US CANNABIS COUNCIL

USCC Response to the Cannabis Administration and Opportunity Act

Contents

I. Introduction

Thank you for the opportunity to review and respond to the discussion draft of the Cannabis Administration and Opportunity Act (CAO Act). The US Cannabis Council (USCC) applauds the goals outlined in the proposed measure, the carefully considered approach, and the incredible support the sponsors have for this important issue. We will not have serious justice reform in our country until we end the federal government's harmful war on cannabis, and this measure is the first, truly comprehensive approach to a solution.

The USCC is a strategic alliance of 65 companies and nonprofits working in the licensed, medical and adult-use cannabis industry in the United States. We represent the U.S. regulated cannabis industry, which supports more than 320,000 full-time jobs and has already generated $7 billion in state and local tax revenues from adult-use cannabis sales. With adult-use sales projected to reach $19 billion by 2025, the Congressional Budget Office estimates that descheduling cannabis would boost federal revenue by nearly $14 billion over the next decade.

USCC's business members -- including many of the largest cannabis companies in the nation -- employ tens of thousands of American workers and collectively generate over $6 billion in annual revenue, resulting in a market valuation of over $65 billion. Our nonprofit members are leading organizations focused on cannabis policy, criminal justice reform, veterans' rights and more. Together, USCC's members form the broadest and most diverse collection of organizations, businesses and individuals ever assembled

to end federal cannabis prohibition and create an equitable and values-driven cannabis industry with social, financial, and environmental benefits shared by all.

Legalization laws have been in effect in the U.S. since 1996, when voters in California adopted a law that allowed residents in California -- those with certain qualifying medical conditions -- to cultivate and consume cannabis under specific circumstances. Other states quickly followed and regulatory systems became far more sophisticated. Today, two out of three states (including well over half the U.S. population) is a jurisdiction in which qualified adults and minors qualified by the state for medical purposes can access and consume cannabis products that were grown and processed in the state. That same approach was then applied to consumption by all adult consumers starting in 2012 and today, nineteen states allow access for all adults 21 or over, with eight of them including New York, New Jersey, Virginia, New Mexico, Montana, South Dakota, Arizona, and Maine, bringing programs online by the end of 2022. More states will follow.

The medicinal use of cannabis and social equity for those who participate in the regulated cannabis system are two issues that are essential to our members, as well as to the formation of the cannabis industry itself. These issues must be carefully addressed by Congress. Important voices have emerged in this area, including USCC member the Association for Cannabis Health Equity and Medicine (ACHEM), a cannabis medical association for healthcare professionals and healers of color that work to bring health and social equity to the public through the cannabis industry. Other important voices include the Minority Cannabis Business Association (MCBA) and the Cannabis Regulators of Color Coalition (CRCC) which also represent important perspectives in this critical area.

We appreciate the questions posed by the sponsoring offices as the federal government considers how best to enter the discussion. We believe that like other areas of regulation, the most effective approach will be one that relies on a carefully considered framework built from a combination of both federal and state agencies and resources, working in coordination to finally end the disparate impact and harmful effects of years of the current drug policy.

This response is divided into multiple parts. Following this introduction is a brief executive summary. We then explore some of the broader issues the USCC believes the sponsoring offices should consider in evaluating the initial draft, and where it may be improved before being introduced, along with our recommendations. We believe there are effective alternate approaches that can achieve the sponsors' goals, future-proof the regulatory model further, and minimize avoidable harm. The subsequent part addresses many of the sponsoring offices' stakeholder questions. Finally, our recommendations are summarized in the last part.

II. Executive Summary

The USCC applauds the scope of historic nature of this legalization proposal, and our members, who represent many of the largest businesses that operate within the legalization and medical cannabis system today, support these goals.

A national, comprehensive regulatory system is urgently needed in the United States. For decades, the war on marijuana has been a war on Black and brown Americans, who have been arrested at rates that are many times that of their white counterparts, even though they consume cannabis at about the same rates. We will not see justice until we remove this unfair system of prohibition laws. Instead, the federal government should implement a meaningful, comprehensive and carefully-considered regulatory system, which we think the sponsoring offices have proposed. We must end our patchwork system and identify best practices which can be adopted by all states with

cannabis-related activity. This will open tremendous opportunity for coordination and cooperation between state and federal regulators as they reign in the underground market and improve state programs in key areas. Finally, federal participation can help reduce racial disparity in many state programs and provide meaningful access to funds and assistance for social equity and small businesses.

In most of the policy areas presented in the CAO Act proposal, the USCC supports the framework and approach. We are happy to support these efforts and contribute our knowledge and experience to further the work put forth by the sponsoring offices. However, there are several significant areas in which we think regulation should take a different direction. Accordingly, these comments are split between our own comments as they touch on these important priority policy issues, and our responses to the sponsoring offices' questions for stakeholders.

Several issues rise to the top. First, we believe that Alcohol and Tobacco Tax and Trade Bureau (TTB), not the Food and Drug Administration (FDA), should serve as the primary regulator in the U.S., and that it should work closely with state regulators which have successfully regulated cannabis for years. Significantly shifting regulatory oversight in the U.S. to FDA will have negative consequences and invites uncertainty, which is discussed in our comments below. Not the least of which, an FDA-centric system will place enormous financial pressure on social equity and minority-owned businesses, which we think would be unlikely to survive in any form like they exist today. Furthermore, FDA's own track record with the cannabis plant over the past several years shows it is simply not the right agency for the role ahead.

Related to this, we believe strongly that state medical cannabis programs must be protected so states can ensure access to medical cannabis products for those who qualify. FDA, which is charged with overseeing drugs in the U.S., is not suited to ensuring these programs will remain intact. TTB should instead work with the states to create a regulatory framework that relies on FDA's guidance on health and safety standards for products and non-cannabis ingredients. As with alcohol, TTB and states should regulate, with FDA helping set policy in areas of health and safety.

Secondly, we believe the U.S. must plan its transition timeline carefully and extend it beyond current expectations for several reasons. From state programs which rely on tax revenue to our international treaty obligations, to serious Constitutional challenges that could be raised in states following descheduling, it will take time for governments, regulators, and businesses to consider, adopt new approaches, and adapt to them. Perhaps different aspects of the program can follow along different timelines with some moving more quickly than others, but the USCC believes the timelines as provided in the CAO Act are too aggressive to avoid a destabilizing impact in today's regulated markets.

Third, we think that application of the alcohol model will work but should be adapted to better fit the cannabis production system. Further, the tax rate is too high, imposed too quickly, and it ramps up too fast for states to adapt while in the midst of the other aspects of the transition. Rather than the proposed seemingly arbitrary percentages, the sponsoring offices should consider their long term goals, carefully study the market and the best tax rate and rate of increase, and calibrate the transition length and the total amount of revenue accordingly. We look more closely at these three issues in Part III below.

Part IV addresses many of the stakeholder questions put forth by the sponsoring offices, and many also touch on these areas already mentioned.

Above all, we support the leadership and vision of the sponsoring offices and thank their staff for the incredible effort behind the Cannabis Administration and Opportunity Act.

Where we disagree we do so as allies, and we hope to engage in dialog to address concerns we all share.

III. Primary Issues

As previously stated, the USCC shares the goals of the sponsors and those outlined in the CAO Act and the need for a national, comprehensive, federal regulatory program. But there are several critically important areas in the draft that we believe -- in their current form -- will fall short of achieving their intended results. We explore these areas and look forward to finding solutions as we develop the best framework possible:

A. FDA Should Not Be the Primary Regulatory Agency

The FDA will certainly take a role to help ensure the health and safety of those who consume cannabis products, and the USCC strongly supports the agency's mission. As the country adapts to a new regulatory footing, FDA's ability to set standards and inform state programs and consumers of critical health and safety information will be essential.

However, the USCC believes that the CAO Act, as currently written, places too much emphasis on the FDA's role in the emerging regulatory system. Instead, we believe that commercially processed intoxicants should be primarily regulated by TTB, similarly to alcohol, and with significant cooperation with FDA in specific and important ways. The USDA could also play a significant role as it does in other agricultural crops in the U.S.

At the outset, the safety profile of cannabis shows it is far less addictive than other regulated products such as alcohol, and the regulatory regime should reflect that. In addition, the cannabis market is vibrant, varied, widespread, and growing rapidly. Recent actions by FDA with respect to hemp-derived products and CBD clearly demonstrate that it is not the most effective agency to regulate cannabis. This is particularly true given the many challenges related to cannabis due to its nature as both a health aid and as an intoxicant, and in light of a successful track record through state-level regulation. Simply put, FDA is not the right lead regulatory agency for cannabis for a variety of reasons.

A heavy FDA approach will create an extraordinarily challenging environment for small businesses that are newly launching in legalization states. If history is any indication, the process of proposing, reviewing, and approving cannabis products is likely to be extremely expensive and time consuming. When combined with the already high costs associated with operating a cannabis business, this will place cannabis businesses beyond the reach of most. We predict that an FDA-led program will lead to a rapid consolidation of existing businesses within the industry due to the specialized nature and cost -- a disaster for "mom and pop" shops seeking to operate in state programs. This will skew future development in the industry towards large enterprises and thwart the development of smaller, diversity-owned enterprises.

The single greatest barrier to entry for social equity businesses is financial, and the shift of regulatory authority to FDA is indicative of a broader challenge when it comes to the CAO Act: costs are significantly higher for those seeking to be licensed - not because of licensing fees (which can be waived in some circumstances) but because of the incredible burden they will have to meet once operational. These types of requirements would create extraordinary barriers to entry for any business except the most heavily capitalized, leaving social equity and emerging businesses well outside the realm of participation. In fact, it runs the risk of becoming a new form of redlining.

For quite some time, states have been regulating the licensing, production, processing, sales, and consumption of cannabis. State programs include a wide range of products subject to production standards and safety testing. While studies vary, there does not appear to be a significant increase or decrease in crime following adult-use legalization based on available data.[1] These programs are the means by which states have decided to regulate, and their track record is one of the reasons why legalization continues to gain support among residents and voters around the country. States programs helped ensure tainted products which appeared in the market leading to EVALI[2] were not available through the regulated market. We support an FDA role in which health and safety standards are identified and made available for state regulators and consumers, but we do not believe that rebooting today's system with FDA serving as the primary regulatory authority will in any way improve the regulatory framework for cannabis in the U.S.

As is highlighted in other areas of this set of comments, the primary driver of interest in cannabis reform in the U.S. is medical cannabis, and medical cannabis programs are by far the most common form of legalization - including 36 states. FDA is not suited to oversight of a product recognized as "medical" at the state level, at the same time as it regulates drugs made from the same constituents. And very recently it has shown how difficult it will be for cannabis companies to participate, through the recent determination in the Charlotte's Web case.[3]

The prospect of FDA overseeing a national regulatory framework that consists primarily of medical cannabis programs is troubling. While we believe health claims should be reserved for drugs overseen by the FDA, there are obvious possible areas where FDA may have conflicts of interest as it regulates pharmaceutical drugs made from the same constituents. The preclusion doctrine is a serious consideration and should be factored into the regulatory landscape. Further, we think that the use of flower by consumers and the presence of cannabis in a wide range of consumable products - while long a staple of the state programs - will not be supported by the FDA. We do not believe the FDA, whether in the short or long term, is likely to allow state medical cannabis to continue as they do today. This will have a profound impact on the very social equity and minority-owned businesses the bill seeks to support, much less the patients themselves who would face an uncertain future in which state-sanctioned "medical cannabis" as we know it today may or may not exist.

We believe the proper role for FDA is to set standards for labels, standards for added ingredients besides cannabis, including prohibited additives, standards for serving sizes, testing standards, and food ingredients and other additives that are not commonly part of the market today. FDA should be prohibited from interfering with the integrity of state medical cannabis programs and the states' role in defining who participates, qualifying conditions and ages, and role as regulators. Any product that makes a health claim should be subject to the FDA's drug pathway. The agency should enter into a Memorandum of Understanding (MOU) similar to one currently in place between TTB and FDA related to alcohol, which could serve as a model for a similar arrangement with

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[1] Mary K. Stohr, Ph.D., Dale W. Willits, Ph.D., David A. Makin, Ph.D., Craig Hemmens, J.D., Ph.D., Nicholas P. Lovrich, Ph.D., Duane L. Stanton Sr., Ph.D., Mikala Meize, MA, Effects of Marijuana Legalization on Law Enforcement and Crime: Final Report, Department of Criminal Justice and Criminology Washington State University, June 30, 2020, https://www.ojp.gov/pdffiles1/nij/grants/255060.pdf, and Angela Dills, Sietse Goffard, Jeffrey Miron, & Erin Partin, The Effect of State Marijuana Legalizations: 2021 Update, CATO Institute Policy Analysis No. 908, February 2, 2021 https://www.cato.org/policy-analysis/effect-state-marijuana-legalizations-2021-update

[2] EVALI stands for e-cigarette or vaping use-associated lung injury. The term was coined for severe lung illness cases related to using e-cigarette and vaping products. Health officials pointed to vitamin E acetate (an additive in some THC vaporizers found in products largely outside the regulated state cannabis system) as the primary, but not the only, cause of EVALI.

[3] Charlotte's Web, Inc., FDA NDI Denial Letter (July 23, 2021)(available at: https://s22.q4cdn.com/636117063/files/doc_downloads/2021/08/FDA_NDI_CW.pdf)

respect to cannabis. Limits should be placed on FDA's ability to prohibit products based on the preclusion doctrine except where there is specific concern related to a particular product (as opposed to objecting to a class of products available on the legalization and medical cannabis market today). Additionally, the agency's ability to limit commonly-available cannabis products based on additives or food ingredients should be limited to situations in which there are clear and specific concerns.

The USCC believes that TTB is a better choice as the primary regulator. It is in a better position to be responsive to the rapidly-changing needs of a quickly growing and innovative new industry. TTB also has a proven track record of being an effective choice when it comes to dealing with socially sensitive products, successfully helping to protect consumer safety. It is in a better position to understand the needs of small businesses and accordingly, those of social equity businesses. As previously mentioned, TTB can work with FDA as needed to help set standards and guidance in areas such as labels, testing, and other key areas. It is also less likely that TTB would need to build out its staffing and infrastructure to the extent FDA would, given FDA's regulatory history.

In addition to our recommendation that the primary regulatory agency be TTB rather than FDA, the USCC believes the CAO Act should clearly articulate the important role states are to serve. While the sponsoring offices made clear their intent to "preserve the integrity of state cannabis laws,[4] the means of achieving that goal should be more clearly spelled out in the CAO Act. As mentioned, state systems are already regulating a broad range of cannabis-related activity, from licensing, to cultivation, to processing, to sales. Careful considerations should be given to the proper role of federal support in light of these existing systems, and the right balance long term. Both Colorado and California, for instance, have invested considerable time and resources into their regulatory frameworks.

With essential protections and best practices established by the federal government, states should remain the primary regulator even after legalization, offering oversight of cannabis pursuant to their police power and other authority granted by Congress. Accordingly, states should continue to manage regulatory programs that license businesses, regulate sales between residents or entities within the territorial limits of a given state, set reasonable health or safety standards that exceed those set by federal regulators, and tax cannabis-related commerce.

We believe that while federal regulators consider and adopt the wide range of regulations needed for an effective framework, state programs should continue to operate largely as they do today. For many of the same reasons outlined above, we do not believe cannabis products should or need to be significantly regulated by the FDA.

Recommendations

- Primary regulatory authority should be with TTB
- TTB should be empowered to:
    - Have primary regulatory responsibility for setting standards for state licensing programs and licensees
    - Identify minimum state regulatory best practices consistent with today's

[4] Available at: https://www.democrats.senate.gov/imo/media/doc/CAOA%20Detailed%20Summary%20-.pdf

marketplace, under which all states should operate to facilitate the transition to interstate commerce

- Work with FDA to help ensure the health and safety of consumers of cannabis products
- Administer taxes

- FDA should be empowered to:
  - Regulate any product making health claims outside the scope of state medical cannabis programs
  - Subject to limitations, FDA could regulate anything they normally would outside the plant, including additives, fillers, or non-standard food ingredients.
  - Regulate products which have not been commonly available in a regulated market, or which fall outside a range of acceptable levels (such as a monograph).
  - Provide minimum standards for labels, testing, and serving sizes
  - Work with TTB in support of its mission to support health and safety through an MOU similar to that in place for alcohol regulation
  - FDA should not be allowed to pre-approve cannabis products that are commonly on the market today, and should look to common standards such as monographs when possible
- CAO Act should clearly articulate role states should serve:
  - States may continue to operate without violation of the Dormant Commerce Clause through a transition period
  - Continue to serve as primary licensing authority
  - Continue to manage social equity programming
  - Work with TTB and FDA (and perhaps USDA) to develop and enforce standards

B. We Need a Transition Period Prior to Interstate Commerce or Import to Protect Public Health and Safety, and to Preserve Stable State Markets

A transition period between the system we have today, and one in which cannabis products flow freely across state lines, is essential. There are many considerations - from legal, to budgetary, to logistical, that will need to be addressed in order to avoid significant disruption to the effective state systems that are currently in place.

However, as drafted, the CAO Act provides for immediate interstate commerce and importation. This scenario will only serve to disrupt stable state markets, put public health and safety at risk, and put social equity license holders and other small businesses at risk of immediate extinction. Instead, we suggest a transition period to ensure that reasonable federal regulatory mandates contained in the bill can be accomplished. Keeping existing state regulatory systems intact until the federal government establishes its own rules and accomplishes the regulatory goals contained in the bill will ensure that there is a safe and effective roll-out following de-scheduling.

Many of our members in the cannabis industry have been working to establish a legal, ethical, effectively-regulated, state-legal industry for nearly a decade. It will take time to ready public policy priorities and related state and federal regulatory structures, but a well-considered system will pay dividends for years to come, and help grow our domestic economy and the communities in which we serve. Without a transition period prior to the allowance of interstate commerce or importations, we are likely to see significant disruption in the legal cannabis industry with detrimental effects nationwide.

A reasonable transition period prior to interstate commerce or importation will:

- Preserve, protect, and accelerate critical social equity programs in the states;
- Protect public health and safety by first developing and implementing national standards, federal regulations, a federal track and trace system, and Good Manufacturing Practices;
- Safeguard stable state markets; American jobs, and American businesses; and
- Allow us time to complete critical research and renegotiate relevant international treaties.

Below, we highlight the more significant public policy reasons why we consider such a transition period critical, and request that Congress specifically identify which areas of policy should be considered essential before allowing cannabis products to flow from state to state or to allow imports from other countries.

1. Support Equitable Market Access, Wealth Creation, and Social Justice Reforms

The first priority of comprehensive cannabis reform must be equitable wealth creation and repairing past harms caused by the War on Drugs. We need to take the time needed to get state and federal social equity and restorative justice programs up and running (few of which are currently functional) and to make certain that people who have been negatively impacted by the War on Drugs have a real opportunity to succeed in this new industry. We must allow time to see the positive results from the benefits of state social equity programs, which are designed to ensure cannabis licenses are awarded to qualified social equity applicants and to allow for people to transition from the illicit market to the legal market.

As mentioned elsewhere, we must carefully consider the process of identifying former offenders and expunging criminal records for those who have been indelibly sanctioned for marijuana offenses, and we should take further actions to repair other wrongs created by the War on Drugs. For any of this to be successful, it will take time to continue to bolster state revenue sources that are crucial in supporting social equity programs and reverse the damage that has been done through unjust and harmful drug policies.

We commend Senate drafters for including robust social equity and criminal justice reform measures in the bill. Under the discussion draft, the Small Business Administration (SBA) would establish an Equitable Licensing Program to provide funding to eligible states and localities to implement cannabis licensing programs to minimize barriers for individuals harmed by the War on Drugs. Eligibility would be contingent on states and localities taking steps to create an automatic process for expungement of criminal records for cannabis offenses, among other criteria.

If interstate commerce were allowed immediately without protections for state programs and small businesses, it is likely that larger cannabis companies could displace small businesses - including social equity license holders and applicants - and make these reform provisions obsolete and the related goals unattainable. A transition period is the

only way to get these programs up and running and see them succeed before recipients are faced with intense competition.

2. Establish Agency Jurisdiction, Promulgate Rulemaking, and Set National Standards

Creating an intentional pathway to a regulated market could not be more essential for the safety of the American public. Rushing the marketplace immediately will not allow enough time for the federal government to get the right regulatory structure in place to protect the public health, nor will it preserve the hard work done at the state level over the past decade to keep consumers safe. As we have seen with the rollout of hemp/CBD, merely legalizing the plant without first developing a federal regulatory plan, national standards, and testing protocols will lead to confusion in the marketplace and result in consumer harm.

We cannot afford to create another regulatory vacuum that gave rise to the bathtub gin problem of the 1920s, the vape crisis of 2019, or the hemp rollout over the past two years. The rollout of the 2018 Farm Bill should serve as an important lesson. A "gray" market erupted immediately upon de-scheduling hemp, leading to the unfettered production and distribution of CBD and Delta-8 products. We are now paying the price for allowing this regulatory void. The FDA has still not issued regulations on how these products may be formulated and used; there is mass confusion in the marketplace; and unregulated, untested, but intoxicating products are being sold indiscriminately across the United States in gas stations, convenience stores, and online.

The cannabis industry urges policymakers to act more deliberately with cannabis, and to take the time required to get regulations right and firmly in place. Specifically, we should ensure promulgation of comprehensive, safe and effective national standards for federal transportation, product testing, pesticide usage, environmental standards, product labeling and packaging, and other important national standards to protect the health and safety of our citizens.

Further, emerging medical and/or adult-use states deserve and need ample time to create their own markets, as well as to stand up state enforcement and regulatory systems. They also need an on-ramp to develop an appropriately staffed, well-funded, and well-developed federal regulatory and enforcement structure, including a plan for dismantling the illicit market.

If we do not regulate intentionally, the illicit market will surely take advantage of unprecedented market disruption and be in a position to produce, transport and sell illicit products around the country with impunity. Without regulatory controls firmly in place, the illicit market will be virtually impossible to distinguish from its legal competitors. Finally, we need to harmonize state regulatory programs across the country, as is practicable. This must all be done deliberately and will take significant time to develop and implement.

Under the proposed legislation, TTB and FDA would have dual jurisdiction related to certain aspects of cannabis regulation. Accordingly and as previously mentioned, the agencies are compelled to enter an MOU to govern agency interaction within 180 days of enactment of the discussion draft. Then, regulations will need to be drafted. Pursuant to the Administrative Procedure Act, agencies must post comment periods prior to rulemaking and consider public comments received. This will take a considerable amount of time to get right.

The Act also provides authority to FDA to set national standards to protect the public health. Private organizations such as the United States Pharmacopeia (USP) and ASTM International are leading, globally recognized, non-profit organizations that help in the development and delivery of voluntary consensus standards. Today, tens of thousands of standards are used by industrial sectors across the United States and around the world to improve product quality, protect the environment, enhance health and safety, and strengthen market access and trade. A transition period is warranted for the federal government, in partnership with the private sector, to develop and implement national standards before interstate commerce or importations are permitted.

3. Promulgate and Implement Required Good Manufacturing Practices

The proposed measure requires the FDA to require and implement Good Manufacturing Practices (GMPs). GMPs represent the minimum level of acceptable standards/best practices that ensure the production of safe and consistent products for human/animal use. GMPs have been around and evolved since the 1960s (starting in pharmaceuticals) and are required globally. They ensure our pharmaceutical drug, food, and natural products are created under a certain level of control that minimizes the risk of products being unsafe for human/animal use. GMP programs fill in the gaps where final product testing alone is not sufficient (current model most states have implemented). GMPs benefit all parties, including producers, by providing clear guidelines to establish standardized controls that reduce liability through reduction of risk, consumers, by benefitting from safer and more consistent products, and regulators, through a consistent framework to ensure products are safe and can identify company deficiencies based on decades of use in other industries.

GMPs need to be created and vetted because industry has been operating under the different requirements of 37 states. The development of a quality system with GMPs will take significant time and resources. Companies need a minimum of twelve months to realistically be prepared to meet these requirements (after they've been provided with clear guidance on what GMPs are required of them). And the FDA will need time ahead of that process to determine through rulemaking, what GMPs will be required. In order for the federal government to create, and for companies to become compliant with GMPs, there must be a transition period prior to interstate commerce or imports to protect the public health.

4. Implement a Federal Track and Trace System

The Act requires that track and trace rules be promulgated 12 months after enactment. Depending on what federal track and trace regulations require, it could take businesses another year for track and trace companies to adjust and for cannabis companies to become fully compliant. Incorporating mandatory electronic tracking requirements into federal cannabis reform is critical to ensuring public safety. Electronic tracking technology allows for the ability to follow a cannabis seed through every stage of the cannabis supply chain, collecting data and maintaining regulatory compliance through the processes of cultivation, manufacturing, testing, packaging, distribution, and sale. “Seed to sale” tracking provides us with a detailed chain of information during any given point of development of the specific plant product. Ultimately, this provides an unprecedented level of visibility and transparency into a supply chain that is unrivaled by any other industry, allowing us to track the product to prevent diversion and protect consumer safety. Electronic tracking technology enables operators and governments to keep track of cannabis inventory down to the gram level, including waste. This level of granularity is also critical in tracking and collecting all taxes owed. Furthermore, it

provides consumers with the confidence that each product they purchase has been tested and is in compliance with state regulations through the entire supply chain, from seed to sale.

Creating standards for levels of visibility and transparency simultaneously fulfills a second public policy goal – eradicating the illicit market. Not only does electronic tracking provide transparency into the creation of consumer goods, but it also provides more data points available to capture, identify, and destroy illicit products. These types of anti-counterfeit measures could prevent illicit market items from entering legal operations and posing a threat to public safety, as seen during the vape crisis in 2019. Electronic tracking through software built specifically for the cannabis industry is the most efficient way to maintain compliance standards and uphold public safety. Promulgation of regulations and then the establishment of a critically important national track and trace system will take time – time that necessitates a transition period prior to interstate commerce and imports.

5. Preserve and Protect Stable State Markets and Protect Small Businesses

The modern, licensed cannabis industry was built through American cultivators, dispensary operators, craft cannabis companies, and consumables manufacturers. These American cannabis companies have invested hundreds of millions of dollars in intellectual property, brick and mortar growing spaces that required significant investments in hydroponics, lighting, and infrastructure, not to mention expensive state and local licenses to grow, produce and distribute cannabis within every state that has a medical or adult-use marijuana program. Nearly a quarter-million new American jobs have been created as a result. Majority Leader Schumer agrees and has made clear that his priority is to protect American businesses and to make certain that everyone has an equal opportunity to participate in the American cannabis story.

An example in the beer context demonstrates what will happen if interstate commerce and imports take immediate hold. According to the National Beer Wholesalers Association, the beer market is currently dominated by three large brewers who accounted for about 70 percent of all beer sold in the United States in 2019. This type of consolidation is also evident within big tech, where just two corporations hold 99 percent of mobile operating systems (Apple and Google), and in E-commerce, where Amazon and Walmart control 50 percent of the market.

Stable state markets have also been at the core of the legal industry since the first market opened in Colorado in 2014. As true laboratories of democracy, more than three dozen states have created regulated cannabis markets where consumers receive safe products, state residents receive tax-funded benefits, and industry entrepreneurs profit from their substantial investments. These markets are small and medium-sized businesses that make up the local supply chains. These markets grew quickly and absorbed the illicit market and reached stability in short order.

A rush to allow imports and interstate trade would destabilize these markets, creating conditions for rapid market consolidation and concentration in low-cost states. The state-administered social justice and equity programs so highly touted in Illinois, New York and other states are at risk if funding dries up. Federal legalization must support state market stability during the legalization process to fulfill the promise of the American Dream for small businesses while simultaneously establishing equity in the cannabis industry. The only way to effectuate this public policy ambition is to specifically require a transition period to allow these markets to develop prior to allowing interstate commerce or international importations.

6. Establish Safety Protocols for Imports and Manage International Treaty Obligations

We need to act to specifically preclude importation of cannabis and cannabis products into the United States until we have robust safety protocols in place, whenever that may occur. In light of the draft legislation's text, it appears that the Senate is poised to open US markets to foreign producers/sellers for the importation of cannabis upon the eve of American federal legalization. However, we need to establish safety protocols for imported cannabis, to ensure that such products are not rushed to market without first demonstrating that they are safe for American consumers. Establishing a plan for inspection, certification and oversight of foreign facilities and imported cannabis products is essential for the safety of American consumers and the integrity of the U.S. cannabis market. It's also critical that we take steps to make certain that the illicit market isn't fueled by immediately opening our borders to imports. We need to regulate deliberately and make certain that any imports, once allowed, are generated from legitimate sources and not from the illicit market.

International drug treaties to which the United States is a signatory permit trade in cannabis products for industrial, scientific, research, and medical purposes.[1] These treaties will need to be re-negotiated prior to the allowance of international trade. This process could take years, and therefore a specific provision in law is warranted that requires adherence to, and the renegotiation of, international treaties prior to the allowance of international trade.

7. Complete Critical Research

The Act mandates the Comptroller General to issue a report on the societal impact of cannabis legislation within two years after the enactment of this Act. Congress has also provided a mandate to HHS to issue a report related to the public health effects of cannabis with an end-date of 2025. And Congress mandated that the Secretary of Transportation collect data on highway safety. Notwithstanding housing the best medical research institutions in the world, cannabis research in the U.S. severely lags behind other nations. While convincing research on cannabis safety and therapeutic utility of medical cannabis products is being generated in Europe and Israel, federal prohibition in this country obstructs open research into the science of cannabis therapeutics for products, despite millions of Americans currently buying and using medical cannabis routinely. The research objectives in the bill are therefore critical to protect the public health and safety and will take time to get right. We should get this done prior to the allowance of interstate commerce or foreign imports.

A successful transition to federal regulation must also support a clear pathway for insurance reimbursement for state-sanctioned medical cannabis. There are currently three dozen medical programs serving more than 3,500,000 patients in the United States, with cannabis programs rapidly providing treatments and treatment plans designed to displace opioid prescriptions. The NIH/NIDA is currently funding a number of efforts to document and enable the successful treatment of patients with pain with cannabinoids in order to reduce their use/overuse on opioids. However, due to the lack of insurance reimbursements, nearly all of these costs are being absorbed by patients. Some states have noticed the pharmacoeconomic advantage that cannabis treatments can provide over existing therapies in specific indications, and their Medicaid programs are evaluating reimbursement for these situations. In addition, many workers compensation programs nationwide are taking similar steps.

As a first priority, Congress should intentionally and specifically permit coverage by private insurance companies. Cigna already allows reimbursement for CBD products.

This should flow naturally from de-scheduling, but an intentional and specific provision by Congress authorizing this pathway would stave off private litigation risks and Executive Branch overreach through regulation. Congress should also specifically provide for the allowance of HAS/FSA funds to be used for medicinal cannabis. These tax-deductible contributions are already currently being used on alternative care, including acupuncture, aromatherapy, ayurvedic medicine, homeopathy, nutritional counseling, and unregulated traditional Chinese medicine. These provisions are not currently contemplated in the Act, and will take time to promulgate, coordinate, and ultimately administer.

For the foregoing reasons, a transition period prior to interstate commerce or the allowance of the importation of cannabis from foreign countries is warranted to preserve critical social equity programs, protect the public health and safety of American citizens, to support the small business entrepreneurs that have built this industry, and to safeguard the stable state markets that support them.

8. Relieve Pressure Caused by Constitutional Impediments Surrounding State Regulatory Authorities

Apart from impact on state budgets, a concern of paramount importance is the effect that the Dormant Commerce Clause ("DCC") and related Supreme Court precedent will have on states as the federal government begins its transition.[5] The DCC is a free trade principle that bars states from implementing laws, rules, or regulations that negatively impact interstate commerce. Without the Dormant Commerce Clause, states would be free to enact legislation favoring local commerce in all cases where Congress has not legislated on a particular matter. The sponsoring offices have made clear they want to empower states to implement their own cannabis laws. However, this intention is not clearly articulated in the text of the CAO Act, and the lack of clarity will only serve to promote litigation later, unless Congress acts with clarity now.

For decades, the Supreme Court has taken up matters interpreting the very same state's rights language provided in section 111 - particularly in cases involving the interstate trade of alcohol. As applied to alcohol, the Court has held that this same section 111 language allows states a small amount of authority to enact measures that its own citizens believe are appropriate to address the public health and safety effects of alcohol use. However the Supreme Court has been clear that states may not adopt protectionist measures with no demonstrable connection to those interests,[6] and if Congress means to grant that authority, it will need to be clear.[7]

This presents a significant challenge for states. Over the past several decades, the states have operated on the premise that the Dormant Commerce Clause does not apply to the cannabis market because Congress has banned all commerce in cannabis. Under this premise, states have created 37 unique markets, none of which engage in any form of interstate commerce.

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[5] This Constitutional problem was identified and is being explored by Professors Scott Bloomberg and Robert Mikos in Legalization Without Disruption, (forthcoming 2021).

[6] Tennessee Wine and Spirits, 588 U.S. ____ (2019), slip op. at pp. 31-32.

[7] In order for Congress to override the default rules of the DCC, the grant of authority to states must be "unmistakably clear." Only twice in the last seventy-five years has the federal government done so, see Douglas Amendment to the National Bank Holding Company Act, and Prudential Insurance Co. v. Benjamin, 328 U.S. 408 (1946).

Each of these markets has its own set of rules, the vast majority of which place both direct and indirect restraints on interstate commerce, including blanket bans on the sale of cannabis products across state lines; the use of pesticides; testing, labeling and packaging; bonus points on applications for in-state residents who live in certain zip codes (often for social-equity licensing purposes); social equity licensure set-asides; closed-loop track and trace; collection of state taxes; company size, ownership, and vertical integration; energy consumption and sustainability; employment practices and so on. All of these state-based regulations necessarily violate the Dormant Commerce Clause. If cannabis is descheduled, without a carefully considered transition that will allow state programs to come into conformity with the U.S. Constitution, state-based restrictions will be immediately invalid and states could lose significant control over key aspects of their programs. The DCC will disrupt the states' ability to enforce state tax regimes and other regulations, unless Congress either suspends application of the doctrine to the cannabis regulatory system, or provides a sufficient amount of time for states to adapt.

Finally, it is worth noting that an additional advantage to working with states and coordinating with state regulatory authorities, described in the previous section, is that state involvement throughout the process can help minimize disruption. State programs offer a significant backstop to unintended negative consequences that could come as cannabis regulations change nationally, simply because they are, in fact, where cannabis-related regulated activity has been taking place, in many cases, for years.

A rush to interstate commerce or importations may subject existing state programs to significant legal challenges, place state social equity programs at risk, jeopardize needed state revenue, and disrupt systems that have been both successful and popular. After 80 years of prohibitionist policies by the federal government, the federal government should create a reasonable and predictable runway before transitioning to a new regulatory framework. And the only way to accomplish that goal is to establish a transition period prior to importations or interstate commerce until the federal regulatory system is firmly in place.

Recommendations

- Existing state regulatory systems should remain unchanged, and interstate and import/export should be paused until rules can be put in place
- Consider whether safe harbor provisions are needed during the transition period
- Federal agencies, including TTB and FDA, should be mandated to ensure a smooth transition
- Agencies should work with states to identify ways to minimize disruption and adopt rules before the transition period has expired and federal mandates are in place
- The CAO Act should be unmistakably clear that it grants authority to the states to continue to enforce and implement state rules, notwithstanding the Dormant Commerce Clause during the transition period

C. Taxes Should Be Lowered and Imposed More Gradually

There are obvious parallels between cannabis and alcohol, and the tax model the CAO Act includes based on alcohol is a useful starting point. But not every aspect of the currently-proposed regime is the best fit for cannabis, and these differences are worth consideration in formulating the tax system.

There are two primary distinctions that lead to complications when alcohol provisions related to tax are applied directly to cannabis. The first lies in the structure of alcohol's three-tier system versus the much different structure for cannabis businesses, and the second is the wide range of products that contain cannabis, compared with the relatively narrow range of alcohol products. Determining the point at which tax liability attaches is not as clear in the case of cannabis products as it is with alcohol; and determining tax based on average wholesale price is complicated by the fact that many retailers in the cannabis industry are also wholesalers and can affect wholesale prices. These are not insurmountable challenges - but should be factored into the ultimate framework.

Also note that apart from the three-tier model itself, a significant difference between alcohol and cannabis systems is that the regulated alcohol industry doesn't face nearly the same challenges with illicit competition. To be sure, illicit alcohol production takes place. In the cannabis space, it is likely that regulated operators represent a small minority of the total cannabis-related activity happening in the U.S. and as previously mentioned, illicit operators have significant competitive advantages - for all practical purposes operating without taxes or oversight.

It is worth pointing out that the USCC takes a strong position against the belief that simply removing the 280E tax penalty[8] will compensate for the imposition of a high tax rate for several reasons. These include the fact that 280E impacts different types of businesses in the cannabis industry differently. For instance, small or social equity businesses are likely to be disproportionately impacted by this penalty because a large percentage of these smaller businesses are retailers. And because of how 280E impacts businesses, retailers carry a far heavier burden than cultivators, which tend to be more heavily capitalized businesses. In addition, the proposed tax rate greatly exceeds the financial impact 280E has on most businesses, although that line is likely different for each company.

Note that it is not clear what the figures, which describe a year-to-year tax increase, actually apply to, and could be either wholesale or retail prices. Nonetheless, the USCC advises against setting target revenue figures at the outset, since there is much we do not yet know. As we have seen at the state level, the higher the tax rate, the more the underground market will benefit and proliferate. If the rate is too high, like it has been in Canada or as some would argue California, the U.S. will not capture the market. In Canada it is estimated that the licensed business community represents only about 40% of the market, and in California, the figure is closer to 20%. The optimal tax rate that can maximize both participation and gross revenue should be the goal.

We also believe the switch in the fifth year to a market based on the average of wholesale from the previous year should be considered as it might be destabilizing. One of the

[8] Internal Revenue Code section 280E specifically denies a deduction or credit for any expense in a business consisting of trafficking in illegal drugs "prohibited by Federal law or the law of any State in which such trade or business is conducted." No exemption is available for state-licensed cannabis businesses that pay a disproportionate tax burden compared to other businesses under the auspices of the 280E tax penalty.

unintended consequences of a tax break at $20M in revenue is that it is likely to result in the proliferation of companies that break up operations to take advantage of the limit. One significant additional meaningful benefit would be to waive taxes completely for low income businesses, which is discussed more fully in the stakeholder questions in the next Part.

Just as we believe that burdensome regulations will put significant pressure on small and equity businesses, the new tax system should be evaluated to determine whether it unfairly burdens the businesses the sponsors wish to support. We believe there should be a robust analysis of the market as it operates today and an understanding of how rates and the rate of implementation will impact the underground market and state programs. Our belief is that the tax system should be introduced slowly, and it should be at a lower rate to ensure long term health and stability in the market, particularly in light of the significant taxes already imposed by states.

In addition, it is imperative that individuals who are registered in state medical cannabis programs not be subject to federal taxes for the sale of cannabis products when purchased in compliance with state law.

Finally, note that there will likely need to be a transition for state programs as well, as some including Arizona have laws that are inconsistent with the tax rates proposed in the CAO Act, and those laws would need to be amended, perhaps through state constitutional amendment processes.

Recommendations

- The sponsoring offices should consider the appropriate tax rate in light of their goals, including increasing reducing criminal activity, supporting public health and safety, and gaining broad support
- The USCC believes the tax burden should start low and increase gradually, but there should be a careful analysis of the most appropriate tax levels and rate of increase to capture these concerns
- The bonding requirement may or may not be needed, since the three-tier model doesn't apply. Consider using track and trace
- Consider the array of products available in the market today, from edibles to inhalants, and how each might need its own criteria for attaching tax liability
- Individuals registered with state programs as medical cannabis patients should not be subject to a federal tax

IV. Response to sponsoring offices questions

The Sponsoring Offices have not specified responsibilities or membership of the Advisory Committee and request comments on:

1. *Criteria for Advisory Committee membership to ensure diverse viewpoints and policy priorities are properly represented*

2. *Roles and responsibilities of the Advisory Committee*

3. The role of the Advisory Committee in agency consultation, including the administrative and rulemaking process

The draft would establish an advisory committee which FDA would convene and consult before promulgating regulations. The recommended framework below is consistent with other FDA advisory committees like the Tobacco Products Scientific Advisory Committee.

Members of the committee should be knowledgeable in the fields of medicine, science, or technology involving the cultivation, manufacture, evaluation, or use of cannabis products. It is important that members understand the history and context of cannabis regulation in the U.S. to better inform decisions affecting social equity, access, and safety in the development of regulations related to cannabis products. In addition, members should have expertise related to the various parts of the cannabis industry and should represent all geographic locations with current or developing cannabis markets and with no adult use or medical marijuana programs.

Specifically, the committee should have members and a chair with representatives from the following categories:

- One representatives on behalf of the industry (cultivators, processors, transporters, distributors, wholesalers, retailers, social equity operators)
- Two representatives on behalf of consumers and patients
- One representative on behalf of state cannabis regulators
- One representative on behalf of scientists and researchers (with domestic and international cannabinoid research experience)
- One representative on behalf of physicians (with experience treating patients using medical cannabis)
- One representative on behalf of the Office of National Drug Control Policy
- One representative on behalf of the Veterans Administration (VA)
- One representative on behalf of the TTB
- One representative on behalf of the National Governors Association from a state with a legal adult use program
- One representative on behalf of the National Governors Association from a state with medical marijuana program

<u>Roles and responsibilities of the Advisory Committee</u>:

The committee will help inform the agency and make recommendations in areas of cannabis policy to ensure products are safe and access is reasonable for those who qualify. The committee will submit reports and recommendations as needed on cannabis-related topics, and provide independent expert advice to the FDA in particular areas of interest.

<u>The role of the Advisory Committee in agency consultation, including the administrative and rule making process.</u>

The Committee should advise the Commissioner or designee in discharging responsibilities within the scope of the agency's jurisdiction, and help the FDA make decisions based on the reasonable application of sound scientific principles in furtherance of the goals of safety, access and social equity. The Committee should provide recommendations to the Secretary of HHS regarding regulations to be promulgated under the Act, and information which either the FDA or the Advisory Committee determines would be useful to the agency carrying out its goals.

The FDA should consider the recommendations and information provided by the Committee and incorporate feedback from all experts serving on such Committee when promulgating relevant regulations. In the event that the FDA does not incorporate specific suggestions from Committee members, FDA should provide an explanation in writing to the committee and publish such exceptions on the FDA website. The committee should be funded by licensing fees or excise taxes.

The Sponsoring Offices believe cannabis reform must protect the rights of states that choose to legalize cannabis, as well as those that choose not to. Strong anti-diversion rules are necessary to ensure cannabis produced and sold in legal states is not illegally trafficked into other states with the purpose of circumventing state-level laws relating to the sale, production, or taxation of cannabis. The Sponsoring Offices request comments on states' rights and anti-diversion provisions, including:

1. The interaction between state primacy regarding cannabis regulation, and the need for interstate consistency for product standards and regulation, including any responsibilities that should be reserved explicitly for states or the federal government

2. Rules relating to interstate commerce involving cannabis, including state-level taxation and interactions with state-level distribution systems

This draft would establish federal product standards intended to provide regulatory clarity for all consumers in every state.

The interaction between state primacy regarding cannabis regulation, and the need for interstate consistency for product standards and regulation, including any responsibilities that should be reserved explicitly for states or the federal government

<u>Product Safety Standards</u>

Product standards should be consistent from state to state to ensure consumer and regulatory parity, particularly as it relates to access, product integrity, education, safety, and utility. Patients travel, and regardless of where consumers purchase cannabis products, be it in state or out of state, it is reasonable for consumers to expect that products are manufactured to minimal standards. This includes qualitative standards, stratified quantitatively (with respect to both concentration and purchase limits) into reasonable access tiers that meet the true needs of all consumers, especially patients who might benefit from or depend on highly concentrated preparations. Products should be clearly and comprehensively labeled in a standardized fashion to minimize consumer confusion while maximizing consumer confidence and education around product offerings as consumers navigate appropriate and responsible personal or medical use. TTB, working in coordinated manner with FDA and state regulators, can enforce these standards and maintain the transition timeline among all states in which cannabis-related activity is taking place.

Labelling, in particular, should meet minimal labeling standards typical of federally regulated goods, and should include cannabis-specific standards such as the "CBD to THC" ratio and other significant markers. In addition to a varieties' common strain name or indica/sativa/hybrid designations, labels should indicate:

- Product form (e.g, *tincture*),
- Strength (e.g., *low-, high-, or medical-strength*),
- Dominant cannabinoid (*e.g., THC dominant*),
- CBD:THC ratio (or other cannabinoid ratio),
- Number of servings per package (e.g., *5, 10, 20, or 30 servings*),
- Milligrams (mg) of each significant cannabinoid per serving (e.g., *5mg THC/serving*),
- Total mg of each quantifiable cannabinoid and terpene per package (e.g., *50mg THC, 2mg CBD, 0.1mg Limonene, 0.2mg Myrcene*),
- Lot/batch #, and expiration date

Labels must also include a Quick Response, or QR code, verifying testing for consistency and purity, health warnings for vulnerable populations, expanded safety information and warnings for high- and medical-strength products, edibles, and potable liquids (e.g., duration of effect, risk of potentiation with fatty foods, and possible adverse effects including psychedelic effects and psychosis), and disclosures about origin, specifically whether cannabinoids and/or terpenes are cannabis-derived, natural, semi-synthetic, or synthetic.

We agree with the definition of diversion, but suggest including the definition to include the shipment of marijuana products into the U.S. from any country that is not authorized to do so. All foreign exporters of marijuana products into the U.S. should be approved by the Consumer Product Safety Commission (CPSC) before entering the U.S. marketplace and should meet all other product safety and labeling standards as U.S. producers.

The Sponsoring Offices request comment on the retail sale age and quantity restrictions, including the interaction between state minimum age laws and use of medication containing cannabis by minors

As stated in the introduction to these comments, we support the sponsors' efforts to establish a national framework and we appreciate the benefits that national, consistent standards will bring. There is perhaps no better example of the value of national standards than through age limits for cannabis-related products. The USCC strongly supports a national age limit of 21 or older for adult-use cannabis sales. We further support the need for more research and sufficient funding in key areas such as the impact of cannabis consumption for both minors and adults, medical use, and in areas related to education, prevention, and detection of cannabis by impaired drivers.

And as we have also indicated, there are suggestions we offer that we believe will help achieve some of these goals more directly. Here are a few we believe will further help protect the health and safety of consumers and the public as our nation turns to a regulatory model

- There are a number of research projects and reports outlined in the proposed measure that are likely to affect many areas of government and would be of interest to the public. We suggest expanding the Interagency Coordinating Committee on the Prevention of Underage Drinking (ICCPUD) to include underage cannabis consumption, with funding sufficient to include the broader scope of work.

- When it comes to the prevention of cannabis-related crashes and injuries, we suggest changing primary oversight from the Director of the Centers for Disease Control and Prevention to the Department of Transportation and the National Highway Traffic Safety Administration. NHTSA already has the expertise and has been working on these issues - with programs currently underway including public education campaigns and countermeasures.

- Congress should consider a competitive grant to help states prevent drug-impaired driving within their borders.

- We believe the sponsors should include the provisions of S. 1999, the Multiple Substance Impaired Driving Prevention Act, should be added to this legislation if not passed earlier, and we believe the research outlined related to driving should include research on impaired driving due to use of multiple drugs.

- The sponsors may also wish to include or expand a grant program to ensure toxicology labs are equipped with staff and equipment needed to ensure timely processing of chemical tests - critical for obtaining evidence in impaired driving cases before samples lose probative value.

- The DOT should gather information from the National Safety Council and the Society of Forensic Toxicologists to create data guidelines included for efficient toxicology lab testing and recommended lab standards and protocols. This could help alleviate the lack of standards and protocols for state toxicology testing laboratories. As with the grant program, states will need substantial funding. NHTSA should also create a Traffic Safety Resource Toxicologist program to help the states, similar to current information programs available for others in the criminal justice system including judges, prosecutors, law enforcement and probation.

- States should be incentivized to screen and assess impaired drivers using a tool validated for DUI offender populations to identify repeat and multiple substance impaired drivers for substance use disorders and mental health disorders. This can help ensure those who need interventions are identified.

- All states should be encouraged to provide DRE data for a national DRE database in order to capture data related to DUI-related arrests, for instance by making it a requirement for eligibility in the state grant program.

- The state grant program could also be available for state Traffic Records Coordinating Committees to enhance data collection. These state committees determine what data gets collected at the state level. As with the other areas related to research, detection and prevention, this should be well funded. We believe $10M a year should be sufficient.

- While there are references to drug courts, veterans courts, and mental health courts, we suggest also including DUI courts. We believe these courts are better equipped, when available, to address impaired driving issues.

- We suggest a grant program administered by Substance Abuse and Mental Health Services Administration (SAMHSA) aimed at addressing undergage cannabis consumption including the prevention of underage sales.

- Address essential exceptions to the 21 age limit, and in particular, use by individuals who have been registered in state medical cannabis programs. Federal law should allow states to adopt laws similar to those in place with respect to alcohol, including allowing underage drinking exceptions for parents/guardians with their own children, of-age spouses to underage spouses, culinary exceptions for cooking schools, and religious exceptions. There are circumstances in which states will need to consider exceptions to their 21 laws for cannabis and provide clear guidance. In those situations, the federal government should support state efforts by highlighting best practices.

- There should be more robust provisions related to social sources of alcohol for underage consumers - specifically, addressing adults who knowingly provide cannabis to underage consumers without authorization.

- A state grant program could also be used to educate youth and minors on the reasons to delay cannabis consumption until after age 21, and to discourage adults from providing to unqualified, underage people.

- Such a program could also educate and train servers and dispensary personnel on age verification and best practices for preventing sales to people who are visibly intoxicated/impaired.

Medical cannabis

Apart from allowances for age limits related to medical cannabis use, there must be protections to allow states to continue to allow access to medical cannabis as it exists today in state marketplaces for those who qualify under state medical cannabis programs. Such programs are essential to ensuring that patients of any age have legal access to cannabis products (not just "drugs or medicine containing cannabis" as defined in the CAO Act) that might be of benefit to them, and these laws should be consistent around the country. A medical cannabis caregiver of a minor – typically a parent or legal guardian - should be afforded the same rights and access afforded to adult consumers in legalization states and medical cannabis patients who are over 21 in medical cannabis states, provided that they meet all state program requirements.

Program services which could be supported through the FDA or at least left to the states should include education to properly inform the caregivers of minors and minors of discerning ages of cannabis-related health information. Areas of information should include, among other things, condition-specific continuing education, the meaning of appropriate medical use, responsible consumption, and how to identify signs of misuse as well as proper or effective use, methods to minimize "diversion" or "sharing" cannabis products purchased for medical use with others (especially other minors), and public health insights and trends related to cannabis use in the state.

Considerations and accommodating concessions may need to be made regarding the medical quantitative thresholds (with respect to both concentration and purchase limits), but should be reasonable such that they do not prohibit patient access to affordable cannabis products at concentrations and quantities adequate for meeting their medical needs. It may be helpful to stratify access to cannabis products based on strength, ensuring medical cannabis patients always have access to the highest-concentration cannabis products when authorized by state programs to do so. Measures should also be taken to ensure patients can access amounts of cannabis sufficient to meet their need, such as the 30-day intervals as in the case of prescription drugs.

Sponsoring Offices request comment on whether some or all cannabis products should be required to undergo premarket review before marketing and, if so, which cannabis products and the evidentiary standards for any proposed premarket review pathways

There should be no pre-market review for any cannabis-related product currently in the marketplace and available through a state-regulated program. Unprocessed flower, new products that make only structure/function claims (or, products that do not make any health claims), should not be subject to pre-market review by FDA or any other federal agency. However all productions should require a filing, in writing to FDA, explaining the safety profile of any new product being marketed in interstate commerce.

The Sponsoring Offices believe that robust enforcement against commercial bribery and uncompetitive practices is critical to ensure that small and independent cannabises have an equal footing in the marketplace. In addition, consistent labeling and disclosure rules serve to protect the public and prevent misleading practices by market participants. The Sponsoring Offices request comments on cannabis administration and trade practices enforcement, including:

1. *Whether additional rules may be necessary to prevent uncompetitive practices, and the interactions with trade practice rules administered by other agencies, including the Federal Trade Commission*

2. *Transition rules to address cannabis products that already exist in the marketplace or those introduced in the marketplace, including before TTB and FDA issue regulations or other guidance*

3. *Design of the track and trace regime to prevent cannabis diversion while minimizing compliance burdens*

While we agree that there should be serious consideration given to anti-bribery and non competitive practices, the federal government should endeavor to ensure those limitations do not create barriers to entry or participation for those impacted by the war on cannabis or a redline created to bar individuals because of race. Our membership seeks to normalize cannabis commercial activity, so the guardrails placed around non-cannabis businesses should be adequate to govern a regulated cannabis industry, too.

As stated more fully below, the federal government should seek to amend or enter into a new international agreement that recognizes the legal status of cannabis for adult use and medical use consistent with state medical programs, as well as production and use by indiginous peoples in countries that allow cannabis-related activity.

Once international trade is authorized, imports of cannabis and cannabis products into the U.S. for adult use and use by those registered in state medical programs should be subject to substantially similar regulations as those of domestically-produced cannabis products, and should participate in the same track and trace system to be administered by TTB. Federal regulations and international policies should ensure the health and safety of Americans using cannabis imports, as well as U.S. national security, competitiveness of the domestic market, and attention to international relations with non cannabis-producing nations where reasonably possible, as well as respect for the domestic drug policies of other nations so long as they are humane and consistent with other U.S. policies.

Cannabis-producing nations with protectionist policies should not be allowed to import cannabis products into the U.S. if they do not themselves allow substantially similar products to be imported into their own countries. In light of the inherent difficulties with transparency and access to foreign cannabis entities, ensuring the quality and safety of foreign-produced products poses unique challenges to U.S. regulatory bodies. The CAO Act should specify whether, how and when a robust regulatory regime will apply to imported cannabis and cannabis products to ensure the health and safety of U.S. consumers and the other reasons specified above. This should include provisions that prohibit foreign-produced cannabis products until such time that the responsible agencies issue a report to Congress indicating how they can ensure the protection of the public's welfare and safety by implementing a strong regime to regulate, inspect, test and generally enforce U.S. requirements substantially similar to those that apply to domestically-produced cannabis products.

There is reason to be concerned that limitations should be specifically included in the CAO Act. The legalization, and by extension the importation, of hemp authorized by the Agriculture Improvement Act of 2018 led to mass importations, confusion in the market and among customers, agency enforcement challenges, and these problems persist

today. A well considered and articulated regulatory system is required to ensure meaningful federal preparation for cannabis imports.

Transition rules should be adopted to address cannabis products that already exist in the marketplace or those introduced in the marketplace, including before TTB and FDA issue regulations or other guidance

The USCC agrees with the Sponsoring Offices that, along with the benefits of legalizing marijuana, comes the responsibility to protect against commercial bribery and uncompetitive practices.

We believe that the protections provided under existing federal laws, including those that address commercial bribery and antitrust, the powers granted to federal law enforcement agencies to enforce those laws, and corresponding state laws adequately protect the public. When needed, Congress has the ability to direct federal agencies to prioritize these issues through its appropriations and oversight powers.

The Small Business Administration also has an important role in supporting small businesses, including cannabis start-ups, and the Department of Justice can investigate and prosecute any mistreatment, anti-competitive behavior or discrimination against new diverse/minority entrepreneurs and others entering the cannabis business disadvantaged by the war on cannabis.

With regard to labeling and disclosure rules, the USCC agrees that the FDA can and should be empowered to ensure proper labelling of cannabis products and adequate disclosure rules to protect the public. Likewise, here again, existing federal agencies and the laws they enforce are designed to protect against misconduct by bad actors and are effective in that regard.

The U.S. Congress, in order to allow for the lawful and proper growth of the cannabis industry in the U.S., should create a legal and regulatory environment which protects and allows U.S. cannabis businesses to thrive. In many cases, these entities have gone to great extent to operate under uniquely challenging circumstances -- including most notably a lack of banking services -- and have spent years operating under state laws. These entities have gone through significant review in order to operate, and are held to ongoing health and safety standards, testing, inspections and review imposed by states with respect to products and facilities. Unlike in other industries, many of those who have operated cannabis businesses have been active and positive contributors to an end to a harmful phase of U.S. history. These organizations should be allowed to be part of the post-descheduling regulatory environment and not simply squeezed out as federal agencies move in.

The cannabis industry members have worked to establish a legal, ethical, and effectively regulated industry at the state level for nearly a decade, and we believe there must be a reasonable transition period as the industry embraces this next stage of growth. Taking the necessary time to prepare public policy priorities and related state and federal regulatory structures will be essential as the system launches. If done properly, the cannabis industry can continue to grow our domestic economy and be beneficial contributors to the communities in which we serve.

A reasonable transition period prior to interstate commerce or importation will (a) preserve, protect and accelerate critical social equity programs now launching in the states; (b) protect public health and safety by first developing and implementing national standards, federal regulations, a federal track and trace system, and Good Manufacturing Practices; (c) safeguard stable state markets; American jobs, and American businesses; and (d) allow time to complete critical research; (e) allow the U.S.

time consider its role and respond to international obligations and geopolitics surrounding cannabis policy.

Further, state jurisdictions that have recently adopted adult-use or medical cannabis programs should be given sufficient time to create and launch their own markets, along with the enforcement and regulatory systems needed in support. Federal agencies should also ensure they are appropriately staffed, well-funded, and have a well-developed federal regulatory and enforcement structure prior to imposing a system on existing programs. This should include a plan for dismantling the illicit interstate market. These transition rules should be created and implemented in conjunction with the tax scheme adopted, including a slow increase in tax rate as local markets and licensees respond.

Design of the track and trace regime to prevent cannabis diversion while minimizing compliance burdens

We agree that incorporating mandatory electronic tracking requirements into federal cannabis reform is critical to ensuring public safety. Electronic tracking technology allows for the ability to follow a cannabis plant from seed through every stage of the cannabis supply chain, collecting data and maintaining regulatory compliance through the processes of cultivation, manufacturing, testing, packaging, distribution, and sale. It will also be useful in determining the point at which tax liability attaches to the many types of products along the production chain, and if needed, distinguish between products intended for sale to adult consumers versus those intended for sale to those registered in state medical cannabis programs, and identify waste and possible diversion.

The Act requires that track and trace rules be promulgated 12 months after enactment, which we believe is aggressive, and a longer period should be allowed for a transition. There would need to be careful considerations of what is to be tracked and by whom, how such a system relates to existing state systems, and how enforcement questions are addressed between state and federal regulators. Throughout the process, operators should be capable of operating in full compliance with both state and federal requirements without being forced to operate in an unfairly burdensome system that places them at a significant competitive disadvantage compared with underground operators operating in tandem in the same markets.

Indeed, the illicit market should be eliminated. Creating standards for levels of visibility and transparency simultaneously fulfills a second public policy goal – eradicating illicit operators gaming the system. Not only does electronic tracking provide transparency into the creation of consumer goods, but it also provides more data points available to capture, identify, and destroy illicit products. These types of anti-counterfeit measures could prevent illicit market items from entering legal operations and posing a threat to public safety, as seen during the vape crisis in 2019. Electronic tracking through software built specifically for the cannabis industry is the most efficient way to maintain compliance standards and uphold public safety.

Promulgation of regulations and then the establishment of a critically important national track and trace system will take time – time that necessitates a transition period prior to interstate commerce and imports. While the Act does not require it, the sponsoring offices should consider that track and trace apply to all retail establishments that distribute or sell cannabis products.

The Sponsoring Offices believe reducing barriers to entry is a crucial component of restorative justice. At the same time, allowing illegal operators to maintain a cannabis permit while repeatedly and intentionally violating the law does a disservice to those cannabis entrepreneurs that pay their taxes and comply with public health and public safety laws. The Sponsoring Offices request comment on establishment and permitting provisions, including:

1. Additional recommendations on streamlining the permitting and establishment process involving multiple government agencies

2. The operation of the permitting transition rule for entities already in operation as well as those that may commence business shortly after enactment

Additional recommendations on streamlining the permitting and establishment process involving multiple government agencies

Current operators exist under robust state regulatory regimes serving millions of medical patients and qualifying adults. These programs have created hundreds of thousands of jobs and allowed the safe access to cannabis to millions of Americans without significant incident. Federal legislation should not disrupt existing programs and states should continue to operate as the primary regulatory body within their borders, working closely with TTB and enforcing FDA standards where applicable.

As addressed elsewhere, federal regulations must provide an appropriate transition period for current operators prior to the imposition of any new standards, which is longer than contemplated in the discussion draft. Current operators are duly licensed and regulated by a myriad of state and local units of government responsible for the health and safety of the public, and those protections should remain in place while states and operators adjust to TTB oversight and the tax rates.

The operation of the permitting transition rule for entities already in operation as well as those that may commence business shortly after enactment

The USCC agrees that Small Business Administration funding should be made available to legitimate cannabis-related businesses to minimize barriers to cannabis licensing and employment for the individuals most adversely impacted by the war on cannabis. These initiatives should include grants for programs that provide funds for loans to assist small businesses in the cannabis industry that are owned and controlled by socially and economically disadvantaged individuals. However, while we agree these are important goals and the most likely agencies to administer such programs, we are concerned that they will not help those intended to help without serious consideration on ways to ensure they can be effective.

We also agree that legislation should include non-discrimination protections for cannabis use or possession. The denial of any federal public benefit (including housing) based on the use or possession of cannabis or a prior conviction for a cannabis offense must be prohibited. Finally, the denial of benefits and protections under immigration laws on the basis of a cannabis-related event (e.g., conduct or a conviction) must be prohibited.

We support the regulatory regime contained in the draft that would require the U.S. Treasury Department to provide permits to cannabis sellers and permitting and

registration of cannabis producers as long as such sellers and producers in fact meet the criteria for licensing or permitting.

The Sponsoring Offices request comment on cannabis excise tax provisions, including… the appropriate sales or production threshold for the small producer credit;

We believe the $20M rate seems like an appropriate small producer credit that is in line with many other tax programs, but it is not clear if the line drawn achieves the goals of the sponsors. Also, because it is a credit, the benefit will not take place immediately but rather the next tax year, and the amount of benefit is not clear beforehand. This is less compelling as a solution for social equity applicants, who may need more immediate financial relief. A closer look at the likely winners and losers is needed, but we think the overall approach of incentivising smaller entities is sensible.

We would further recommend a zero-tax level designation for social equity and minority small businesses similar to the alcohol rule in which no excise tax liability applies if the tax for the year is $50,000 per year. The credit as written only applies for "qualified domestic manufacturers" without further definition or the entities are or who might qualify, and we believe that definition should be broadened to include all categories of licensee that could benefit as long as they meet all requirements.

The proper manner to measure potency of a cannabis product and which products should be subject to a per-THC content tax rather than a purely weight-based tax;

At the outset, the USCC acknowledges that potency will likely be one of the criteria by which taxes are levied. However, we do <u>not</u> believe potency is the best approach to taxes, and it will lead to future-proofing problems and unintended consequences. Considerations should be given to ways to ameliorate some of these through other means. Some of these challenges include:

- "Potency" will be difficult to define in a meaningful way without significantly more research into the constituents of cannabis, their relationship to each other, and what neuropharmacological effects actually lead to intoxication. Basing potency on THC alone is likely to result in unintended consequences, since there are almost certainly constituents of cannabis apart from THC that could lead to intoxication, and it is too early to base a regulatory system on a simple THC-to-potency equivalency.
- A potency-based tax is targeted at the perceived externalities and social costs of over-consumption, but consumers adopt consumption methods to achieve the desired effect, regardless of potency. As we have seen from alcohol, consumers will simply buy more products to achieve their desired results. More taxes will be paid as a result, and more additives and other non-cannabis products will also be consumed. A policy that leads to consumers purchasing and consuming more products and paying more for them simply is not good policy.
- A THC measurable cannabis product means, in part, a product that can be measured with a reasonable degree of accuracy (i) consistent with good commercial practice and (ii) sufficient to protect the revenue and the public. These are not yet defined and would be critical to understanding what the tax implications would be.

- There are pros and cons for both a potency-based as well as a weight-based tax.
    - A potency tax will lead to products or practices designed to circumvent the tax by maximizing factors such as non-regulated cannabinoids, cannabinoid ratios, terpenes, product types, or delivery methods, in order to achieve the desired level of intoxication.
    - By contrast, weight based taxes incentivize production of lower weight and higher potency THC products that will receive a lower tax rate, even where customers may not prefer these types of products.
- Either way, the application of a varying tax based on product potency or weight distorts production incentives, pricing, and consumer choice in the process, but a weight-based approach also has additional drawbacks:
    - Consideration will need to be given to ways regulatory agencies to update regulations and provide clear guidance to the industry and to states as new products enter the market.

The appropriate entity and methodology for measuring the prevailing price of cannabis for purposes of setting annual rates of tax

Our primary concern here is that the alcohol model does not fit the realities of cannabis production regarding the point at which taxes attach, or in the types of product available in the cannabis market compared with products in the alcohol industry. More specifically:

- The model is pulled from the tax regime around alcohol, which is itself based on a constitutionally mandated three-tier model in which vertical integration is prohibited. Many cannabis companies, but certainly not all, are vertically integrated (and some states currently require vertical integration). When it comes to applying wholesale rates, there can be unfair advantages to some companies if not accounted for.
- The proposed system could inadvertently (or even deliberately) favor a three-tier model and impose that approach on state systems, none of which have currently adopted it. The federal government should not impose such a dramatic change on states.
- The proposal includes a bonding system and warehousing, which likely isn't an appropriate fit for the cannabis industry with its comparatively complicated contract relationships and products. The bonding system is, in effect, an archaic track and trace system, and we believe a well managed track and trace system like that described for TTB can achieve the same results without a significant disruption in the marketplace, given sufficient time and preparation is made for states and businesses to adapt.
- With so many different types of licensees from state to state, who would qualify and under what circumstances?
    - Contract relations are complicated among licensees (partly due to the fact there is little institutional lending and parties rely on other sources for financial support, most often other cannabis businesses).
    - The definition of a producer is any person who plants, cultivates, harvests, grows, manufactures, produces, compounds, converts, processes, prepares, or packages any cannabis product. Consideration should be given to whether or not the definition is too narrow or broad to capture the businesses it is aimed to address, and whether it is even necessary for purposes of the excise tax if it is meant to be paid by taxpayers that are bonded?

- Products make it to retail through many channels, from hand lotions to edibles to raw cannabis products to extracts. In turn, these channels can vary from state program to state program. Finding a parallel point for tax to attach in the many product channels and contract relationships will be a challenge for regulators and likely burdensome for licensees.

With respect to the tax rate itself and its calculation, the USCC believes a primary goal of the CAO Act should be to establish a safe and comprehensive regulatory program that is inclusive of those who choose to participate. The tax rate proposed, and the rate at which it increases from year to year will undermine this policy goal. It will both harm businesses operating within state programs, and embolden the broad, untaxed, and unregulated market.

Our data shows that we will see prices skyrocket from 30% increases in places like Oregon, to as high as 125% in New York, or 240% increases in price in New Jersey when added to the tax imposed today by states. This tax rate will be particularly burdensome for small businesses and social equity entrepreneurs coming into licensing regimes in larger state markets -- NY, NJ, IL, and MA -- and contemplated as part of adult-use legislation pending in PA & OH.

A federal retail excise tax rate of 5% or lower would create stability in these nascent state markets as they intend to capture more patients and customers businesses into the regulated marketplace, and support the inclusion of small, independent, or social equity owned businesses in the cannabis industry.

A much longer phase-in period for taxes is needed for several reasons. States will need to adapt not only laws and regulations imposed by TTB and FDA, but they will need to find alternate sources of revenue. While the tax regime may be changing, it should not significantly undermine states in the process.

It is also worth pointing out as we have elsewhere in these comments that private companies are already under a significant financial pressure under existing tax state tax systems and should have a reasonable amount of time to adapt to the additional tax burden.

Finally, consider that illicit operators seeking to enter the market will not only face the prospect of new taxes at both the state and federal levels, but also a significant 280e tax penalties. Those entering into the market should be given an appropriate ramp to incent those who would participate, particularly during the transition period and before the new law enforcement framework is fully implemented.

Considerations related to the non-application IRC 280e, including transition rules and interactions with tax incentives for activities that may have occurred while a business was subject to the limitation on credits and deduction;

As mentioned, there must be a period of intentional regulatory transition and a well-specified timeline. This could include a look back for expensing or deductions for business expenses or capital investments that were not allowed prior to the time of enactment which could offset some of the challenges.

The Sponsoring Offices request comment on additional, general, and unspecified items, including any other areas of concern to stakeholders, federal agencies, members of Congress, and state and local regulators

We believe, as the sponsors do, that social equity takes a paramount role in the consideration of the best regulatory program. There are several positive ways in which the CAO Act accomplishes the underlying goal of a more inclusive and equitable industry than we see in other sectors, and there are ways to improve.

The first priority of comprehensive cannabis reform must be equitable wealth creation and repairing prior wrongs. We need to take the time needed to get federal social equity and restorative justice programs up and running and to make certain that people who have been negatively impacted by the so-called War on Drugs have a real opportunity to succeed in this new industry. We must allow time to reap the benefits of state social equity programs designed to ensure cannabis licenses are awarded to qualified social equity applicants and to allow for people to transition from the illicit market to the legal market. The existence and preservation of state programs designed to license, establish, and nurture these programs is referenced in the CAO Act, but we believe specific protections should be put in place that can ensure they will continue to serve their important function.

Importantly, we must also develop a robust and comprehensive process to expunge criminal records for those who have been indelibly sanctioned for marijuana offenses and to repair other wrongs created by the War on Drugs. For any of this to be successful, it will take time to continue to bolster state revenue sources that are crucial in supporting social equity programs and reverse the damage that has been done through unjust and harmful drug policies.

We commend Senate drafters for including robust social equity and criminal justice reform measures in the bill. We support the Equitable Licensing Program to provide funding to eligible states and localities to implement cannabis licensing programs to minimize barriers for individuals harmed by the War on Drugs. However as mentioned elsewhere, care should be taken to ensure these programs are effective and funded to the degree needed to meet the goals of the sponsors.

Federal cannabis legalization legislation should allow new members of the cannabis industry to access banking and other critical financial services. In addition to the provisions included in the H.R. 1996, the Secure and Fair Enforcement Banking Act of 2021 or SAFE Banking Act, federal legislation should also open capital markets to the U.S. cannabis industry. Allowing U.S. cannabis operators to access capital markets will unlock critical funding opportunities for entrepreneurs, social equity operators and small businesses, as well as growing more established companies.

Congress should enact legislation that specifically permits and allows U.S. cannabis companies that operate in accordance with state laws to register securities on a national securities exchange, such as the National Association of Securities Dealers Automated Quotations (Nasdaq)Nasdaq and the New York Stock Exchange (NYSE), leveling the financial playing field for American companies.

Currently, the U.S. senior exchanges allow the listing of foreign cannabis companies but will not list U.S.-based cannabis companies because of federal illegality. As a result, US cannabis companies are unable to receive the benefits of investment capital, unlike international competitors. Allowing U.S. cannabis operators to access capital markets will unlock critical funding opportunities for entrepreneurs, social equity and small businesses., as well as growing more established companies. An injection of this critical investment will accelerate the creation of quality jobs, increase tax revenues and further community reinvestment.

Cannabis operators must have access to financial institutions for safety and business reasons. Without access to banking, operators must pay taxes and conduct business

with cash, which presents significant safety concerns for workers and the public, plus opportunities for diversion, loss, theft and inaccurate books and records. Provisions such as those included in the proposed SAFE Banking Act are particularly critical to ensure the success of social equity applicants and small business owners. Currently, financing a cannabis business is extremely difficult without access to financial institutions.

As previously discussed, Internal Revenue Section 280e prevents state-legal cannabis businesses from taking standard business deductions and receiving tax credits - an absurd limitation in light of state authorization and compliance standards, as well as state and local taxes. Cannabis businesses are ineligible for standard business deductions including employee salaries and training, health insurance and advertising and marketing, and accounting and other professional expenses. Cannabis businesses are also ineligible for credits, including the renewable energy investment tax credit among many others. Section 280e hinders entrepreneurs, especially social equity applicants and minority small business owners from securing tax relief, effectively limiting their ability to become profitable, reinvest in, and scale their business.

We appreciate the drafters recognize there are two groups that are included in the social equity discussion, and each is deserving of its own consideration. Over the years, the war on cannabis has impacted countless individuals and their families through prohibitionist laws that keep them from fully entering the marketplace. These individuals should not be held back because of anti-cannabis laws that have no place in a post-prohibition regulatory environment. At the same time, there are racial minorities and especially Black and brown communities that have been disproportionately impacted by the war on cannabis through uneven law enforcement. We need measures that address both on their own terms or we will miss the mark. The USCC recognizes that both the CAO Act and H. R. 3617, the MORE Act of 2021 which preceded it, both take steps to address these groups at the same time.

However, we do have serious concerns related to the CAO Act as it relates to social equity and reform, many of which we share with the Minority Cannabis Business Association. These include:

- As we have argued in many other places in these comments, the proposed system would place an extraordinary amount of authority with FDA which would set a high bar for newly-formed businesses. Add to that a high tax burden with a short ramp to a fully-taxed system, and there is an exceptionally high burden on the same small, minority, and social equity businesses the sponsor's seek to assist. The current draft does not provide sufficient assurance to think the proposal can overcome the inherent challenges built into the proposed model.
- We believe there should be more consideration to the definition "socially and economically disadvantaged individuals" to ensure it includes both those who have been impacted by the war on cannabis and racial minorities from groups who have been disproportionately impacted, and narrowly tailored to avoid those who are not intended to benefit.
- With regard to expungement provisions, serious consideration should be given to:
    - Whether or not one year is enough time to identify, review, and adjudicate all impacted cases
    - What circumstances qualify as "non-violent" cannabis offenses, which should require a violent act in furtherance of the cannabis-related offense - rather than mere proximity to a weapon
    - The impact on courts in light of those who may petition the courts for determinations
    - Any due process considerations that may be implicated by notifying former offenders after the adjudication

- There should be guidelines for resentencing, and how plea agreements leading to admissions to offenses outside those within the Controlled Substances Act might be impacted or adjudicated
- Similarly should there be additional offenses included beyond those who have "been arrested for, or convicted of, the sale, possession, use, manufacture, or cultivation of cannabis"?
- Whether or not the ability to deny a previous conviction under oath will apply under state law as well as federal proceedings as written, or whether it will need to be articulated differently?
- The list of options for states, including expungement, destruction, or sealing, should be more narrowly crafted to avoid states circumventing the intended goal of eliminating records for cannabis offenders.

- Section 401 of the Discussion Draft would establish operational rules for cannabis manufacturers similar to alcohol and tobacco requiring them to maintain a bond to ensure excise taxes are paid. Similar to exceptions granted to small alcohol producers, small businesses owners who qualify for the Equitable Licensing Program should be exempt from this requirement.
- The Discussion Draft calls for a fee waiver for first-time applicants with income below 250% of the federal poverty level. This should also include those who have previously been charged with a cannabis offense as defined by the Office of Cannabis Justice to limit barriers for individuals to transition from the illicit market.
- The waiver should also apply to first time licensees, not first time applicants (who may not successfully apply the first time).

The first priority of comprehensive cannabis reform must be equitable wealth creation and repairing prior wrongs. We need to take the time needed to get state social equity and restorative justice programs up and running and to make certain that people who have been negatively impacted by the War on Drugs have a real opportunity to succeed in this new industry. We must allow time to actually reap the benefits of these social equity programs so they can ensure cannabis licenses are actually awarded to qualified social equity applicants. And as argued elsewhere, it is important to allow people to transition from the illicit market to the legal market.

Interactions with international obligations and treaties.

The U.S. is party to three international treaties that are used to schedule narcotics (1961 Single Convention on Narcotic Drugs, 1971 Convention on Psychotropic Substances, and 1988 UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances).[9] If passed, the CAO Act would clearly put the U.S. in contravention of these treaties. Constitutionally protected national cannabis regimes carry significant weight within United Nations (U.N.) institutions, putting the U.S. on a course in which member states will certainly see the U.S. in contravention of its treaty obligations, and likely they already do in light of our state-level adult-use programs.

Critically, passage of the CAO Act should not be impeded in any way by these international obligations and treaties, but just as with the domestic transition that will take place following descheduling, the U.S. should also plan a carefully considered path forward to minimize disruption in the international community.

[9] *"This (1961 Single) Convention on Narcotic Drugs aims to combat drug abuse by coordinated international action. There are two forms of intervention and control that work together. First, it seeks to limit the possession, use, trade in, distribution, import, export, manufacture and production of drugs exclusively to* ***medical and scientific purposes.*** *Second, it combats drug trafficking through international cooperation to deter and discourage drug traffickers."* [Introduction of 1961 Single Convention on Narcotic Drugs]

The U.S. should take a proactive stance at the U.N. and pertinent institutions and prepare them for the downstream impacts the CAO Act would have on these international agreements. In particular, this would include protecting State-level programs already in place, ensuring continuity of their social equity programs, and a particular focus on ensuring uninterrupted access for medical patients.

After years of failed prohibition policies, the CAO Act represents a more meaningful step towards the original goals of these international treaties than the current set of international laws -- namely, protecting public health and reducing the harms of illicit crime associated with cannabis trafficking. In fact, Uruguay and Canada have taken similar measures to end prohibition despite these international obligations, specifically for many of the same purposes behind the international treaties themselves. The U.S. will be in a strong position to take a leadership position as drug laws steer away from a criminal perspective.

Even before the CAO Act is passed, the U.S. should actively seek updates to these international drug treaties. Currently there is no agreed upon definition of adult use cannabis use within the international treaty system, with the plant and its constituents only being named for very specific medical/scientific, horticultural, or industrial use. As key proponents of these narcotic drug control treaties, the US will need to lead a conversation within the World Health Organization (W.H.O.), U.N. and associated bodies like the U.N. Food and Agricultural Association, to work towards updating the definition of cannabis and accommodate for the Member States using cannabis outside of the scope of these treaties.

In line with updating the definitions of cannabis and cannabis extracts, there is a pressing need for the U.N. and affiliates to move away from controlling adult use cannabis as a narcotic crop, and towards regulations more aligned with an agricultural crop. This clarification would be one of the most meaningful steps towards facilitating an international economy of cannabis for adult-use purposes, as well as enabling Member States of the U.N. to enact domestic controls on cannabis within the confines of international law. This aligns with much of what advocacy groups such as Civil Society are requesting through U.N. dialogues, as well as moving more closely in line with the World Health Organization.

These treaties are in place to protect public health, as well as eliminate diversion of narcotics into the illicit market. Descheduling cannabis through the CAO Act is likely to do more towards these goals than any current U.N. scheduling systems, and the U.S. should lead this discourse, particularly when opponents to reform are already active in international forums.

Broadly speaking, (and similar to FDA), cannabis as a plant and substance does not fit neatly into these international treaties, causing significant room for interpretation. When the CAO Act is introduced, and it is clear the U.S. is moving towards descheduling cannabis, opponents of reform within the U.N., as well as domestically, will be able to point towards various treaty-based arguments to impede progress on reform. Therefore, it will be important to neutralize these arguments ahead of time.

Considerations on International Institutions ahead of the CAO:

- WHO's Determination to Keep Cannabis in Schedule I and Advocate for Future Reform: In December 2020, the U.N. Commission on Narcotic Drugs (UNCND) voted on six recommendations put forward by the W.H.O. following a comprehensive scientific review. Only one recommendation was passed, which recognized the medical properties of cannabis. While the passage of recommendation 5.1represented a significant step in the modernization of the UN Treaties, cannabis remained classified in Schedule I of the 1961 Convention (reserved for substances considered "highly addictive and liable to abuse"). This Schedule I classification remains at odds with scientific evidence that informed the WHO's recommendations, as well as public health policies of the U.S. and many countries.

When this process was first initiated, the WHO also made it clear to the Commission [CND] that they felt removal of cannabis from Schedule 1 would require a rewrite of the treaties at questions, and they felt their mandate was to make scheduling recommendations - not to rewrite the treaty.

The W.H.O.'s Expert Committee on Drug Dependence (ECDD)'s then conducted a Critical Review in 2019—which formed the basis for the Recommendations—and acknowledged the medical efficacy of cannabis and recommended its removal from Schedule IV of the 1961 Convention. However, the WHO neglected to recommend the removal of cannabis from Schedule I, for example, by proposing placement in the less stringent Schedule II, or even removing cannabis from the lists of the 1961 Convention altogether. The WHO's decision appears to ignore the fact that ECDD's review concluded that cannabis was less harmful by comparison to other substances on the same list, such as heroin and cocaine. Considering the clear findings of the ECDD review, the WHO's decision to effectively recommend keeping cannabis in Schedule I (a recommendation that does not require a vote, because no change is being proposed) calls for closer scrutiny of the underlying evaluation methods and decision-making process, lest the WHO review be cited as scientific confirmation that cannabis indeed belongs in Schedule I.

Going forward, the U.S. should challenge this questionable and consequential aspect of the WHO's recommendations, pointing out that the placement of cannabis in Schedule I of the 1961 Convention: (i) is inconsistent with science-based evidence and is not a logical conclusion from the outcome of the ECDD review, which unambiguously concluded that cannabis is less harmful than other substances in Schedule I; (ii) and has the effect of affirming policies rooted in racism and colonialism that have resulted in devastating consequences for millions of people globally over decades—especially minority groups and those suffering from medical conditions.

As the U.S. addresses these same issues domestically, reflecting on its own troubled history and candidly addressing racism and its deep wounds in our own society, the U.S. will position itself to lead on this issue globally. Its silence would be a misstep.

- Minimize Tensions Regarding Cannabis Control among Member States arising out of the Recommendations: The State Department has been attempting to recruit other countries to join the U.S. in issuing an "Explanation of Position" (EOP) emphasizing that, regardless of countries' different voting stances on the Recommendations, the process has affirmed that cannabis remains "properly subject to the full scope of international controls of the 1961 Single Convention because of its continued placement in Schedule I." The EOP being promoted by the U.S. would therefore characterize the review process as bolstering with the latest scientific evidence a global consensus for the continued strict control of cannabis in Schedule I.

  Although the classification of cannabis as Schedule I under the 1961 Convention is certainly consistent with current and historic federal policy, the EOP's endorsement of the current and inappropriate classification of cannabis as Schedule I is clearly at odds with the direction the U.S. and many other countries are headed. Going forward, it will be important for Congress to understand that a U.S. position of advocating for the *status quo* classification of cannabis as a highly dangerous substance internationally, while simultaneously advancing decriminalization and regulation domestically will be widely seen to be hypocritical and will undermine the ability of the U.S. to engage candidly with other governments chafing at the confines of the prohibitionist drug treaty regime and exploring options for reform.

  The U.S.' desire to alleviate the obvious tensions at the UNCND surrounding differences over cannabis policy is understandable. But the differences across countries are very real—with some Member States still staunchly committed to the complete prohibition of cannabis and others opting to legally regulate adult-use cannabis—and cannot be papered over by appeal to a faux consensus.

Members of Congress committed to cannabis policy reform should therefore distance themselves from the EOP, making clear that continuing to classify cannabis as Schedule I under the 1961 Convention is a backwards approach, contrary to science-based evidence (including the ECDD review), and cannot be maintained while the U.S. and other countries proceed with medical and adult-use cannabis regulation.

Looking ahead, Congress should engage with the State Department to focus on the future of cannabis regulation and to identify areas in common with other countries that are proceeding with cannabis regulatory regimes. For example, a coalition of the U.S. and like-minded countries could seek further reviews by the W.H.O., mindful that scientific evidence continues to accumulate. The first W.H.O. review on cannabis cannot also be the last, especially given the serious questions surrounding the decision to keep cannabis in Schedule I. In doing so, the State Department can actively engage with other Member States to discuss options for reconciling the legal regulation of adult-use cannabis with their obligations under the UN Treaties, including if cannabis remains in Schedule I.

Regardless of the CAO Act's status, the above issues can and should be addressed by Congress to ensure a smooth transition as we end prohibition and it's enforcement.

Treaty Issues Created by Passage of the CAO:

- Section 811(d)(1) of the Controlled Substances Act (CSA) requires the U.S. Attorney General (AG) to reconcile any proposed re- or-de-scheduling with international treaty obligations, if prompted by International Authorities (UN or INCB). The CAO Act needs to explicitly state that the AG is not permitted to schedule "marihuana" and THC under 811(d)(1)'s authority and that any future scheduling can only occur after Congress passes a bill scheduling marihuana and THC. As it stands, the US AG would not have authority to veto the CAO if passed by Congress and signed into law by President Biden, however, the AG might be able to overturn this descheduling under the CSA's section 811(d)(1)'s authority, if UN institutions make a formal request for the US to do so. This is a loophole that will need to be addressed with specific language.

  Worth noting, is this issue similarly applies to the 2018 Farm Bill and the removal of "Hemp" (cannabis containing 0.3% THC or less) from the Controlled Substances Act schedules. Presumably, the AG, at any time under 811(d) authority, could place "hemp" back onto Schedule I if requested by the U.N. to do so.

- Several treaty solutions have been put forward by leading international drug policy experts through the UN's engagement with Civil Society. Two of these leaders, Martin Jelsma of the Transnational Institute, and John Walsh of the Washington Office on Latin American, have outlined many of the hurdles the US will face, as well as several potential treaty solutions that exist. Their paper outlines how the US's current position has a limited "shelf-life" within international institutions regardless of the CAO Act, as well as containing potential solutions to neutralize any treaty-based arguments against reform. Solutions proposed in their paper outline steps both with regard to the U.N. as a whole, and which the U.S. as a Member State could take to resolve these treaty issues. Namely, they are:

  - Independent U.S. Treaty Action (complete withdrawal or attempting to amend the UN treaties to accommodate for reform).

  - Treaty withdrawal and re-accession with reservations.

  - an *Inter se* treaty modification (could be used in combination with other reforms).

  Currently at the U.N., only opponents to reform have been able to reach consensus, and protecting the integrity of these international agreements is paramount to their

position. Each of these scenarios have strengths and weaknesses, but manage to work within the current treaties themselves, eliminating a significant point of contention.

Descheduling cannabis at the international level would not only allow Member States to conduct reform at home, but further their ability to conduct research and apply existing federal labor, environmental, and regulatory protections.

Finally, any treaty reform at the UN level would require consensus among Member States through a majority vote to amend the treaties in any way. Regardless of passage of the CAO Act, or implications under these U.N. treaties, treaty reform as described above should be explored so that we move past prohibition as a drug policy, globally.

Any other areas of concern to stakeholders, federal agencies, members of Congress, and state and local regulators.

Environmental

The sponsors did not specifically inquire about environmental considerations, but they warrant attention. There are concerns in some parts of the country in critical areas such as energy use, waste, pesticide use, nutrient runoff, and water use. Our members are committed to environmental sustainability and improving the environmental footprint of the cannabis production sector. As the framework is being built for the regulatory system of the future, we have the ability to do so in a way that implements environmental sustainability in a realistic way.

Moving cannabis from an unregulated market to a regulated one is improving the environmental footprint of operations that have not traditionally been set up for environmental efficiency. Continued federal prohibition hinders research and innovation in manufacturing practices that could help cannabis businesses improve their operations including in areas such as efficiency. Despite these challenges, our members are already bringing innovations to the industry and participating in programs to improve operational efficiency.

Any legal cultivation framework should allow product manufacturers, operators and regulators to collaborate and create opportunities to improve sustainability. For example, access to energy efficiency rebates through utility operators has helped to spur adoption of low energy LED lighting and dehumidification systems in grow rooms in many states, helping to begin an energy efficiency transformation. Federal reform should ensure that cannabis companies have access to tax offsets such as carbon reduction incentives, other energy efficiency grants, as well as federal and state grants for renewable energy projects.

Our members are committed to addressing water efficiency, production waste, and packaging waste challenges as well. Our support for a national system includes environmental controls that can be implemented as best practices around the country. We believe that federal reform is also an opportunity to review well-intended but draconian state level requirements that create unfair burdens or may hinder optimal environmental efficiency.

Related to these matters but also looking toward international relations, the U.S. should advocate for cannabis to be considered an agricultural crop internationally (rather than a narcotic crop) which will open regulations that will steer the industry towards environmentally viable practices, along with other benefits mentioned elsewhere in these comments. And these environmental controls have a major secondary benefit -- additional enforcement discretion when pursuing illicit operators internationally.

V. Recommendations

In addition to responses to specific stakeholder questions included in Part IV, the primary recommendations to the sponsors include the following:

- Primary regulatory authority should be with TTB
- TTB should be empowered to:
    - Have primary regulatory responsibility for setting standards for state licensing programs and licensees
    - Identify minimum state regulatory best practices consistent with today's marketplace, under which all states should operate to facilitate the transition to interstate commerce
    - Work with FDA to help ensure the health and safety of consumers of cannabis products
    - Administer taxes
- FDA should be empowered to:
    - Regulate any product making health claims outside the scope of state medical cannabis programs
    - Subject to limitations, FDA could regulate anything they normally would outside the plant, including additives, fillers, or non-standard food ingredients.
    - Regulate products which have not been commonly available in a regulated market, or which fall outside a range of acceptable levels (such as a monograph).
    - Provide minimum standards for labels, testing, and serving sizes
    - Work with TTB in support of its mission to support health and safety through an MOU similar to that in place for alcohol regulation
    - FDA should not be allowed to pre-approve cannabis products that are commonly on the market today, and should look to common standards such as monographs when possible
- CAO Act should clearly articulate role states should serve:
    - States may continue to operate without violation of the Dormant Commerce Clause through a transition period
    - Continue to serve as primary licensing authority
    - Continue to manage social equity programming
    - Work with TTB and FDA (and perhaps USDA) to develop and enforce standards
- Existing state regulatory systems should remain unchanged, and interstate and import/export should be paused until rules can be put in place
- Consider whether safe harbor provisions are needed during the transition period
- Federal agencies, including TTB and FDA, should be mandated to ensure a smooth transition

- Agencies should work with states to identify ways to minimize disruption and adopt rules before the transition period has expired and federal mandates are in place
- The CAO Act should be unmistakably clear that it grants authority to the states to continue to enforce and implement state rules, notwithstanding the Dormant Commerce Clause during the transition period
- The sponsoring offices should consider the appropriate tax rate in light of their goals, including increasing reducing criminal activity, supporting public health and safety, and gaining broad support
- The USCC believes the tax burden should start low and increase gradually, but there should be a careful analysis of the most appropriate tax levels and rate of increase to capture these concerns
- The bonding requirement may or may not be needed, since the three-tier model doesn't apply. Consider using track and trace
- Consider the array of products available in the market today, from edibles to inhalants, and how each might need its own criteria for attaching tax liability
- Individuals registered with state programs as medical cannabis patients should not be subject to a federal tax

Conclusion

The USCC strongly supports the goal of ending cannabis prohibition and replacing it with a sensible regulatory system that reduces the harm of the War on Drugs, ensures patients have access to medical cannabis, and protects small businesses including social equity businesses and ensures they have an opportunity to thrive. It is worth repeating that we will not have serious justice reform in our country until we end the federal government's harmful war on cannabis, and this measure is the first, truly comprehensive approach to a solution.

We also strongly support a robust federal regulatory framework that can harmonize the patchwork system now in place, provide needed guidance to help protect the health and safety of consumers (including preserving age limits for adult consumers), provide baseline "best practices" for state programs to follow, and guide our regulatory system from the one we have today, to one in which the federal government takes an active role.

However, the proposals here present significant challenges toward achieving the goals the sponsoring offices have outlined. A program that relies heavily on the FDA will be prohibitively expensive for small business operators, and the FDA is unlikely to support state medical cannabis programs or access for patients - now state law in two out of three states in the U.S. We propose a program that is led primarily by TTB, but with an important role for FDA on an ongoing basis.

We also believe the federal government should take a measured approach to the transition from today's system of cannabis licensee regulation to one guided by federal agencies. The government should not initiate the transition without a careful plan including protections for small businesses and other sideboards in place, or risk avoidable, destabilizing effects which will harm the public, consumers, and the businesses that sponsors seek to support.

The tax scheme is workable although consideration should be given to the unique aspects of cannabis in terms of production and processing. The tax burden is too steep and will perpetuate underground operators who will operate at a significant advantage. And state budgets are likely to face shortfalls as revenue is potentially diverted from states

operating programs to the federal government overseeing them. We strongly urge Congress to consider what the market can bear, and what the long term goals of regulation are.

The USCC is proud of the work our members have done and will continue to do on behalf of cannabis reform as states continue to grow their programs and more states join. Thank you for the opportunity to contribute our perspective to this draft, and we look forward to continuing the discussion.

Attachment A

State Revenue and Jobs in the Cannabis Industry

In 2019, Colorado collected $302 million in taxes and fees on medical and recreational Cannabis with sales over $1.7 billion. In the same year, California cannabis sales generated $411.3 million in excise tax, $99.9 million in cultivation tax and $335.1 million in sales tax reported. This and over $1 billion in tax revenue from recreational Cannabis in 2020 which is up 62%. After Massachusetts' first year of opening in 2018 cannabis retailers gross sales generated $393.7 million, with more than $440,000 in sales at two stores on opening day.

Cannabis sales country wide in 2019 were $12.2 billion. In 2020, sales were up 71% while most companies were shut down due to Covid-19. The cannabis industry, in most states, was considered essential. Colorado State University-Pueblo's Institute of Cannabis Research found that the legal cannabis industry has contributed more than $80.8 million to the local economy in 2017 primarily through taxes and other fees. If cannabis becomes legal on the federal level, it could generate an additional $105.6 billion in aggregate federal tax revenue by 2025. Below is the 2020 revenue for a few legalized states and the projected growth into 2021.

Legalized Levy Excise taxes on Cannabis:

1. Massachusetts;
    a. Revenue Fiscal Year 2020: $51,684,592.00
    b. Projected Revenue Fiscal Year 2021: $104,428,106.00

2. Michigan;
    a. Revenue Fiscal Year 2020: $31,364,000.00
    b. Projected Revenue Fiscal Year 2021: $75,000,000.00

3. Illinois;
    a. Revenue Fiscal Year 2020: $52,698,873.00
    b. Projected Revenue Fiscal Year 2021: $315,645,689.00

4. Colorado;
    a. Revenue Fiscal Year 2020: $307,278,327.00
    b. Projected Revenue Fiscal Year 2021: $410,584,023.00

5. Nevada;
    a. Revenue Fiscal Year 2020: $105,180,947.00
    b. Projected Revenue Fiscal Year 2021: $153,227,327.00

6. California;
    a. Revenue Fiscal Year 2020: 525,943,734.00
    b. Projected Revenue Fiscal Year 2021: $757,482,335.00

7. Oregon;
    a. Revenue Fiscal Year 2020: $133,150,349.00
    b. Projected Revenue Fiscal Year 2021: $175,106,330.00

8. Washington;
    a. Revenue Fiscal Year 2020: $468,502,946.00
    b. Projected Revenue Fiscal Year 2021: Not Available

9. Alaska;
    a. Revenue Fiscal Year 2020: $24,540,009.00
    b. Projected Revenue Fiscal Year 2021: $29,051,904.00

Sales continue to be on the rise but so is the job growth the cannabis industry brings. In the United States as of January 2021, 321,000 Full Time Equivalent jobs are within the legal Cannabis industry.[10] To put that increase in perspective:

- 2017: 122,800 jobs
- 2018: 149,300 jobs
- 2019: 211,000 jobs
- 2020: 243,700 jobs

The data clearly shows that even through the global Covid-19 pandemic there was continuous job growth. California estimates at least 81,000 additional direct, indirect, and induced jobs as a result of legalizing cannabis and labor income is projected to increase by at least $3.5 billion. Nevada since legalizing cannabis projects job growth could hit 41,000 jobs through 2021 while generating over $1.7 billion in labor income. One report predicts the impact of federally legalizing cannabis could suggest 1 million jobs by 2025.[11] This affects not just urban areas with creating jobs in software development, finance and construction but also helps rural areas by the need to farm, process and cultivate cannabis-based products.

Rural communities and small towns have already received a boost from the cannabis industry. For example the state of Illinois. Cresco Labs in Lincoln, IL (a town of about 13,000) created more than 250 jobs with higher wages showing a 50% increase in income for those who live in the area. 75 miles away in Barry, IL (a town of 1,500), Ascend Wellness generated 300 jobs. Nature's Grace in Vermont, IL (a town of 800) generated 145 jobs which is up from the original 50 jobs they had prior to legalization and soon to add 30 more. Revolution Global in Delevan, IL (a town of 1,800) generated 135 jobs and will be doubling it's facility in the near future. You can see the Cannabis industry jump started new employment in these rural areas that need more opportunities. Pharmacann in Dwight, IL created 75 full time jobs including benefits in a town of just over 4,000 residents.

As more states legalize cannabis and with hope, a Federal legalization, the cannabis industry could positively benefit so many licensed businesses, small communities, and urban cities all over the country. The cannabis industry continues to generate new jobs, more employment opportunities, and a multitude of financial growth.

Sites Used:

The Economic Benefits of Marijuana Legalization (investopedia.com)

Legal Marijuana States Have Generated Nearly $8 Billion In Tax Revenue Since Recreational Sales Launched, Report Finds | Marijuana Moment

Map of Marijuana Legality by State (disa.com)

States Projected to Post Higher Marijuana Revenues in 2021 (taxfoundation.org)

The US cannabis industry now supports 321,000 full-time jobs | Leafly - Aug 2021

[10] Cite 2021 Leafly Jobs Report

[11] Cite New Frontier report

Weed cultivation centers grow jobs in rural Illinois | HawkeyeReport.com (rivals.com)

Here's how much money people in Massachusetts spent on (legal) marijuana in the first year of sales (boston.com)