on identified cannabinoids that occur naturally in the plant in usable quantities. This alone will be a significant endeavor, and it will offer businesses ample opportunities.

THC and CBD should be the immediate priority, to ensure the most common cannabinoids have a clear pathway to regulated commercial production and sales. Other commonly known cannabinoids, such as CBG and CBC, can then follow the FDA process for approval of new food and dietary supplement ingredients so they can be appropriately classified and made available to consumers under suitable safeguards.

Otherwise, federal policy should only permit synthetic cannabinoids in pharmaceuticals because those products are subject to the strictest approval and production safeguards. Also, the pharmaceutical industry has significant relevant experience in safely manufacturing these types of compounds.

Federal policy should also put limits on the conversion of cannabinoids and subject conversion processes to strict oversight. For example, the existing process for converting CBD to THC, a common practice in the hemp industry, is known to create unidentified byproducts that have no safety precedent and could be harmful to consumers.

Finally, cannabinoids that are technically naturally occurring but not at usable levels should not be permitted until there is additional research into their safety profiles. While some day there could be clear commercial or medical value, we already know that some present significant public health risks, such as THC-P that has 1,000x the intoxicating potential as typical THC.

Manufacturing Processes, Contaminants, and Recalls

Consumable products in the U.S. are subject to federal product safety systems designed around critical control points based on the unique risks posed by the production

[16] Russo, E. B. *History of Cannabis and Its Preparations in Saga, Science, and Sobriquet.* Chemistry & Biodiversity, 4(8), 1614–1648. (2007).

[17] There are some products, such as meter-dosed inhalers, that could also be appropriate for pharmaceuticals.

process. Absent federal regulatory support, states have foregone this risk-based approach; instead, they have implemented mandatory testing programs that require cannabis products to be uniformly tested for specified contaminants at specific chokepoints in the supply chain. It is applied to all products regardless of the unique risks presented by different production processes.

This approach is necessary because states do not have the institutional knowledge needed to develop the necessary standards, nor do they have stand-alone enforcement apparatuses to respond without support from their federal counterparts. As a result, state-based cannabis programs are both under-inclusive, sometimes failing to address certain risks that are beyond the capacity of state regulators, and over-inclusive, sometimes imposing needlessly strict standards or requiring duplicative investments in product safety that could be redistributed toward more critical risks posed by that specific process or product.

Transitioning to GAP and cGMP

Integrating cannabis into the federal regulatory system presents a unique opportunity to bring cannabis products in line with traditional approaches to product safety. Cannabis cultivation should be subject to Good Agricultural Practices (GAP), while producers of finished goods, including cannabis flowers, should be subject to current Good Manufacturing Practices (cGMP). The expectations required under these systems should be based on recommendations developed by technical standards organizations and incorporated into federal regulations by the appropriate agencies, including:[18]

- U.S. Department of Agriculture (USDA) for cultivation,
- FDA for food, dietary supplements, cosmetics, and pharmaceuticals, and
- FDA and the U.S. Treasury Department's Alcohol and Tobacco Tax and Trade Bureau (TTB) for adult-restricted products, with product safety overseen by the FDA and taxation, registration, and authentication overseen by the TTB.

A minimum set of uniform public standards for cannabis and cannabis-derived products should be established, and adherence to them must be required. They should include standardized quality attributes for cannabis and cannabis-derived compounds, including CBD; risk-based limits to control contaminants; standardized cannabis nomenclature guidelines determined by appropriate analytical tests; and standards for labeling.

Shifting focus from "chokepoint" testing to process controls would not eliminate cannabis product testing. All consumer goods are subject to testing programs, but, unlike cannabis products, they are based upon risk evaluations and not uniform mandates. Businesses would still need to regularly test products; they would just also be required to make investments in supply chain management, input analysis, critical control point identification, appropriate materials and surfaces, process re-evaluation when issues arise, and recall systems to address public health concerns. This broadening of focus and redistribution of existing investments will yield better public health outcomes for millions of American consumers.

State regulators will still play a critical role in product safety under this new system, just as they do with food and other comparable products. Each state should provide state and local regulators with broad authority to identify products throughout the supply chain to undergo additional testing and require recalls based on established precedents for other consumer products. While most states have this authority to some extent, they are often a facsimile of existing systems that require duplicative staffing and shortcuts to address federal funding restrictions or the lack of support from federal partners.

To complicate matters further, existing state labs cannot test regulated cannabis while maintaining necessary federal certifications from the DEA. States are required to fund entirely separate cannabis laboratories to conduct public sector testing to assess contamination or validate private sector results. Therefore, descheduling cannabis and activating federal regulators will yield tangible benefits for state regulators, who are all asking for the support.

[18] The National Technology and Advancement Act of 1995 allows federal agencies to adopt technical standards from voluntary consensus bodies. Many federal agencies already use the voluntary consensus process to reference standards developed in the private sector. For example, American Society for Testing and Materials (ASTM) International standards are incorporated by reference in several existing federal regulations, such as safety requirements for children's toys and testing methods to determine biobased content for the BioPreferred Program. ASTM International and other organizations, such as the American Herbal Products Association (AHPA), are already developing GAP and cGMP standards for cannabis, which the federal government can leverage in the regulatory process.

Pesticides

The existing federal system for pesticide control, which is overseen by the Environmental Protection Agency (EPA), requires no adjustments to accommodate the regulation of cannabis. Pesticide rules are generally set at the federal level, and the only current challenges stem from some cannabis plants ("hemp") being descheduled, while the rest are still classified under Schedule I of the CSA.

For example, many pesticides approved by the EPA for hemp cultivation are not approved for marijuana cultivation. Instead, pesticides get authorized state by state, giving rise to significant variability and forcing regulators to make evaluations that may be outside of their expertise. The result is a patchwork of rules and inconsistent enforcement.

Under existing federal rules, pesticide manufacturers must be federally registered, which requires robust toxicity studies based on route of administration. Applying these rules to pesticides used on cannabis would sufficiently ensure consumer safety for inhalable products and other product types. By removing the sole source of confusion—ending the unnecessary bifurcation of the cannabis plant—current pesticide approval requirements will apply, and those already approved for hemp can be used on all cannabis when appropriate.

Labeling Standards

Inconsistent labeling requirements are one of the greatest challenges for consumers and businesses in state-regulated cannabis markets. Every state has some unique nuance to its marijuana or hemp label requirements, creating confusion for consumers and increasing costs for operators.

Consumers must have access to the most pertinent safety information, and it should be easy to read and found in the same location in every state. Businesses should not have to print dozens of different labels for the same products due to minor, non-substantive variations across different state markets.

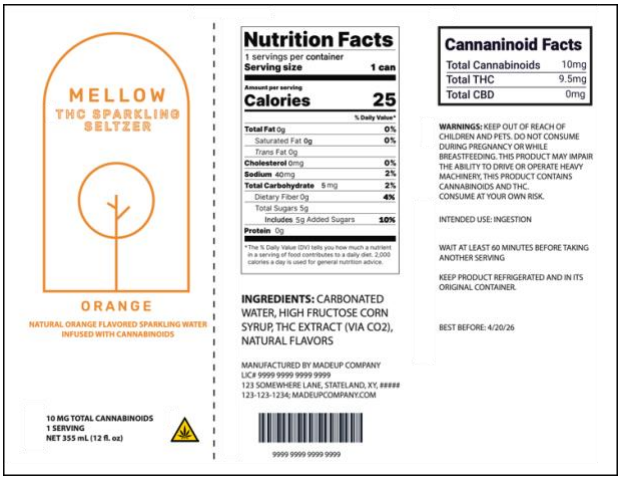
A good example of divergence among state cannabis labeling policies is the "universal" symbol. Most state marijuana markets and some hemp markets require a universal symbol be included on labels to alert consumers to the presence of intoxicating cannabinoids. However, there is significant variation in the appearance of the symbols, not only from state to state, but also between hemp and marijuana products the same state.

States have adopted over a dozen different "universal" symbols to identify intoxicating cannabis products

This problem is unique to cannabis because federal policy establishes national standards for other consumer products. All products regulated by the FDA have standard labeling requirements, and the TTB sets standards for labels on the products it regulates. National standards organizations, such as the American Society for Testing and Materials (ASTM), have developed labels consistent with existing federal labeling best practices that regulators can look to when setting this national standard.

A national cannabis labeling standard codified by the FDA and TTB would help resolve these issues. States can also adopt additional requirements, as they can with other consumable products, but most will likely default to federal policy.

ASTM International's standardized label for marijuana products



Preventing Youth Access

Protecting youth is a critical public health and safety priority at every level of government. When it comes to cannabis, this starts with the product classification scheme described on page 13, particularly designating those that do not meet existing safety standards as

adult-restricted products. It also includes taking steps to prevent such products from being accessed by minors.

States with regulated cannabis markets have been highly successful at preventing sales and discouraging use among underage people—see page 10—but their efforts could be strengthened by a more proactive and pragmatic federal regulatory approach.

Minimum Purchasing Age

To protect the health and safety of children and young adults, the federal government should prohibit the sale of cannabis products that are intoxicating or do not meet existing safety standards to individuals under 21 years of age. This reflects the consensus of U.S. jurisdictions that have legalized marijuana for adult use, and it keeps cannabis in line with other adult-restricted products, particularly alcohol and tobacco.

In 2019, the federal government raised the minimum age for purchasing tobacco from 18 to 21, without exceptions.[19] While the federal government has not established a national minimum drinking age, a law enacted by Congress in 1984 and later upheld as constitutional by the U.S. Supreme Court requires states to set the legal drinking age at 21 as a precondition for receiving federal highway funding.[20, 21]

Every state now prohibits the sale and public possession of alcohol for people under 21 years of age, but state laws can and do have exemptions, such as for medical or religious purposes. Likewise, states should be able to allow exemptions for cannabis consumption for medical or religious purposes, and a mechanism should be established to address such use by individuals under 21 years of age in a manner that mitigates the risk of diversion and ensures consumer and public safety.

Some stakeholders question whether the establishment of a national minimum cannabis age would constitute commandeering and, therefore, violate constitutional restrictions on federal power. Similarly, constitutional considerations—particularly the 21st Amendment, which repealed federal alcohol prohibition—were among the factors that led Congress to use the power of the purse to incentivize state action rather than establishing a national drinking age directly.

If the federal government decides to avoid establishing a minimum age directly, the creation of a federal cannabis tax would provide new revenue that could be used to incentivize states to adopt a national standard, without using existing federal revenue or conditioning compliance on existing federal funding mechanisms. Whereas universal state adoption of the national minimum drinking age took about six years, it would likely be instantaneous with cannabis since 21 is already the minimum age in all adult-use legalization states and no states have considered setting it any lower.

States with regulated cannabis markets have been highly successful at preventing underage access and use, but their efforts could be strengthened by a more proactive and pragmatic federal regulatory approach

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Age Gating

Every state-regulated marijuana market requires customers to present valid, government-issued identification to enter a dispensary or retail location. The federal government should support states' efforts to age gate adult-restricted cannabis products by establishing clear standards for age verification that align with existing federal standards for alcohol.

Online sales are not widely permitted, but some jurisdictions authorize customers to make online payments for pick-up, delivery, or direct-to-consumer sales. In most but not all circumstances, states have established clear requirements for age verification and secure delivery protocols, such as presentation of government-issued identification and/or customer signature at the time of delivery. Where direct-to-consumer sales are permitted, they are likely to occur across state lines, so a national standard should be established to align state policies and ensure age-verification upon delivery for all age-restricted cannabis products. This would also establish a clear pathway for the federal government to support enforcement actions that promote compliance and reduce underage people's access to adult-restricted cannabis products.

[19] Further Consolidated Appropriations Act, 2020. H.R. 1865 (2019).

[20] National Minimum Drinking Age Act of 1984, 23 U.S.C. § 158 (1984).

[21] South Dakota v. Dole, 483 U.S. 203 (1987).

Medical Exceptions

A significant number of Americans under the age of 21 have received a physician's recommendation authorizing them to use cannabis for medical purposes. While some of them may eventually shift to cannabis-based pharmaceuticals—a small number already exist, and many more will likely be developed and approved following descheduling—many of these underage patients will rely on non-pharmaceutical medical cannabis during the interim and beyond.

An exemption to the national minimum cannabis age should be structured for underage patients who participate in state-based medical cannabis programs. While a uniform policy can be adopted for all patients under the age of 21, some distinctions should be made for those under 18. For example, patients 18-20 should be able to access medical cannabis directly, whereas those under 18 must access it via a parent or legal guardian.

Some states have adopted policies designed to protect young patients and mitigate the risk of diversion to their non-patient peers by engaging parents or guardians, imposing standards on physicians, or leveraging technology to limit purchases. These policies could serve as models for federal standards that respect physicians' role in medical assessments, protect states' role in setting their own policies, and align with the federal government's priority of preventing unauthorized youth access.

These standards should include the following requirements:

- For patients under 18, a parent or guardian must consent to a physician's issuance of a medical cannabis recommendation and to the patient's designation as a medical cannabis patient.
- For patients under 18, a parent, guardian, or authorized caregiver must purchase the medical cannabis on behalf of the patient.
- Patients can only receive medical cannabis recommendations from a physician with whom they have a bona fide physician-patient relationship, as defined by state medical boards.
- Medical cannabis recommendations must specifically identify the form factor, cannabinoid content, and monthly purchase allotment recommended for the patient.
- The state must develop a system (or participate in a national system) that restricts patients to purchasing medical cannabis within the confines of their physicians' recommendations, akin to an opiate prescription monitoring program.

Child-resistant Packaging

Accidental ingestion of cannabis products by children is a legitimate public health concern. While efforts should be taken to prevent accidental ingestion of all cannabis products, they should be focused predominantly on products with active cannabinoids, such as cannabis-infused edibles and certain types of cannabis oils.

To reduce the potential for accidental ingestion, states with regulated cannabis markets have enacted policies that require cannabis products be sold in child-resistant packaging that reduces the potential for incidents of accidental ingestion. However, they often apply these rules too broadly, requiring unnecessary childproofing of products that do not pose significant risk of accidental ingestion. For example, whereas young children may attempt to ingest edible products that look like common foods, they are unlikely to eat raw cannabis flower because it does not resemble anything kids are typically interested in eating. Also, cannabis flower is not intoxicating, so the public health risk is relatively minimal.[22]

Edibles and other intoxicating products with a higher risk of being accidentally ingested should be required to come in child-resistant packaging. Rules for packaging inactive products, such as cannabis flowers, should be left to the states.

Marketing and Advertising

Every state with a regulated cannabis market has adopted restrictions on cannabis-related marketing and advertising. While these policies have generally fulfilled their purpose of preventing potentially harmful promotion, particularly to young people, they differ widely from state to state and lack clarity in key areas. The resulting patchwork, which is often marked by vague or inconsistent definitions, creates substantial compliance challenges for businesses and enforcement challenges for regulators. It also introduces avoidable public health risks by increasing the likelihood of

[22] Raw cannabis contains only inactive acidic cannabinoids, such as THCA, which are not intoxicating. Through the process of heating cannabis, known as decarboxylation, those inactive cannabinoids are converted into active ones, such as THC, which give cannabis its psychoactive effects.

inadvertent violations and uneven application of safeguards.

The federal government should establish clear national standards that ensure adult-restricted cannabis products are marketed and advertised responsibly and in a manner that is not attractive to children.

Pathways to Regulation

Federal oversight of marketing and advertising varies by product category. Advertisements for dietary supplements are regulated by the Federal Trade Commission (FTC) and the Food and Drug Administration (FDA).[23] The FDA also has jurisdiction over advertising of pharmaceuticals.[24]

When it comes to age-restricted products, the national approaches to tobacco and alcohol provide useful context for cannabis. Restrictions on marketing and advertising tobacco products emerged largely through settlement agreements, while alcohol restrictions combine industry self-regulation with traditional federal oversight. Both systems underscore the importance of clear national baselines to mitigate public health risks.

Settlement-driven policy is not an optimal pathway for cannabis regulation because it typically follows a history of adverse outcomes. Cannabis policy should instead be proactive, mitigating foreseeable harms at the outset rather than reacting after the fact. Tobacco settlement agreements do, however, offer some precedent on restrictions that should be considered for adult-restricted cannabis products.

The 1998 Master Settlement Agreement (MSA) between the nation's largest cigarette manufacturers and 46 state attorneys general included prohibitions on the use of cartoons, sponsorship of certain events, naming rights for stadiums or sports teams, and advertising on billboards or transit systems.[25]

Alcohol advertising restrictions have been developed primarily through self-regulatory organizations (SROs) working in collaboration with government regulators. In this model, the industry essentially polices itself. For example, the Beer Institute, the Distilled Spirits Council of the United States (DISCUS), and the Wine Institute have adopted a standard advising against advertising where more than 73.8% of the expected audience is under age 21.[26] States have adjusted and incorporated this benchmark into their own regulatory systems.

Although SROs have detractors, they have demonstrated efficacy and foster responsibility and compliance within the industry.

Alcohol advertising is also federally regulated by the TTB. These rules extend beyond youth protection and ensure truthful, non-misleading marketing. Requirements vary by product classification, but generally include identification of the business, product classification, alcohol content (for spirits), and disclosure regarding neutral spirits used in the product. The TTB also prohibits false statements, disparagement of competitors, obscene designs, misrepresentation of tests, and claims inconsistent with labeling.

Notably, the TTB does not require pre-approval of advertisements, but it does offer businesses the opportunity to voluntarily request pre-publication review.

National standards for marketing and advertising, paired with the opportunity for voluntary pre-clearance, would improve public health outcomes by strengthening existing safeguards and addressing interstate inconsistencies as they arise

[23] Federal Trade Commission, Bureau of Consumer Protection. *Dietary Supplements: An Advertising Guide for Industry*. Federal Trade Commission, 2001.

[24] 21 U.S.C. § 352(n).

[25] National Association of Attorneys General. *The Master Settlement Agreement*, 1999.

[26] Beer Institute. *Advertising/Marketing Code and Buying Guidelines*, September 2023; Distilled Spirits Council of the United States. *Code of Responsible Practices for Beverage Alcohol Advertising and Marketing*, July 2025; Wine Institute. *Wine Institute's Code of Advertising Standards*. Webpage accessed November 20, 2025.

National Standards and Voluntary Pre-clearance

Regardless of whether cannabis marketing and advertising restrictions are implemented through federal regulation, SROs, or a hybrid approach, national standards are necessary to address the public health risks associated with unfettered advertising of intoxicating or adult-restricted cannabis products. Development of a unified national regulatory framework creates an opportunity to not only incorporate lessons from tobacco and alcohol, but also to improve upon them.

Clearer, more objective standards paired with a voluntary pre-clearance option, would strengthen existing safeguards and address interstate inconsistencies as they arise. Consistent with current federal roles, the TTB is well-positioned to regulate advertisements for intoxicating or adult-restricted cannabis products, while the FDA should regulate advertisements for food, dietary supplements, and pharmaceuticals containing cannabis- derived ingredients.

Prohibiting Copycat Products

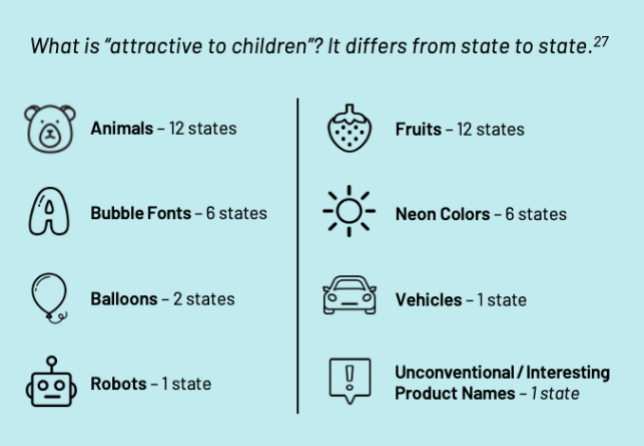
The federal government should establish an unambiguous prohibition on adult-restricted cannabis products that mimic existing commercial food products by using the same or similar name, branding, or specific imagery. This will prevent "copycat" or "look-alike" products with recognizable packaging that improperly appeals to underage people. It will also reduce the potential for accidental consumption by children and adults who may mistake cannabis products for recognizable non-cannabis products.

Bans on copycat products have long been central to state marijuana regulation, and such products are now found only in the illicit market. There has also been a resurgence in this marketing practice among unregulated intoxicating hemp products.

Defining "Attractive to Children"

Whether it is through an SRO, direct regulation, or a combination, a clear national baseline for acceptable marketing and packaging should be developed that balances a consumer's right to access accurate information about legal products with strong protections against advertising likely to promote youth use.

Specifically, the federal government should also establish clear and unambiguous guidelines for what constitutes "attractiveness to children." States with regulated cannabis markets have all adopted rules prohibiting products that appeal to underage people, but they have applied inconsistent and vague definitions that frequently amount to an express or implied "we know it when we see it" standard. This creates significant compliance challenges for businesses, especially those operating in multiple states, which must adapt their products and packaging to maintain compliance in each state.



Stakeholders interviewed for this paper noted that the standards for "attractive to children" have remained stable only in the few states where reviews have been performed by the same agency staff member since the programs' inception. This highlights the underlying subjectivity of current state systems. Greater objectivity is needed to reduce inadvertent noncompliance and enable businesses to more thoroughly assess their branding options prior to making significant investments.

Objectivity can be introduced by establishing clear guidelines for permissibility in common gray areas. For example, using an illustration of a fruit to indicate a product's flavor should be acceptable, while anthropomorphizing fruit into a cartoon character with arms and legs should not. These distinctions can be subtle, so expectations should be clarified through concrete examples of permissible and impermissible marketing.[28] There could potentially also be separate standards for brand logos versus on-product packaging.

[27] These figures reflect the numbers of states with statutes or regulations that explicitly prohibit these design elements. They do not include states with vague definitions of "attractive to children" that may result in banning them through supplemental guidance or enforcement memos.

[28] For example, there have been extensive regulatory conversations in Colorado about whether a circular, orange-colored product is shaped like a fruit, which is prohibited, or whether the design would need to include a stem and leaf to qualify as a fruit shape.

Taxation and Product Authentication

Consistent with TTB's regulation of tobacco and alcohol, there will be a critical need to appropriately tax and authenticate products containing cannabis derivatives. Authentication plays a critical role in tax collection but, even more importantly, it helps to ensure all products are produced under appropriate product safety standards and sold to consumers who meet the legal minimum age.

To properly tax and authenticate products, the federal government will need to register businesses engaged in commercial cannabis activity, which also creates the necessary mechanism for the federal government to support state enforcement actions in a manner consistent with their typical collaboration. TTB already has systems that can be applied to cannabis-related taxation, authentication, and registration, and it can leverage new technologies to reduce costs and ensure compliance.

Taxation

Federal cannabis regulation creates an opportunity to generate significant new tax revenue. This paper focuses on tax policy considerations and generally does not contemplate how tax revenue should be appropriated. It is worth noting, however, that revenue could be used to cover expenses associated with cannabis regulation, or as a lever to incentivize states to take desired regulatory actions (e.g., requiring states to restrict sales to adults 21 and older to be eligible for federal funding generated by cannabis tax revenue).

National Cannabis Sales Tax

The simplest approach to taxing cannabis at the federal level would be to establish a national cannabis sales tax administered by the TTB. This tax could be imposed on retail sales of all adult-restricted cannabis products, or it could be more narrowly applied only to those products that contain THC and any other intoxicating cannabinoid(s) later authorized for sale by the FDA. Like other taxes on retail sales, the rate could simply be a percentage of the purchase price of the product.

This type of sales tax is recommended because it is most consistent with the tenets of fair tax policy—simple, stable, transparent, equitable, and adequate. Removing the complexity from federal tax policy will increase compliance rates, reduce enforcement costs, and avoid some of the challenges state regulators have encountered with other types of taxes.

A national cannabis sales tax would be simple, stable, transparent, equitable, and adequate, and it would avoid some of the challenges states have encountered with other types of taxes

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Complications with Cannabis Production Taxes

The federal government imposes a production tax on alcohol, which is perhaps the most comparable product. However, states that have adopted cannabis production taxes have experienced significant policy and operational complications that could be avoided with a more basic sales tax.

Some states have imposed volume-based production taxes on cannabis, like those applied to alcohol. While they are relatively simple to implement and offer a greater level of stability for tax collectors, they can create challenges for businesses. Specifically, decreases in cannabis prices—a common occurrence across all state regulated markets—result in an increased tax rate as a percentage of purchase price. For example, Alaska initially established an excise tax of $50 per ounce of flower, which at that time was equal to a 20% tax on the average wholesale price of $250 per ounce. Within a few years, the average wholesale price dropped to $145 per ounce, effectively raising the tax rate to 35%.[29] This level of fluctuation can be economically unsustainable and likely to force policymakers to adjust their approaches.

To avoid such scenarios, other states have structured production taxes as a percentage applied to sales or transfers at the wholesale level (e.g., from a cultivator to a retail store or product manufacturer). This approach works well for arms-length transactions, but it tends to create problems in the many states that permit cannabis businesses to vertically integrate. These states must engage in complex calculations to determine an average market rate upon which they can base the taxation of internal transfers.

[29] Tax Foundation. *A Road Map to Recreational Marijuana Taxation*. June 9, 2020.

While cannabis production taxes tend to create headaches for regulators and businesses, they do have one particularly notable advantage over sales taxes. There will likely be fewer producers than retailers, which means fewer businesses subject to taxation, fewer tax submissions to be processed, and fewer businesses that must be monitored for compliance.

Structuring a Production Tax

If federal policymakers prefer a production tax, it should consider a volume-based tax on intoxicating cannabinoids (THC and any others approved by the FDA) that is consistent with how the federal government taxes alcohol.

All manufactured products should be taxed at a flat rate per milligram of THC because cannabinoid content can be consistently controlled through manufacturing processes and systematically confirmed through testing. Cannabis flowers, on the other hand, should be subject to a flat per-gram rate due to the natural variation in cannabinoid content. It varies from plant to plant, even if they are the same strain, and there can be variation within flowers of the same plant. The inherent variability of an agricultural product, as opposed to a controlled manufacturing process, creates a level of complexity that would necessitate federal and private sector resource investments that would not produce sufficient benefits.

Production taxes should be applied at the point when an adult-restricted cannabis product containing an intoxicating cannabinoid is packaged for consumer sale. This point of taxation avoids taxing farmers and disincentivizing commercial applications for non-intoxicating cannabis products, such as foods, cosmetics, and dietary supplements. It also avoids taxing product inputs that eventually fail quality control, which would increase incentives to circumvent the system and place potentially unsafe products into the stream of commerce.

Finally, any volume-based production tax should be coupled with mandatory rate adjustment periods to account for modulation of prices following descheduling.

Tax Rates

Regardless of whether the federal government opts to create a simple sales tax or a more complex production tax, it is critical that tax rates be set relatively low and remain generally equivalent to alcohol taxes.

State and local governments already impose a significant tax burden on regulated cannabis businesses, with taxes exceeding 40% of the purchase price in some jurisdictions. This high rate of taxation is not in line with other commodities, even those with a "sin tax," and it inhibits the regulated market's ability to displace the illicit market. Also, if federal taxation rates are set too high, the combined federal, state, and local effective tax rate will almost certainly become economically unsustainable, shuttering regulated businesses and allowing the illicit market to thrive.

The federal government should follow the lessons learned when ending alcohol prohibition, where tax rates were intentionally set low to allow the regulated market to supplant the illicit one

The federal government should follow the lessons learned when ending alcohol prohibition, where tax rates were intentionally set low to allow the regulated market to supplant the illicit one. Even though alcohol prohibition ended 100 years ago, federal tax rates on alcohol are much lower than the tax rates state and local governments are currently applying to cannabis in most regulated cannabis markets. The average tax on beer is only about $0.05 per can, which is about 4% of the cost of a $9 six-pack.[30] Wine often only has a federal tax of about $0.21 per bottle, which is less than 2% of the cost of a $15 bottle.[31] Taxes on distilled spirits are more complicated to calculate but often amount to a little over $2 per 750ml bottle of 80 proof liquor.[32]

Although this amount modulates based on product quality and category, the total alcohol tax burden is less

[30] Based on the rate of $18 per barrel, which is the highest federal excise tax rate paid by brewers that produce more than six million barrels annually. The rate is lower for small domestic producers that produce less than two million barrels annually.

[31] Based on the base federal excise tax rate of $1.07 per wine gallon for still wine under 16% alcohol by volume. Many producers are entitled to tax credits that lower the effective tax rate. Sparkling wine and higher alcohol wines are subject to different tax rates.

[32] Based on the full federal excise tax rate of $13.50 per proof gallon. Smaller producers are subject to lower rates.

than some municipal cannabis taxes, let alone state taxes and a new federal tax.

In addition to exercising moderation when setting federal cannabis taxes, the federal government could create incentives that encourage state and local governments to reconsider excessively high tax rates. For example, states or cities that tax cannabis below a certain tax rate could receive more federal funding, from cannabis tax revenue or otherwise, to support a related government program.

Federal Cannabis Tax Registration

All businesses engaged in commercial cannabis activity should be required to obtain a simple federal cannabis tax registration from the TTB.

Even though many companies will not be required to pay federal taxes under the previously outlined tax structures, this registration will allow the federal government to identify businesses engaged in commercial cannabis activity and where that activity is occurring. It also establishes federal regulatory authority to enforce against noncompliant businesses, which may be necessary at times when states require enforcement support.

Federal cannabis tax registration can be simple, and complex matters, such as suitability for licensure, can be left to states that already have bureaucracies in place to license cannabis businesses based on standards set by state policymakers. A costly and complex registration process may also disincentive farmers and other small businesses from self-identifying.

Instead, federal policy should focus on a simple registration process to confirm that the business and its owners have not been suspended or prohibited from engaging in commercial cannabis activity by the federal government. This strikes the appropriate balance between incentivizing compliance, allowing states to set their own policies, and ensuring the federal government can take administrative action when necessary.[33]

The federal government's ability to assume its traditional regulatory role in supporting enforcement efforts is a critical benefit of descheduling cannabis. Addressing cross-border issues is one of the biggest enforcement challenges state regulators face, and they will benefit from federal engagement when their ability to police out-of-state actors is hampered by large enforcement costs or a lack of jurisdictional authority. The mere adoption of a federal registration system would have a chilling effect on noncompliance, as businesses will recognize there is greater likelihood of enforcement and more to lose if they are caught.

Federal cannabis tax registration can be simple, and its mere adoption would have a chilling effect on noncompliance

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Under this system, most compliance issues can be handled by state actors, like they are for alcohol. Federal involvement would only be necessary when there is "material noncompliance with federal priorities," which could include:

- Selling cannabis to minors persistently
- Advertising cannabis in a manner designed to be attractive to children
- Intentional noncompliance and material violations of product safety rules
- Operating in states that do not permit commercial cannabis activity
- Interstate safety-related violations or selling cannabis interstate in a manner that violates state law
- Failure to pay taxes

Product Authentication

Another key regulatory function of the federal government should be authentication of products that are produced and sold in the regulated market. This is critical to ensure compliance with taxation, product safety standards, and age-gating requirements. Federal authentication will also facilitate interstate commerce, which would be challenging for states to do on their own and typically falls within federal regulatory purview.

[33] Minnesota required businesses manufacturing and selling low-potency hemp edibles to fill out an online business registration application at no cost. More than 6,000 businesses registered with the state, and registration status has been tied to enforcement efforts, with civil penalties of up to $10,000 for selling products without state registration.

With alcohol, the federal government prohibits vertical integration and requires all products to pass through a distributor for tax collection and product authentication. This is a significant market intervention that would have severe economic consequences if applied to cannabis. It would immediately shutter many vertically integrated cannabis businesses, triggering massive job losses around the country. It would also impose an outdated regulatory system on a new, post-prohibition industry, creating an economic vacuum and unnecessary compliance costs that hinder its ability supplant the illicit market.

Fortunately, technology has evolved considerably since the development of alcohol's three-tier system, and products can now be authenticated through inventory transparency. The federal government already has systems to collect these data points, such as USDA requirements for agriculture reporting and TTB requirements for alcohol production reporting. States also have robust data collection systems that have amassed more than a decade of data on various supply chain inputs and outputs, which have been used to develop algorithms and employ artificial intelligence to identify risk points.

Through slight modifications of existing requirements and leveraging of modern data analysis, the federal government can clearly identify products being inverted into the supply chain or diverted out of it by actors seeking to avoid taxation, conduct underage sales, skirt product safety laws, or engage in other unlawful activity. This would help focus regulatory enforcement efforts on those businesses that present the greatest risk for noncompliance.

There are various ways to set up such a system. At a minimum, federal policy should include the following requirements:

- Cultivators should report mostly the same information collected by the USDA, such as number of plants, harvest volumes, and sales. The only additional information they should be required to report is whether their cultivation is taking place indoors, outdoors, in greenhouses, or a combination thereof. The frequency of such disclosures should be increased to permit swifter federal action should the need arise.[34]

  Companies selling or purchasing cannabis from another entity should disclose the weight of cannabis flower or units of specific products being sold or received.[35]

- Companies engaged in multiple phases of production (cultivation, extraction, product manufacturing, etc.) should disclose certain inputs and outputs to account for commercial activity that occurs outside arm's length transactions.

- Companies engaged in the retail sale of cannabis to consumers should disclose total sales of specific products or product categories on a commercially reasonable frequency.

Through registration and inventory disclosure, the federal government will be able to identify who is engaged in commercial cannabis activity, where that activity is occurring, and statistical anomalies that would allow for the prioritization of investigatory resources to best protect public health and safety. The more points where the federal government can collect data, the more accurate and secure the system will be. While a bad actor could easily manipulate a single data point, the disclosure of multiple data points throughout the supply chain would make it much more difficult to cheat the system.

Existing federal systems can be used to identify products being inverted into the supply chain or diverted out of it by actors seeking to avoid taxation, conduct underage sales, skirt product safety laws, or engage in other unlawful activities

[34] The federal government should endeavor to minimize additional inventory disclosure requirements on farmers to encourage additional cultivation for various commercial purposes beyond producing intoxicating products. It is critical to establish oversight of intoxicants, but there are many other commercial applications for cannabis that offer opportunities for innovation and business formation that should be exploited to the country's benefit.

[35] A transfer manifest is not required for data collection if everyone in the system will have a federal tax ID or a federal tax registration number.

Transition Period

Although the proposed federal regulatory framework largely leverages existing agencies and systems, it will take time to integrate cannabis into them and for states and businesses to adjust to the new model.

Instead of rushing this process, which will likely take multiple years, the federal government should establish a limited, clearly defined transition period. This should be done in statute to give regulators and businesses more certainty that the timeline will be maintained, as opposed to via regulation, where it can more easily be amended or extended. All states should be required to enter the federal interstate system by a specified date.

Federal policy should allow state systems to continue operating temporarily and provide for a strategic implementation of the federal overlay in a manner that balances positive public health and economic impacts with the risks posed by a major market adjustment.

Federal Considerations

During the transition period, relevant federal regulatory agencies will need to develop standards and either adapt existing systems or create new ones in the limited cases where they are needed. They should largely be able to fit cannabis into existing regulatory channels and systems, which will facilitate this process. For example, the FDA and TTB have the expertise to establish a national standardized labeling requirement, and standards organizations have already established a strong starting point. Still, these federal bureaucracies will need time to adopt regulations and identify and activate appropriate staff. A firm transition timeline with clear deadlines will ensure efficient and successful implementation.

Consideration of international commerce should be postponed until after interstate commerce is established, giving American businesses a chance to establish themselves and regulatory systems sufficient time to develop. This additional transition period will be necessary, as it would be extremely difficult to establish a national regulated market while simultaneously addressing the complications of international treaties and trade policies.

State Considerations

During this defined transition period, states would continue to set standards and manage enforcement for their regulated cannabis markets. States could continue to prohibit any form of commercial cannabis activity, but as previously noted, they should not be able to prohibit transportation of cannabis through their states, as it would undermine the goal of allowing federally regulated interstate commerce. During this time, states should be expressly permitted to authorize interstate commerce under their own rules or through interstate compacts.

Most states that created regulated cannabis markets under federal prohibition established completely intrastate supply chains in accordance with federal guidance. These states will need to modify their statutes and regulations to permit interstate commerce. Laws and regulations will also need to be modified in states that have permitted interstate commerce for intoxicating hemp products or the authorization of interstate compacts. This will take time, especially considering the wide variance in legislative calendars and timelines for the adoption of administrative regulations. For example, some state legislatures do not convene annually, but states should not be required to hold costly special legislative sessions or adopt emergency regulations.

Private Sector Considerations

Many companies have invested in business models that will be significantly altered by the onset of federal reform. As interstate markets open, costly infrastructure investments may be rendered obsolete. Businesses may need to adjust, which may be particularly difficult for small businesses if they lack sufficient capital. A national marketplace supported by the traditional partnership between state and federal regulators will increase investment and innovation in the long run, but a rush to interstate commerce could cost many Americans their jobs as businesses adjust in the short run.

If businesses are not permitted sufficient time to adjust, it could undermine efforts to eliminate the illicit market. For example, producers in traditional export markets like California, Vermont, and Oregon would be able to quickly absorb market share in newer state markets where prices have yet to stabilize, causing prices in those states to crash. Also, without sufficient time to prepare, businesses with large quantities of existing inventory might struggle to find a market for their products at the prices envisioned in their models, creating an incentive to divert cannabis outside the regulated system. If there is adequate time for markets and businesses to adjust, supply will eventually level out with demand and production will naturally shift to the most efficient places.

Data Collection and Health Monitoring

The federal government has traditionally overseen the systematic collection, analysis, and dissemination of data by government agencies to detect and respond to health threats. It has reported on cannabis-related metrics, but prohibition has long constrained the scope and reliability of the data.

Descheduling and federally regulating cannabis would allow the federal government to reclaim this core public health and safety function. Bringing cannabis above board would improve data quality, enabling regulatory frameworks to evolve based on real-world evidence and allowing consumer education to be targeted more effectively—especially toward vulnerable populations.

Although states currently collect cannabis data, federal descheduling creates an opportunity to expand and harmonize these efforts. State systems vary widely in what they collect, how they report it, and when data are released, producing a fragmented picture that limits rigorous analysis and forecasting. A unified, national data resource covering metrics such as sales, product categories, pricing, and consumption patterns would strengthen research, inform policy, support businesses, and enhance consumer protection. Consistent, high-quality data is essential to tracking public health outcomes, understanding market dynamics, and identifying emerging risks and best practices. In turn, better data would enable smarter regulation, more effective interventions, and more durable policy over time.

Conclusion

The federal government's prohibition on cannabis and bifurcated policy approach to "hemp" and "marijuana" are not sustainable. As long as federal law treats the same plant as two different commodities, regulators will chase loopholes, consumers will lack consistent protections, and the market will continue to be distorted in ways that reward chemistry over compliance.

The one-plant solution proposed in this paper offers a single, science-based federal framework—one plant, one set of rules—that would establish clear federal standards and maintain states' autonomy so they can continue to serve as laboratories of democracy. This is essential not only for economic coherence, but for public health and safety. Uniform guardrails are critical to ensuring product safety, preventing youth access, supporting responsible consumption practices by adults, and obtaining dependable data for researchers and clinicians.

Congress's recent action to recriminalize hemp has created a rare inflection point; policymakers should use it to build a durable, comprehensible U.S. cannabis policy that ends the two-track confusion and delivers the clarity the country is ready for.