



September 1, 2021

The Honorable Chuck Schumer
Majority Leader
United States Senate
Room S-221, The Capitol
Washington, DC 20510

The Honorable Cory Booker
United States Senator for New Jersey
717 Hart Senate Office Building
Washington, DC 20510

The Honorable Ron Wyden
United States Senator for Oregon
221 Dirksen Senate Office Building
Washington, DC 20510

*RE: Request for Comment on the Cannabis Administration and Opportunity Act
Submitted via electronic mail to cannabis_reform@finance.senate.gov*

Dear Senators Schumer, Booker, and Wyden:

The National Cannabis Industry Association (NCIA) thanks Senate Leader Schumer, Committee Chair Wyden, and Senator Booker for the opportunity to provide comments on the discussion draft of the Cannabis Administration and Opportunity Act (CAOA).

Founded in 2010, NCIA is the oldest, largest, and only full-service trade association serving the entire legal cannabis industry. Our membership is composed of several hundred businesses and tens-of-thousands of cannabis professionals from across the United States. For the past decade, NCIA has been leading the charge to protect the legal cannabis industry, defend state laws, and advance federal policy reforms. We are the only organization that broadly represents cannabis-related businesses at the national level, and are honored to provide thorough answers to the questions you posed.

In order to offer the most comprehensive and inclusive feedback possible, we worked diligently with a multitude of stakeholders that comprise our association. This included soliciting feedback from our board of directors, all levels of membership, fourteen sector committees, and dozens of members representing various state and local organizations as well as social equity programs. All told, we have collected and synthesized a vast body of feedback across all stakeholders in the legal cannabis industry to inform our comments and recommendations. As a result, this feedback represents the input from companies of all sizes across nearly every vertical of the legal industry in the U.S, including cannabis cultivators,

manufacturers, distributors, retailers, equity operators, and innumerable ancillary businesses providing support services to these businesses.

Given your demonstrated focus on engaging with the people most directly impacted by cannabis policy reform, we hope the breadth and depth of our feedback will enable you to enact sound legislation which fosters the growth of a thriving and equitable legal cannabis industry. NCIA is committed to creating a vibrant legal industry that can sustain thousands of well-paying jobs while responsibly serving adult consumers and medical patients who rely on cannabis for relief. We are confident that you share this commitment with NCIA and trust you will seriously consider this feedback and that of our advocacy and industry allies. Given the nuances and complexities involved in some of the issues addressed by this draft legislation, there are some areas where NCIA stakeholders did not reach total consensus, or where we were unable to complete a thorough analysis at the present time. In these cases, we have included these viewpoints as viable options and look forward to working with stakeholders and Sponsoring Offices to determine the best paths forward.

That this bill looks to create restorative justice and to consider the complexities of how communities were negatively and disproportionately impacted by cannabis prohibition is of the utmost importance, and is greatly appreciated. In order to achieve this, we are encouraged that this discussion draft will result in the continued dialogue that is necessary to ensure that individual states do not continue to perpetuate illicit markets.

Thank you again for providing us this opportunity to weigh in on this thoughtful legislation. We look forward to working with you on the final draft and addressing any questions you might have in the weeks and months ahead.

Sincerely,



Aaron Smith
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National Cannabis Industry Association
Cannabis Administration And Opportunity Act Discussion Draft Comments
Published on September 1, 2021

The Sponsoring Offices request comments on the new definition of “cannabis,” including comments on —

- The appropriate way to measure the potency of cannabis and cannabis products;
- The interaction between the definition of “cannabis” and the definition of “hemp;”
- The interaction between the definition of “cannabis,” “cannabis product,” and FFDCA drugs containing cannabis;
- The appropriate classification and regulation of synthetically-derived THC; and
- Conforming amendments and interactions relating to the descheduling of cannabis and establishing a new definition outside of the Controlled Substances Act.

The appropriate way to measure the potency of cannabis and cannabis products;

Consistent and accurate potency testing is important to consumers and the industry. In order to maintain the successful markets we currently see at the state level, states should be able to continue to regulate the composition and potency of cannabis and cannabis products sold within their borders. However, to facilitate interstate commerce, consistent and accurate standards for testing of cannabis and cannabis products applicable across these markets are vital to build a transparent interstate marketplace that instills consumer confidence in their purchases.

When establishing testing standards under the Federal Food, Drug, and Cosmetics Act (FFDCA), the FDA should study state-level potency and chemical residual standards for best practices, or consider using voluntary consensus standards created from international Standards Developing Organizations, such as AOAC International.¹ The FDA should work with the states to incorporate the standards into their testing requirements to avoid unnecessary or duplicative testing.

We also urge a practical approach to testing and any potency thresholds established for individual dosage or package units that takes into account the reality of existing state regulated markets and the resilient illicit market. Any potency limits should be considered in light of the reality that such limitations will not be followed by the illicit market and may inadvertently promote purchasing of potentially unsafe unregulated products, as well as the penalization of the communities mentioned in the CAO and thus perpetuating the effects of the War on Drugs on a practical level. We are encouraged and pleased not to see any of these caps included in the draft of the CAO.

¹ In 2020, AOAC’s Expert Review Panel approved an analytical method for detecting and measuring cannabinoids in cannabis. Two standard methods that exist today are AOAC 2018.11: Quantitation of Cannabinoids in Cannabis Dried Plant Materials, Concentrates, and Oils, and AOAC 2018.10: Cannabinoid in Dried Flowers and Oil.

The interaction between the definition of “cannabis” and the definition of “hemp;”

Consumer safety and commercial practicality dictates adopting different regulatory approaches for potentially psychotropic products, products with only *de minimis* levels of potentially psychotropic cannabinoids, and products with no psychotropic effect at all. We urge the Sponsoring Offices to review NCI’s October 2019 white paper, “[Adapting a Regulatory Framework for the Emerging Cannabis Industry](#),” in which we recommended that (i) pharmaceutical cannabinoid drugs continue to be regulated like other drugs, (ii) non-pharmaceutical psychotropic cannabis products be regulated like alcohol, while non-psychotropic cannabinoid-containing products be regulated like (iii) food/dietary supplements (ingested/inhalable products) or (iv) cosmetics (topical products).

Hemp is defined under the 2018 Farm Bill to include “the plant *Cannabis sativa* L. and any part of that plant, including ... all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.”² In contrast, the revised definition of “cannabis” in the CAO only includes “all parts of the plant *Cannabis sativa* L., ... the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin,” and omits the terms “cannabinoids, isomers [and] acids.” We encourage the Sponsoring Offices to conform the CAO definition of “cannabis” to replace the word “salts” with the phrase “cannabinoids, isomers, acids, salts, and salts of isomers.”

The interaction between the definition of “cannabis,” “cannabis product,” and FFDCAs containing cannabis;

It seems clear that cannabis-infused products which include ingredients other than cannabis would be deemed “cannabis products.” However, the Sponsoring Offices should also consider whether isolated cannabinoids derived from the cannabis plant, cannabis concentrates, and products made from cannabis flower are intended to fall under “cannabis” or “cannabis products,” since the CAO already defines “cannabis” to include “every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin.” It may be prudent for the Sponsoring Offices to consult the available state law definitions for various forms of cannabis goods, then consider revisiting the CAO’s definitions of “cannabis” and “cannabis product” as currently drafted.

In the interim, and for greater clarity, the Sponsoring Offices should consider adding the qualifier “containing greater than 0.3 percent delta-9-tetrahydrocannabinol on a dry weight basis,” after the words “derived from cannabis” in the CAO definition of “cannabis product.”³ This additional qualifier would help distinguish between cannabis products and hemp extracts, and conform to the DEA’s current Interim Rule implementing the 2018 Farm Bill. This Interim Rule carves out both plants and plant derivatives “with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis” out of

² 7 USC §1639o(1).

³ Or such cannabinoid thresholds as may be amended or established through future legislation regarding the definition of cannabis under the 2018 Farm Bill.

the existing federal statutory and/or regulatory definitions for “marihuana,” “tetrahydrocannabinols,” and “marihuana extract.”⁴

Given the importance of creating effective regulations for these products, and in order to accomplish the Sponsoring Offices’ stated policy goals, we look forward to further clarifying these definitions with the Sponsoring Offices prior to CAOAs formal introduction.

The appropriate classification and regulation of synthetically-derived THC;

As currently drafted, Sec. 101, of Title I, Subtitle A of the CAOAs removes all “Tetrahydrocannabinols” from Subsection (c) of schedule I of section 202(c) of the Controlled Substances Act (21 U.S.C. 812), which would include synthetic THC molecules that are synthesized without plant material, but are chemically identical to endogenous phytocannabinoids derived from the cannabis plant. The CAOAs full repeal of the prohibition on *all* THC (natural and synthetic) would be consistent with the scope of the prohibition intended by Congress in the first place; put differently, because Congress specifically intended to capture synthetic THC when it initially scheduled this individual cannabinoid, removing THC from Schedule I specifically removes synthetically-derived THC.⁵

That said, NCIA believes there should continue to be meaningful distinctions between “synthetically derived” THC and “cannabimimetic agents.” Such “cannabimimetic agents” like “K2” and “Spice” (which are already separately scheduled under from subsection (d) of schedule I of section 202(c) of the CSA (21 U.S.C. 812)), should remain scheduled given the public health issues caused by their consumption in place of cannabis. Conversely, all synthesized THC should be governed by implementing regulations adopted pursuant to the CAOAs including potential limitations on the use of synthetic THC for potential forms of intended use. Moreover, the Sponsoring Offices may want to consider whether the intended use of such synthetic THC should inform the ultimate choice of applicable regulatory regime – e.g., whether synthetic THC produced for medical research and pharmaceutical drug development should be governed by the FDA, even if the FDA would not be the lead regulator of synthetic THC intended for non-pharmaceutical purposes.

Conforming amendments and interactions relating to the descheduling of cannabis and establishing a new definition outside of the Controlled Substances Act.

NCIA believes that the first and most important step of a comprehensive regulatory system for cannabis would be for Congress to remove “marihuana” and “tetrahydrocannabinols” from the CSA (otherwise known as “descheduling”) as the CAOAs indeed does. We further believe that descheduling is the only way to truly reform federal policy so that cannabis can be regulated in a sensible manner. We call for cannabis products, like other highly regulated consumables, to be regulated by the government agencies that currently regulate most food and drugs, primarily the Food and Drug Administration (FDA) and the Alcohol and Tobacco Tax and Trade Bureau (TTB) within the U.S. Department of the Treasury. Again, this is detailed in NCIA’s [“Adapting A Proven Regulatory Framework for the Cannabis Industry.”](#)

⁴ See “Implementation of the Agriculture Improvement Act of 2018, A Rule by the Drug Enforcement Administration on 08/21/2020” at 85 FR 51639 (<https://www.federalregister.gov/d/2020-17356>).

⁵ See *Hemp Industries Assoc. v. DEA*, 357 F.3d 1012 (9th Cir. 2004) at 1017-1018.

The new definition of cannabis should be defined under the new Federal Cannabis Administration under the FAA Act⁶ so that the TTB is the primary regulatory agency.

The Sponsoring Offices also request comments on agency responsibilities, including —

- The appropriate division of responsibilities between FDA, TTB, and ATF, including ways to increase coordination between agencies and ways to reduce duplication of administrative and compliance burdens;
- Appropriations requests for various agencies involved in cannabis administration in order to ensure that those agencies have the necessary tools and resources to effectively carry out new responsibilities; and
- Whether FDA regulation of cannabis products should be funded through a user fee program or other funding model.

The appropriate division of responsibilities between FDA, TTB, and ATF, including ways to increase coordination between agencies and ways to reduce duplication of administrative and compliance burdens;

We believe that a well-functioning, efficient and effectively regulated national market for cannabis products is essential to meeting the robust demand from the American consumer and essential to supplanting the unregulated illicit market. As noted above, we recommend that the Sponsoring Offices employ the proposals in NCIA's October 2019 white paper, "[Adapting a Regulatory Framework for the Emerging Cannabis Industry](#)," including analysis of the appropriate regulatory regime for four different categories of cannabis and cannabis products, based on their intended uses and THC content. This analysis is summarized in the table below:

Lane #1 — Pharmaceutical drugs	Lane #1 would include all products approved as pharmaceutical drugs by the FDA. Products in Lane #1 would be regulated by FDA, and sales would take place through the existing pharmaceutical model, both by prescription and over the counter.
Lane #2 — Ingested, inhaled, and topically applied THC products	Lane #2 would include all products that are not regulated through Lane #1 and contain more than a de minimis amount of THC. These products would be regulated in a manner similar to alcohol, with TTB, FDA, and the states all having appropriate regulatory roles. Most products

⁶ Sec. 511

	currently being sold through state adult-use or medical cannabis programs would be regulated through this lane.
Lane #3 — Ingested and inhaled cannabinoid products with low/no THC	Lane #3 would include orally consumed and inhaled cannabinoid products with minimal THC concentration. These products would be regulated by FDA in a manner similar to food and dietary supplements. Sales would be allowed anywhere food or dietary supplements are currently available without a special retail license requirement but subject to specific label requirements.
Lane #4 — Topically applied cannabinoid products with low/no THC	Lane #4 would include topically applied cannabinoid products with minimal THC concentration (e.g., topical lotions, creams, and balms). Like the products in Lane #3, these products would be regulated by FDA, and sales would be allowed where other cosmetics are sold without any special retail license.

Additionally, we recommend that the Sponsoring Offices confer with and defer to TTB as to the limited areas of jurisdiction that it believes should be provided to the FDA, and to existing state cannabis regulators who have learned crucial lessons in establishing these markets.

We also recommend that TTB enter into memorandums of understanding (MOUs) with the USDA regarding the cultivation and agricultural aspects of cannabis, and with the FDA on processing (synthesizing, extracting, isolating, etc.) of cannabis products. The CAO A directs the FDA to regulate cannabis farming⁷ but the USDA is better suited to regulate cannabis as the agricultural crop that it is.

Appropriations requests for various agencies involved in cannabis administration in order to ensure that those agencies have the necessary tools and resources to effectively carry out new responsibilities; and

We are still evaluating and calculating this information and look forward to presenting the Sponsoring Offices with this data at a later date.

Whether FDA regulation of cannabis products should be funded through a user fee program or other funding model.

⁷ Sec. 501, which creates Sec. 1105(c)(2) of the new Cannabis Products Section in the FFDCA.

NCIA favors a federal sales tax over user fees, as user fees tend to limit access to markets and create barriers to entry for minority-owned and small businesses. Many states have used a combination of fees and taxes to fund the regulatory programs, however, this has created barriers to entry that excludes individual participation. Other states restricted the fees to only that which is required to fund the regulatory program and no more, with the intention of preventing these fees from being used to fund other functions in the agency.

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 —

- The appropriate quantitative thresholds regarding contraband cannabis;
- The appropriate penalties for violations of anti-diversion provisions;
- Effective coordination between federal and state law enforcement and tax administrators relating to diverted cannabis;
- 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; and
- Rules relating to interstate commerce involving cannabis, including state-level taxation and interactions with state-level distribution systems.

The appropriate quantitative thresholds regarding contraband cannabis;

NCIA finds a ten pound limit for contraband cannabis as an acceptable weight threshold for processed cannabis flower. However, equivalent quantitative thresholds for cannabis products (e.g., cannabis-infused products and cannabis concentrates) also need to be set, so that neither overly-generous or overly-restrictive thresholds are unintentionally adopted for such products. NCIA urges that primary enforcement of personal possession limits remain with the states. To that end, where a state has legalized cannabis and established a higher personal possession limit than the federal standard, federal law enforcement should defer to state laws on personal possession limits by unlicensed parties.

We also encourage the Sponsoring Offices to consider cases where adult home-growers or qualified medical cannabis patients and collectives may store or transport without either a federal license or an express "authorization" from the state, where state law exempts certain persons from licensure requirements.

The appropriate penalties for violations of anti-diversion provisions;

We believe that the penalties included in CAO A regarding diversion may be too draconian, and actually antithetical to the purpose of the legislation. There should be provisions added relating to first-time offenders, and any penalties should be similar to, but no more penalizing than, alcohol or tobacco. We

support first-time offenders receiving a fine, with gradually escalating penalties for repeat offenders. Absent extenuating circumstances (e.g., unauthorized sales to minors, violence, association with organized criminal enterprises, etc.), these penalties should not be deemed felonies.

In order to avoid the perpetuation of the War on Drugs, a pre-trial option should be included in CAO, where education and/or treatment programs are offered and with successful completion, jail time can be avoided, as is already being done in California. In cases involving diversion to minors we also encourage the Sponsoring Offices to examine the inclusion of provisions that consider the actor's intentionality and/or knowledge of the recipient's age.

We further maintain that the true gifting of small amounts of cannabis and cannabis products among adults, in amounts under applicable federal thresholds, should not be considered criminal diversion under federal law, consistent with applicable laws in many legal cannabis states. Likewise, nothing in CAO should be interpreted to limit important trade practices such as the provision of trade samples.

Perhaps most importantly, we strongly believe that a delicate balance must be struck and maintained so that anti-diversion efforts do not essentially re-criminalize cannabis possession and non-commercial transfers by unlicensed actors. Diversion provisions should, at their core, incentivize and facilitate the transition from unregulated market activity to lawful commercial cannabis activity – not gratuitously assign criminal records or facilitate unequal enforcement.

Effective coordination between federal and state law enforcement and tax administrators relating to diverted cannabis;

The bulk of cannabis enforcement does and should occur at the state level and believes that federal legislation should look to provide resources to state enforcement efforts against significant bad actors which threaten the rule of law, public health, and safety. Civil violations should be addressed in a manner roughly similar to current practices for alcohol and tobacco diversion violations, whereby the Attorney General acts through the Administrator of the TTB. A way to do this would be to have the Administrator of TTB enter into a Memorandum of Understanding with the ATF to handle cannabis diversion crimes.

The federal government should immediately suspend funding and support for any collaboration with state and local law enforcement (including, but not limited to, the High Intensity Drug Trafficking Areas, or HIDTA, program) intended to enforce state cannabis laws.

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;

States have been effectively regulating cannabis commerce for well over a decade. Our position is that states ought to have primary regulatory authority over the use, possession, cultivation, processing, storing, testing (using federally set standards), sale, and intrastate transport of cannabis and cannabis products. Currently, all state cannabis programs prohibit interstate commerce of cannabis and cannabis

products, consistent with current federal law. As with other products entering interstate commerce, the federal government can set certain national standards to promote public health, safety, and uniformity.

The TTB is our recommended primary regulatory agency, and should be directed to create regulations for the permitting of all cannabis business entities and to enforce the minimum national standards for permitted businesses selling cannabis or cannabis products in interstate commerce. This should be done in a timeframe that allows the implementation of regulations to move quickly and efficiently but at the same time build in sufficiently long grace periods for state level operators to convert without disruption. The Sponsoring Offices should consider a framework by which state-legal cannabis entities can come into compliance with federal law more readily, by including a grace period for labeling and testing standards to allow these entities time to adjust their processes and avoid unnecessary costs.

One essential goal of the new federal regulatory system should be promoting efficient interstate markets for cannabis products. We urge the Sponsoring Offices to avoid “reinventing the wheel” and to coordinate with existing state regulators on areas that will need to be standardized such as minimum packaging and labeling standards. For example, many markets require cannabis product labels to carry a “universal symbol” to alert consumers that the package contains cannabis or cannabis products. States have adopted different symbols, however, to achieve this purpose. Given the challenges of attempting to include 50 different state “universal symbols” on cannabis packaging, NCIA urges the design of a federal symbol and a regulatory system that standardizes the many required regulatory elements of product packaging and labeling (including but not limited to universal symbols) across states.

Legislation should also codify well-recognized federal priorities (e.g., preventing unlicensed cannabis cultivation on public lands) by directing the TTB to create regulations consistent with those priorities. This will help to ensure that dangerous and illegal practices are not allowed to flourish as a result.

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

NCIA’s Diversity, Equity, and Inclusion Committee (DEIC) put forth a proposal on the topic of interstate commerce that we, as an organization, have not had the chance to fully analyze, but believe it is a valid option that is worth sharing for others to consider.

In order to facilitate interstate commerce, especially while states are in transition, NCIA’s DEIC recommends the TTB create a specific permit for interstate brokers. To do this, the Committee believes the Sponsoring Offices should consider amending the CAO to contemplate priority issuance of interstate broker permits to social equity-qualified operators. Learning from the municipal and state social equity programs, the DEIC seeks to propose amendments that help meet these objectives by:

- Clearly designating the primary agency regulating federal interstate commerce and collecting associated taxes and fees;
- Defining who qualifies as a social equity interstate commerce permit holder, using one or more of the following approaches:
 - Setting a minimum qualifications at the federal level;

- Allowing the federal government to adopt state definitions of who qualifies for social equity status
- Establishing an advisory board for federal regulatory agencies to define social equity qualifications, including income, arrest history, disproportionately impacted area(s) residency or heritage.
- Defining interstate broker permit types and privileges;
- Issuing interstate broker permits exclusively to qualified social equity operators for five years. Such an exclusivity period on licensing should be considered to ensure that communities have time to acquire the education and resources necessary to take advantage of this opportunity.

Historically, NCIA has been opposed to licensing caps and other limited licensing schemes, so the DEIC proposal to limit interstate broker permits for five years would constitute a departure from this precedent, but one worth seriously considering. As such, we expect that continued internal deliberations on the above proposal will occur between the DEIC and other NCIA stakeholders to further improve it. Additionally, the sheer volume of cannabis expected to enter interstate commerce may make it critical to grant interstate broker permits to a broader set of industry participants before the five-year sunset on exclusivity has occurred. In any case, NCIA will update the Sponsoring Offices on any subsequent amendments to, or adoption of, such proposal.

In addition to the request for comment above relating to trafficking in contraband cannabis, the Sponsoring Offices request comment on the retail sale age and quantity restrictions, including —

- Whether additional programs or resources are needed to aid states in enforcing a minimum age requirement or quantitative retail limitations,
- The interaction between state minimum age laws and use of medication containing cannabis by minors,
- Guidance on existing best practices by cannabis-legal states regarding minimum age enforcement,
- The interaction between state minimum age laws and limitations regarding non face-to-face transactions (discussed further in Sec. 501 of the draft), and
- The appropriate quantitative thresholds regarding the limit on retail sales of cannabis.

Whether additional programs or resources are needed to aid states in enforcing a minimum age requirement or quantitative retail limitations.

Age restrictions and retail sales location restrictions should be imposed and enforced by state and local governments. States are already prepared to handle minimum age requirements for alcohol and tobacco, and for cannabis sales in states where cannabis is already legal for adult-use, so additional programs and resources are not necessarily required. States are also prepared to address any quantitative limitations, so additional resources are not needed until and unless this becomes a problem.

The interaction between state minimum-age laws and use of medication containing cannabis by minors.

Countless Americans rely on state medical cannabis programs for their health and well-being, and do so under the professional guidance of their physician. NCIA believes it is crucial that this pathway to cannabis remains available. Accordingly, we support states setting minimum adult purchase ages that take federal guidance into consideration, but with an exception for those under the adult purchase age with a valid physician's recommendation in states that elect to create or maintain such a medical cannabis system. The Sponsoring Offices must, however, consider how this system can be made accessible to communities most affected by the War on Drugs, as certain communities lack adequate access to physicians, and to healthcare in general.

Guidance on existing best practices by cannabis-legal states regarding minimum age enforcement,

In the states that have reformed their cannabis laws and implemented an adult-use consumer marketplace, efforts have already been led by state regulatory bodies to enforce age requirements, including routine licensee verification of proof of age. In fact, the cannabis industry has been doing a great job with age-verification, even better than alcohol and tobacco in some cases.⁸

The interaction between state minimum-age laws and limitations regarding non face-to-face transactions (discussed further in Sec. 501 of the draft),

We ask that the Sponsoring Offices further define and specify what is meant by “means other than a direct, face-to-face exchange between a retailer and a consumer.” Currently, states with legal cannabis markets do not accommodate such transactions; even where home delivery of cannabis is contemplated under these state regulatory regimes, individual personnel of licensed retailers are charged with the task of verifying a consumer's identity and age. Such verification is still possible where cannabis is transferred from a retailer to a consumer by “means other than a direct, face-to-face exchange,” but would require actions by a third-party to execute. Verification methods would also vary depending upon the mode of transfer to a consumer — e.g., delivery by the USPS, common carriers like the UPS or FedEx, delivery via unmanned drones, or transactions occurring through automated vending machines — as well as the likelihood of potential diversion by such third party personnel themselves. As such, we welcome further clarification from the Sponsoring Officers and look forward to additional discussion on this point.

The appropriate quantitative thresholds regarding the limit on retail sales of cannabis.

States should continue to have the ability to develop regulations to limit sales, make decisions about the location of sales establishments, impose purchase limits, etc. This split system, with the states regulating retail and the federal government and the states regulating all of the upstream commerce, strikes an important balance between providing clarity for businesses while respecting state laws and local political conditions.

NCIA supports leaving any quantitative limitations at the retail level to the states, which are already successfully regulating and enforcing their own thresholds.

⁸ Compliance checks done in 2021 by the Washington State Liquor and Cannabis Board showed a 96 percent compliance rate for cannabis sales, while alcohol and tobacco each had a rate of 75 percent. “June 2021 Underage Sales Compliance Rates Show Improvements Needed,” *Bulletin*, Washington State Liquor and Cannabis Board, Aug 5, 2021, available at: <https://content.govdelivery.com/accounts/WALCB/bulletins/2eb8e1c>

In addition, the limitation of ten ounces of cannabis product is vague, which may lead to confusion for operators and regulators. The Sponsoring Offices' summary stipulates a limit of ten ounces, "or the equivalent amount of any cannabis derivative." We encourage the Sponsoring Offices to further detail and specify this topic in future drafts.

The Sponsoring Offices believe that cannabis research should be robustly funded and encouraged and that such research will provide significant public health and safety benefits. The Sponsoring Offices request comment on research, training, and prevention, including —

- The annual and long-term funding needs for such efforts;
- Whether programs can be designed to steer research dollars to Historically Black Colleges and Universities and other institutions associated with historically disadvantaged communities; and
- Additional areas that may benefit from research, including agriculture, environmental protection, worker health and safety, and other areas.

The annual and long-term funding needs for such efforts;

We are still evaluating and calculating this information and look forward to presenting the Sponsoring Offices with this data at a later date.

Whether programs can be designed to steer research dollars to Historically Black Colleges and Universities and other institutions associated with historically disadvantaged communities;

NCIA stands resolute in the belief that this can and should be done. There are [existing grant programs](#) that can be updated to specifically mention cannabis related research projects and curriculum expansion.

Additionally, provisions should be included that move beyond research to include industry training, development programs, and business courses. This would educate and empower a generation of students who may aspire to work in cannabis at the management/executive level. By proxy, training and hiring people who have an established social equity acumen would allow for these same students to reinvest in the community during their tenure as professionals and beyond.

Additional areas that may benefit from research, including agriculture, environmental protection, worker health and safety, and other areas.

For far too long, cannabis' status as a Schedule I controlled substance has severely hindered scientific research on the plant, and it has generally focused on solely potential negative aspects of consumption.⁹ There is currently no reporting infrastructure in place to gather data on the cannabis industry at the federal level due to the lack of NAICS (North American Industrial Classification System) codes. NAICS

⁹ National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Population Health and Public Health Practice; Committee on the Health Effects of Marijuana: An Evidence Review and Research Agenda. The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research. Washington (DC): National Academies Press (US); 2017 Jan 12.15, Challenges and Barriers in Conducting Cannabis Research. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK425757/>

codes are used to track the flow of goods and services throughout the economy and are used to facilitate international trade. NAICS codes are used by banks, BLS, Census, the IRS and the Bureau of Economic Analysis. NAICS codes are refreshed every five years, and without them, analysis of public safety, health, taxes and other areas will not be possible. Currently, the U.S. NAICS department has no plans to create separate NAICS codes for the cannabis industry. As a result, many of the reporting mandates contained in the CAO will not be possible until 2027.

Additional research should be conducted on:

- Therapeutic benefits and risks of cannabis for common conditions including, but not limited to, those experienced by veterans, including PTSD and chronic pain;
- Cannabis packaging requirements for consumer and child safety, as well as impact to the environment;
- Availability of inaccurately labeled and adulterated cannabis products;
- Effect of cannabinoids on immunological responses against bacterial or viral infections.

NCIA's "[*The Medicine of Cannabis: An Overview for Medical Professionals and Policymakers*](#)" white paper suggested prioritizing the following clinical research:

- Explore the impact of the endocannabinoid system on health and disease. Investigate the effect of cannabis on the endocannabinoid system, as well as the factors that influence individualized responses to cannabis such as genetics, environment, and concurrent disease conditions.
- Explore the extensive family of cannabis-derived molecules (including minor cannabinoids, terpenes, and flavonoids). Identify the clinical effects of these molecules when utilized individually, in combination, or in conjunction with pharmaceuticals.
- Explore the interactions of cannabis in patients with psychiatric conditions and behavioral disorders.
- Prioritize rigorous investigation (double blind, randomized, placebo-controlled studies) of existing pre-clinical and anecdotal data, including data suggesting positive clinical outcomes from cannabinoid use in cancer, palliative, and end-of-life care; chronic pain and the reduction of opioid abuse; mental and emotional health; seizures; and neurodegenerative brain diseases such as Alzheimer's and Parkinson's.

NCIA's Scientific Advisory Committee (SAC) also encourages additional research to be focused on:

- R&D – Human Health Risk Assessments for contaminants being tested for, so the regulatory action limits of biological and chemical contaminants are based on safety, toxicology, and exposure data. For example, the committee believes Human Health Risk Assessments for different pesticides in cannabis products including all consumption modes can be used to set appropriate pesticide tolerances that currently do not exist for cannabis products.
- R&D – Consumption data for all the types of cannabis products (e.g., oral, topical, inhalation, transdermal, and suppositories) and how often they are being consumed. Consumption data will directly inform Human Health Risk Assessments with exposure information.

The Sponsoring Offices are aware of additional proposals in the U.S. House of Representatives to expand the Opportunity Trust Fund programs to include SBA technical assistance and loans to socially and economically disadvantaged business owners outside of the cannabis industry. The Sponsoring Offices request comment on similar and additional Opportunity Trust Fund programs, including —

- Expansions similar to those proposed in the House bill to include SBA technical assistance and loans to socially and economically disadvantaged business owners outside of the cannabis industry; and
- Grants to certain business owners to offset administrative and compliance costs associated with the provisions of this Act.

Expansions similar to those proposed in the House bill to include SBA technical assistance and loans to socially and economically disadvantaged business owners outside of the cannabis industry; and

When considering SBA technical assistance and loans to socially and economically disadvantaged individuals, we encourage the Sponsoring Offices to refer back to the “Findings” contained in the CAO A and the overall intent of this legislation. The War on Drugs has had a devastating impact on certain communities, so money derived from those who are now benefiting from legalization should go back into those communities in general, and not solely to start cannabis businesses. Income cannot be the only determining factor, nor current census tract, to qualify for SBA assistance, as both factors may fail to capture the effects of gentrification in dispersing affected communities, or of the personal and professional development of individuals who may have been greatly impacted earlier in life but overcame such challenges despite all obstacles.

NCIA’s Diversity, Equity, and Inclusion Committee (DEIC) put forth a proposal on the topic that NCIA as an organization has not had the chance to fully analyze, but believes it is a valid option that is worth sharing for others to consider. The DEIC urges the Sponsoring Offices to consider the Restaurant Revitalization Fund, an SBA program, as a cautionary lesson. The implementation of this program, while perhaps well intentioned, failed to properly distribute funds due to injunctions from lawsuits that effectively froze the funds and kept those disadvantaged businesses from receiving any funds at all.¹⁰

The Committee believes the SBA is well suited to handle collaboration efforts to define the Minority Cannabis Business (MCB) certification program for both program providers on the educational side and for pre-qualifying federal funding for qualified applicants.

Grants to certain business owners to offset administrative and compliance costs associated with the provisions of this Act.

Many social equity applicants would significantly benefit from SBA assistance to offset the various costs incurred with compliance under the CAO A; particularly, many Black, Latino, and previously disadvantaged youth who might have ample business experience from unregulated and/or legacy cannabis markets, but only limited experience operating in highly regulated industries.

¹⁰ “Judges Halt Race and Gender Priority for Restaurant Relief Grants,” *The New York Times*, June 14, 2021. Available at: <https://www.nytimes.com/2021/06/14/business/restaurant-relief-fund-covid-sba.html>

Additionally, we feel strongly that the funds under such grants should be dispersed as “bridge financing” in anticipation of such costs, rather than after such costs have been incurred, in order to address the lack of access to private capital by most social equity operators.

The Sponsoring Offices request comment on cannabis excise tax provisions, including —

- The appropriate sales or production threshold for the small producer credit;
- Appropriate anti-double-benefit rules regarding the small producer credit, including rules related to substantial processing;
- 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;
- The appropriate entity and methodology for measuring the prevailing price of cannabis for purposes of setting annual rates of tax;
- Whether certain small producers should be eligible for quarterly or annual tax payments, similar to the rules applicable to small alcohol producers;
- 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;, and
- Additional conforming amendments to other parts of tax law, including the definition of tobacco rolling papers tubes and interactions with the alcohol and tobacco tax regimes.

The appropriate sales or production threshold for the small producer credit;

We are very concerned about the mechanics of a small producer credit threshold and believe that as currently written, this section could fail to benefit the very small businesses and equity operators the Sponsoring Offices are most seeking to benefit. To be clear, we wholeheartedly support tax benefits for small producers. However, attention must be made to ensure that the outcome of such benefits aligns with the Sponsoring Offices’ intention to assist small businesses and equity operators.

Paying taxes forward in exchange for a tax credit later should be eliminated, as it takes money out of operators hands and puts their businesses at risk. At its maximum, the 25% tax is the equivalent of a tax payment of \$208,333 every two weeks, \$104,168 of which is an overpayment of the tax liability in the amount of [\\$2.7 million per year](#). As a general example, with such a heavy tax burden, if a small business has a delay in accounts receivable and misses tax payments, this could put them in violation of this law.

We again emphasize that the legal cannabis market is directly competing with an unregulated and untaxed underground market. While taxes should be sufficient to cover the necessary regulatory structure, the rate should be kept reasonable to allow legal cannabis to compete against and minimize the unregulated market.

We encourage the Sponsoring Offices to apply a significantly lower level of taxation on smaller companies and recipients of social equity licenses. Having a single small business threshold ignores that

many businesses that operate with significantly less than others and who may have different needs than the larger businesses with which they're being categorized. The creation of a "craft" tier, similar to the qualifications for craft beer market, could help facilitate more small businesses and provide a viable economic framework that would encourage them to stay small and niche. With such designation, operators would pay taxes at a reduced level, and not be required to pay taxes at the higher level in exchange for a tax credit later.

NCIA's Diversity, Equity, and Inclusion Committee (DEIC) put forth a proposal on the topic that the NCIA as an organization has not had the chance to fully analyze, but believe it is a valid option that is worth sharing for others to consider. The DEIC urges the Sponsoring Offices to consider a tax deduction or exemption for owners who have been impacted by the War on Drugs. Taxing the communities the CAOAs seek to help seems antithetical if the goal is to reinvest revenue back into those communities. Options include creating a third or fourth tier with lower taxes for smaller entities, further helping small businesses. Another tier, also set at a significantly lower rate, could be set for qualifying minority-owned businesses. The DEIC proposes that this tier would be reserved for social equity licensed businesses, but would consider it being specifically applicable to minority-owned businesses to prevent potential injunctions.

Appropriate anti-double-benefit rules regarding the small producer credit, including rules related to substantial processing;

When looking at the sheer volume of rules in the CAOAs related to taxation, including the many questions that have been raised concerning how to craft them, the Sponsoring Offices may want to consider a system of taxation that most of the legal adult-use states already have in place — collecting excise taxes at the retail level as a percentage of the sales price. It would simplify the process at every level, starting with compliance by current cannabis operators, particularly small operators, whose businesses are already set up to operate that way in the state system. Avoiding complexity will assist this nascent industry to get off the ground, and not be another barrier to success for small operators or competitive advantage for the illicit market that pays no taxes, state or federal.

An excise tax at the retail level would also greatly simplify the implementation and enforcement of the rules at the agency level, which could have huge cost savings. Consumers would also benefit from this process as it would drive greater transparency in pricing. Taxation at the wholesale level would add audit complexity and require operators to set up additional systems for compliance and audit purposes. Given the complexity, it is anticipated that federal regulators would be required to set up additional rules and infrastructure to ensure compliance and adherence to taxation 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;

Taxes on cannabis should be crafted to promote efficient markets. Accordingly, NCIA does not support taxing products on a per-THC content basis, nor weight-based, but would rather see a percentage tax of the sales at the retail level.

NCIA’s Scientific Advisory Committee (SAC) proposed another option the NCIA as an organization has not had the chance to fully analyze, but believe it is a valid option that is worth sharing for others to consider. The SAC proposes that these products should not be taxed based on “THC” content, but instead be taxed on their total cannabinoid content.

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

NCIA is concerned with the proposed language relating to prevailing prices, which allows the federal government to set the price for taxation, rather than allowing for market forces to do so, resulting in multiple externalities. For instance, the setting of the price based on prior year’s prices would be an additional tax increase on producers in an environment of falling prices and would not allow for regional pricing differences. Conversely, in a period of price increases, the federal government risks missing out on potential tax revenues. A previous year prevailing price structure also provides a disincentive to drive cost reductions by operators and would potentially make U.S. based operators uncompetitive relative to low cost, internationally-based suppliers. We are concerned that a tax based on prevailing prices from the previous year would require significant expansion of federal bureaucracies, increase compliance and regulatory costs, and add significant audit complexities.

We are also concerned that the prevailing prices provisions may reward inefficient producers and eliminate the competitive pricing advantages of more efficient producers. This will have a negative environmental impact as it disincentivizes innovation that can reduce cannabis impact on the environment, as there would be no incentive to invest in or drive technology innovation [if the taxes do not change for a year.](#)

Why a prevailing price tax has its challenges - Federal government missing out on tax revenue			
Year	2021	2022	2023
Price scenario #1 - prices go up YoY	\$100.00	\$200.00	\$250.00
Tax based on prior year		\$25.00	\$50.00
Total price		\$225.00	\$300.00
Tax if based on current market		\$50.00	\$62.50
Price if based on current market		\$250.00	\$312.50
Comment: Federal government missing out on tax revenue			
Why a prevailing price tax has its challenges - Operators pay more taxes			
Year	2021	2022	2023
Price scenario #2 - prices go down YoY	\$ 100.00	\$ 75.00	\$ 50.00
Tax based on prior year	\$	\$ 25.00	\$ 50.00
Total price	\$	\$ 100.00	\$ 100.00
Tax if based on current market	\$	\$ 18.75	\$ 12.50
Price if based on current market	\$	\$ 93.75	\$ 62.50
Comment: Operator paying higher taxes in a period of declining prices, further hurting small businesses			

Source: Whitney Economics

Whether certain small producers should be eligible for quarterly or annual tax payments, similar to the rules applicable to small alcohol producers;

NCIA believes that the payment of tax every two weeks and resulting tax credit disproportionately impacts smaller businesses and would drive them out of the market, thereby encouraging further

consolidation. Bi-monthly (once every two weeks) payment of taxes to the U.S. Treasury would be an overly onerous burden faced by no other industry in the United States. Additionally, banks would not (and currently do not) have the compliance software infrastructure in place to support this.

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;

The Sponsoring Offices should take into consideration businesses currently operating in state legal cannabis systems who made the right decision to enter the legal marketplace, despite IRC 280E and despite the inability to access proper banking services. Consider tax credits to those businesses that have been paying exorbitant taxes due to 280E. Those who are in arrears specifically due to IRC 280E should not be prevented from obtaining a permit and should be allowed to start fresh without the tax burden created under prohibition. This helps keep legacy operators from potentially reverting back to the underground market because they are discouraged or financially unable to compete with brand new companies entering the cannabis industry without a pre-descheduling tax debt.

While IRC 280E has added a heavy tax burden uniquely to the state-legal cannabis industry, it turns out the proposed taxation scheme would be even more of a burden. According to our calculations, while examining the retail forecast through 2025, and applying the graduated tax model on wholesale, the cannabis industry would pay **more** in taxes over the next five years than under the existing 280E structure, both at the federal **and** state level. With the graduated wholesale excise tax combined with federal business taxes, the U.S. cannabis industry would pay [an estimated \\$1.1 billion in additional taxes](#) under the proposed bill when compared to the existing 280E structure.

Proposed Tax Structure	Industry Wide demand	2021	2022	2023	2024	2025	Total
	Retail revenue	\$25,000,000,000	\$29,661,758,310	\$33,017,999,667	\$39,704,267,742	\$44,922,223,109	
	Wholesale revenue	\$12,500,000,000	\$14,830,879,155	\$16,508,999,834	\$19,852,133,871	\$22,461,111,555	
	G&A expenses	\$7,500,000,000	\$8,898,527,493	\$9,905,399,900	\$11,911,280,323	\$13,476,666,933	
	Taxable corporate profit	\$5,000,000,000	\$5,932,351,662	\$6,603,599,933	\$7,940,853,548	\$8,984,444,622	
	Tax rate	10%	15%	20%	25%	25%	
	Tax	\$1,250,000,000	\$2,224,611,873	\$3,301,799,967	\$4,963,033,468	\$5,615,277,889	
0.21	Federal business tax	\$1,050,000,000	\$1,245,793,849	\$1,386,755,986	\$1,667,579,245	\$1,886,733,371	
		\$2,300,000,000	\$3,470,425,722	\$4,688,555,953	\$6,630,612,713	\$7,502,011,259	\$24,591,605,647
280e Tax Revenue Under Biden							
	Under 280E	2021	2022	2023	2024	2025	
Business Taxes Based on 21%	Retail	\$2,625,000,000	\$3,114,484,623	\$3,466,889,965	\$4,168,948,113	\$4,716,833,426	
	Supply Chain	\$787,500,000	\$934,345,387	\$1,040,066,990	\$1,250,684,434	\$1,415,050,028	
	Total	\$3,412,502,021	\$4,048,832,031	\$4,506,956,978	\$5,419,634,571	\$6,131,885,479	\$23,519,813,080
Business Taxes Based on 21%	Difference ---->	(\$1,112,502,021)	(\$578,406,309)	\$181,596,975	\$1,210,978,142	\$1,370,125,780	\$1,071,792,567
	Percentage	-32.6%	-14.3%	4.0%	22.3%	22.3%	

Source: Whitney Economics|

Moreover, the tax imposed on sales at the state level would also be increased since the selling price would be increased, so this is not only a federal tax increase but also a state one. Given the demand elasticity, the price increases will be borne mostly by operators and less so by the consumer, further eroding margins and driving out small businesses.

Example of state tax increase impact					
Current:			Proposed		Difference
Wholesale price	\$37.50		Wholesale price	\$37.50	
Federal excise tax @ 25%	\$0.00		Federal excise tax @ 25%	\$18.75	
Retail price	\$75.00		Retail price (2x wisle + Tax)	\$93.75	
Tax at 10%	\$7.50		Tax at 10%	\$9.38	\$1.88
Total Price to consumer	\$82.50		Total Price to consumer	\$103.13	\$20.63

Source: Whitney Economics

Additional conforming amendments to other parts of tax law, including the definition of tobacco rolling papers tubes and interactions with the alcohol and tobacco tax regimes.

NCIA is still evaluating and calculating this information and looks forward to presenting the Sponsoring Offices with this data at a later date.

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 —

- The appropriate balance to strike between reducing barriers to entry, while preventing illegal operations that may engage in cannabis diversion, tax evasion, or threaten public health and safety;
- Appropriate criteria for the waiver of a qualifying offense with respect to a permit application;
- Additional recommendations on streamlining the permitting and establishment process involving multiple government agencies; and
- The operation of the permitting transition rule for entities already in operation as well as those that may commence business shortly after enactment.

The appropriate balance to strike between reducing barriers to entry, while preventing unregulated operations that may engage in cannabis diversion, tax evasion, or threaten public health and safety;

We acknowledge that achieving balance in this instance may be difficult, however, the Sponsoring Offices should strive to create a regulatory structure that is not overly cumbersome to engage with. Additionally, unregulated actors must be aware of what penalties they may face if they continue to circumvent regulation and how they can participate in the legal industry. This may be done in various ways; for instance, offering pre-qualified financing upon state approval, access to free information that is forthcoming and easy to digest, and assistance in obtaining licensing and following compliance requirements.

It is vital to reign in the unregulated market by having a healthy, equitable legal adult-use market through rational regulations and fair taxation. Criminal enforcement should always be the last option for incentivizing compliance, as evidenced by the failure of enforcing prohibition, which the CAO's Findings

underscore. This includes establishing and maintaining tax rates at levels that don't incentivize individuals to circumvent the law.

It is critical that any restorative justice language include provisions for the expungement of not only non-violent federal cannabis-related convictions but also for withdrawal of the cannabis-related indictments that led to arrests, trials, and long drawn-out and expensive legal processes regardless of whether they may or may not have led to a conviction, and should be inclusive of the return of assets seized by the federal government from these people as a result of cannabis prohibition. Individuals should have the ability to petition the court seeking the expungement of all convictions that occurred as a result of cannabis prohibition (including certain "victimless" violent offenses).

Appropriate criteria for the waiver of a qualifying offense with respect to a permit application;

Individuals previously convicted of a cannabis-related felony should not be automatically disqualified from becoming a part of the legal industry, but should be considered based on the nature of the felony.

NCIA's Diversity, Equity, and Inclusion Committee (DEIC) put forth a proposal on the topic that the NCIA as an organization has not had the chance to fully analyze, but believe it is a valid option that is worth sharing for others to consider. The DEIC has proposed the following additional criteria for determining whether a conviction arising from an offense involving violence should be waived: If an offense was deemed "violent" (i.e. possession of a firearm while in possession of contraband), but there are no prior convictions for violent acts (i.e. there was no human/animal victim of a prior violent act), and there was no other violent crime committed during this offense other than the possession of a firearm, then the "offender" should still be allowed to participate in the legal industry.

The Committee also proposes that certain cannabis offenses in prohibition states could be waived for candidates applying for federal permits to operate in states with legal cannabis markets. Rather, offenders should be eligible for such waivers if they enroll in and attend remedial education classes for social equity applicants for federal permits.

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

NCIA believes that all producers, manufacturers, and wholesalers of products regulated under "Lane #2" as referenced earlier should have to receive a permit from TTB. Producers and manufacturers would also have to register with the FDA. Retail facilities would not have to register with the federal government and would be regulated solely at the state and local level. The permitting systems for cannabis products and for alcohol products under TTB would be very similar. In both cases, the state would set minimum conditions for persons eligible to hold these permits. There would be no limit on how many permits could be issued. Facilities would then be subject to safety inspections. All facilities producing or manufacturing cannabis products would also be required to register with FDA. This allows the FDA to know where human consumables are being produced. FDA would have the authority to inspect these facilities for compliance with the most directly applicable manufacturing requirements and to monitor products for

harmful adulterants. The law would clarify that no substance derived from the cannabis plant could be considered an adulterant for products sold through Lane #2.

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

NCIA strongly believes that efforts should be made to ensure that state systems and regulatory agencies are disrupted as little as possible by enactment. To that end, NCIA recommends extending the 90-day period outlined in the CAO. Consideration must also be made for social equity operators, as they are defined as having fewer resources than other operators, it would indicate that they would have fewer resources during this transition period as well. This could potentially be ameliorated with dedicated SBA assistance for these operators, among other options.

The Sponsoring Offices request comment on provisions relating to the operations of cannabis production facilities, including whether certain small cannabis producers should be exempt from the requirement to maintain a bond, similar to the exception in current law for small alcohol producers.

The Sponsoring Offices request comment on provisions relating to the operations of cannabis production facilities, including whether certain small cannabis producers should be exempt from the requirement to maintain a bond, similar to the exception in current law for small alcohol producers.

The Sponsoring Offices should make sure that requirements put in place are not too onerous or burdensome that they disproportionately harm small businesses and social equity operators. A bond requirement without an exception similar to that in current law for small alcohol producers would likely affect these businesses first and more severely, and could have other unintended consequences.

The 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.

The 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.

Americans deserve an efficient market for these products, especially in a market locked in fierce competition with an unregulated, untaxed competitor that sells untested products. NCIA urges the Sponsoring Offices to limit unnecessary burdens that would hinder the ability of the regulated market to compete with the illicit market such as premarket review. That is particularly the case for products that are currently sold in existing, regulated state cannabis markets. NCIA believes that a pre-market review process similar to that conducted for new tobacco products is completely inapplicable here. Beyond the many differences between the industries and products, it cannot be obscured that as a result of the federal prohibition of cannabis a division of products into “existing” and “new” is particularly ill-fitting. The delays and costs of a pre-market review would disproportionately impact small producers and would benefit the unregulated market above all.

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

- Criteria for Advisory Committee membership to ensure diverse viewpoints and policy priorities are properly represented;
- Roles and responsibilities of the Advisory Committee; and
- The role of the Advisory Committee in agency consultation, including the administrative and rulemaking process.

Criteria for Advisory Committee membership to ensure diverse viewpoints and policy priorities are properly represented;

NCIA is concerned that the Sponsoring Offices intent of the Advisory Committee may be difficult to achieve with only a dozen seats. We strongly encourage the Sponsoring Offices to appoint a multitude of industry voices, including licensees, equity operators, stakeholders representing communities most impacted by the War on Drugs, regulators, and subject matter experts.

Roles and responsibilities of the Advisory Committee; and

The Advisory Committee should have an explicit mission to advise on the creation of a well-functioning, efficient market that delivers the cannabis products the American public demands. Particularly in the early years of this new federal market, this mission must include advising on the potential impact of federal regulation on the unregulated market and the risks that its untaxed and untested products pose to the American public. At its core, the Advisory Committee should be composed of individuals that have significant experience in the cannabis industry and understand the concerns of the regulated market, as well as equity operators and others who understand the impact that the War on Drugs has had on communities of color.

The Advisory Committee should strive to:

- protect the public interest, including by setting best practices and uniform laws for testing, packaging and labeling;
- promote competitive markets;
- facilitate the fair and equitable treatment of cannabis consumers;
- promote the fair and equitable licensing of cannabis business entities;
- promote the reliability, solvency and financial solidity of cannabis business entities; and
- support and improve local and state regulation of cannabis by promoting best practices in the industry;
- ensure the intent as detailed in the Findings section of this bill to deliver and promote restorative justice is being upheld, and that included provisions are being implemented in a timely, effective, and accessible manner.

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

Consultation between agencies and the Advisory Committee outlined in the CAO should be mandatory during rulemaking. Moreover, agencies should give reasonable deference to the Advisory Committee, particularly during the initial drafting of rules.

With regard to Section 301 and the Opportunity Trust Fund and Small Business Administration Programs, the Advisory Committee should advise on who is eligible to participate in these programs, as well as to monitor and advise on the progress of them.

The Sponsoring Offices believe that robust enforcement against commercial bribery and uncompetitive practices is critical to ensure that small and independent cannabis businesses 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 —

- Ways to reduce compliance costs for small businesses while ensuring that market participants comply with necessary labeling and trade practice rules;
- 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;
- 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;
- Design of the track and trace regime to prevent cannabis diversion while minimizing compliance burdens; and
- Whether and how a single federal track and trace regime could replace the various, complex, state-based seed-to-sale tracking systems.

Ways to reduce compliance costs for small businesses while ensuring that market participants comply with necessary labeling and trade practice rules;

NCIA seeks efficient cannabis markets that will allow the regulated industry to meet the clear demand for these products from the American consumer. To that end, we urge the Sponsoring Offices to weigh the operation of existing state markets and their trade practice regulation. To the extent that new, costly, and complex trade practice rules are introduced, the burdens of revising business plans and ensuring compliance may cause market disruption, favoring the unregulated market and disproportionately harming small businesses.

For example, we strongly support efforts undertaken by multiple states and municipalities to promote social equity in the cannabis industry and to support regulated cannabis businesses operated by individuals disproportionately impacted by the War on Drugs.

We ask that the Sponsoring Offices avoid trade practice regulations that run the risk of prohibiting the types of support provided by larger cannabis operators to social equity operators. After all, we recognize that such regulation would undermine the Sponsoring Offices clear intention in crafting this legislation to help undo some of the harms of the War on Drugs. To achieve the goals that the Sponsoring Offices outlined in the CAO's Findings, it is imperative that language is incorporated to explicitly accommodate the ability of social equity qualified retailers to receive investments, assistance, and incubation from other established cannabis businesses. Such aid should not trigger the punitive application of Sections 304(a)(2)(A) through (F) of the FAA Act (as amended by Section 511 of the CAO). We recommend the following language be incorporated at the end of Section 304(a)(2):

“Complete ownership of a retail business by a non-retail cannabis business is not an interest which may result in a violation of section 304(a)(2) of the Act.

Less than complete ownership by a non-retail cannabis business in a retail business (which retail business otherwise qualifies as ‘a small business concern owned and controlled by socially and economically disadvantaged individuals’) where local or state regulations prohibit such non-retail cannabis business from taking a greater ownership stake in such retail business, constitutes neither an interest in a retail license nor an interest in retail property within the meaning of Sections 304(a)(2)(A) or (B) of the Act. Furthermore, it shall not be a violation of the Act for any non-retail cannabis business to provide the types of assistance set forth in Section 304(a)(2)(A), (B), (C), (E) or (F) to such retail business, provided such assistance is being provided pursuant to applicable state and/or local social equity ordinances.”

While it seems that Section 304(a)(2) of the Discussion Draft will not permit vertical integration (at least as it pertains to retailers and other parts of the supply chain), the TTB regulations at 27 CFR Sections [6.27](#) and [6.33](#) (implementing Sec. 205(b) of the FAA Act) include a carve out for vertically-integrated business enterprises if the retailer is a wholly-owned subsidiary. In order to clarify that the CAO will not force the break-up of existing vertically-integrated companies, NCIA urges the Sponsoring Offices to see the language of this TTB regulatory carve-out is adapted for the CAO and incorporated into the statute itself so that it is codified by Congress (rather than left to the TTB to promulgate later through rulemaking).

Additionally, imposing “Tied House” restrictions from the alcohol market to the cannabis market would cause unnecessary disruption of existing state-regulated marketplaces, without any clear need for such restrictions being defined and/or consideration of less restrictive means. The Tied House rules may make sense in the context of the national market for alcohol, given the evidence of the historical abuses that took place in the pre-prohibition alcohol industry. However, there is no historical precedent for a national cannabis market to refer to, making the application of Tied House rules a solution to a problem that never existed in cannabis.

The Sponsoring Offices should look at existing state regulatory regimes for addressing unfair trade practices that do not inadvertently harm the small businesses that the Sponsoring Offices are trying to protect.

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;

Similar to the above, NCIA believes that there are already sufficient rules in place at the state and federal level, and would not support additional rules on this subject at this time because of the potential for unforeseen deleterious consequences.

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;

NCIA urges the Sponsoring Offices to leverage the expertise and experience of the existing state adult-use markets, and to avoid the risks posed of an extended delay in promulgating rules at the federal level for these products. Accordingly, for core issues such as packaging, labeling, formulation, potency, and testing, we recommend that the Sponsoring Offices consult with key stakeholders in existing state adult-use markets (including their state regulators) and build these standards directly into the Bill. These provisions could sunset after an appropriate time and be replaced by rules promulgated by the lead federal regulator for cannabis. By taking this approach, however, Congress can resolve the significant uncertainty that may otherwise exist and can promote an efficient market that supplants the untested, untaxed, unregulated market as soon as possible.

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

NCIA's State Regulations Committee (SRC) recently opined on [track and trace systems](#) and made some excellent points.¹¹ We believe that the Sponsoring Offices should look to state track and trace programs to determine the most effective and least burdensome way to adequately regulate this new industry, as there have been many lessons learned in this arena at that level. Some areas to consider include:

- **Impact of System Failure:** The current centralized model seen in many states provides a single point of failure: if the system goes down, all licensee operations must stop operating entirely. In some cases, operators may manually record activity during a system failure, and then manually enter the activity when the system resumes. This introduces a high risk of human error. No backup system or alternative means of recording through the use of technology exists since the state relies on only one system.
- **Challenges with Scalability:** The history of performance with centralized track and trace systems demonstrates that there are significant challenges in scalability because of multiple system failures and shutdowns. The system would benefit from a more advanced track and trace

¹¹ "Re-thinking Cannabis Track and Trace Models - A Sustainable and Scalable Approach," NCIA, contributing authors Jennifer Gallerani, Tim Gunther, Elise Serbaroli, and Erin Fay, May 11, 2021. Available at: <https://thecannabisindustry.org/committee-blog-re-thinking-cannabis-track-and-trace-models-a-sustainable-and-scalable-approach/>

capability, specifically with its API (Application Programming Interface). Many times it is not the technology of the licensee system, but the technology design of the state-mandated systems.

- **Fiscal and Environmental Impacts:** Licensees are required to purchase plant and product tags from the single state-mandated vendor, which creates a fixed price system that is typically not in favor of a licensee. It is also creating a sustainability issue in the industry, as the plant and product tags are single-use. More operators are speaking up about the waste it is generating in our cannabis industry.

We believe that by leveraging the knowledge and experience the industry has gained over the last 20 years, we can incorporate best practices from other industries' and other markets' track and trace systems, and set regulators and operators up for success.

Whether and how a single federal track and trace regime could replace the various, complex, state-based seed-to-sale tracking systems.

For CAO to meet the Sponsoring Offices' goals, NCIA urges the avoidance of costly, redundant regulations. To that end, it is crucial that the industry not face multiple track and trace regimes for redundant track and trace systems. We support the TTB tracking cannabis products like it does alcohol and tobacco. By having duplicate reporting systems, cannabis operators will be required to have duplicate data entry, increasing the risk of non-compliance. In addition, multiple compliance systems increase the complexity of conducting interstate commerce.

The Sponsoring Offices request comment on additional, general, and unspecified items, including —

- The necessary funding levels and resources for agencies to carry out the purposes of this Act;
- The necessary amounts appropriated for grants to carry out the purposes of this Act;
- Consideration of transition rules and effective dates;
- Interactions with state and local laws;
- Interactions with international obligations and treaties;
- Interactions and additional considerations regarding hemp;
- Additional opportunities to expand restorative justice and access to capital for historically-disadvantaged entrepreneurs; and
- Any other areas of concern to stakeholders, federal agencies, members of Congress, and state and local regulators.

The necessary funding levels and resources for agencies to carry out the purposes of this Act;

We are still evaluating and calculating this information and look forward to presenting the Sponsoring Offices with this data at a later date.

The necessary amounts appropriated for grants to carry out the purposes of this Act;

We are still evaluating and calculating this information and look forward to presenting the Sponsoring Offices with this data at a later date.

Consideration of transition rules and effective dates;

It's imperative that implementation of regulations move quickly and efficiently, but at the same time, build in sufficiently long grace periods for state level operators to convert without disruption. Something to consider is that whatever rules and timelines are decided upon, social equity operators may require additional time and resources. SBA support could be considered for help with the transition.

In addition, banks require sufficient lead-time to change and deploy complicated compliance software.

The Treasury Department will also need time to develop processes to receive tax payments.

The proposed tax structure would require a complex auditing infrastructure requiring significant auditing processes. The government will then be required to create more rules to be developed to drive compliance, thereby making the system increasingly more costly. The initial auditing process would take time to implement.

Interactions with state and local laws;

As stated in previous comments, we urge the Sponsoring Offices to work with state and local authorities to make this process (or transition to an interstate market) as smooth as possible.

Interactions with international obligations and treaties;

NCIA recommends looking to fellow United Nations member states like Canada and Uruguay, as they have explored ways to reserve their rights to operate national cannabis markets while remaining party to international drug conventions.

NCIA also is concerned that the CAO does not appear to include relief for non-citizens already subjected to lifetime bans on admissibility by the U.S. Customs and Border Patrol (CBP). We propose inserting the following bracketed text into Sec. 313:

“(a) IN GENERAL. — For purposes of the immigration laws (as defined in section 101 of the Immigration and Nationality Act (8 U.S.C. 1101(a)), cannabis may not be considered a controlled substance, and an alien may not be denied [(or continue to be denied, as the case may be)] any benefit or protection under the immigration laws based on any event, including conduct, a finding, an admission, addiction or abuse, an arrest, a juvenile adjudication, or a conviction, relating to cannabis, regardless of whether the event occurred before, on, or after the effective date of this Act. [For the sake of clarity, this includes (but is not limited to) any determination of inadmissibility made by the United States Customs and Border Protection, on the basis of any individual alien’s investment in, or employment by, a state-licensed cannabis company, regardless of whether such

determination occurred before, on or after the effective date of this Act; any such determination shall be deemed void and of no further effect as of the effective date of this Act.]”

Interactions and additional considerations regarding hemp;

There are a few areas of this bill that attempt to address “hemp” and how it interacts with the legal adult-use cannabis market, but they only demonstrate the need to take a closer look at how hemp and cannabis are defined.

Section 511 creates the “Cannabis” section in the Federal Alcohol Administration Act, and in Section 303 would allow hemp that is grown under hemp regulations but “inadvertently” ends up testing higher than 0.3 percent Delta-9 THC, to be transferred to a cannabis operator permitted in the adult-use system. This could have the unintended consequence of incentivizing hemp cultivators to test above 0.3 percent Delta-9 THC and enter into the adult-use market, thus circumventing all the regulations under which cannabis cultivators operate up to that point, which tend to be under much higher standards than hemp cultivation.

NCIA’s Scientific Advisory Committee (SAC) has put forth a proposal that NCIA as an organization has not yet had the chance to fully analyze, but believes is worth at least sharing for others to consider. The SAC asserts that the ASTM International terminology as listed in Volume 15.10 for cannabis and hemp related terms be utilized. In particular, they recommend that the definitions in *ASTM D8245-19, Standard Guide for Disposal of Resin-Containing Cannabis Raw Materials and Downstream Products*, created by ASTM’s D37 Committee on Cannabis be used as a starting point.¹² These definitions do not specify a certain concentration of delta-9-tetrahydrocannabinol or Delta-9 THC and the federal definitions follow this example moving forward by removing the 0.3 percent Delta-9 THC concentration requirement from the definition of hemp.

The SAC proposes that the differentiation in the definitions of “hemp” and “cannabis” is focused on the intended usage of hemp or cannabis (the cannabis product). Specifically, differentiating between phytocannabinoid portions and non-cannabinoid portions of the plant. Phytocannabinoid portions of the plant would include all cannabis resin and chemical extracts. Non-cannabinoid portions would include stalks (hurd and bast fibers), spent material, roots, stems, and seeds.

The SAC proposes this change in definition because the phytocannabinoid containing portions of the “hemp plant” can be collected and concentrated into cannabis resin products. Those cannabis resin products can then be utilized to generate tetrahydrocannabinoids through chemical synthesis and conversion. Separating these items (phytocannabinoids and non-phytocannabinoid portions) from each other would help to eliminate confusion surrounding converted cannabis resin products and establish a defined framework for equal treatment of these compounds by the subsequent agencies.

The SAC feels it is important to note that there are definitions for terms such as cannabinoids, phytocannabinoids, cannabis resin, cannabis seed, cannabis stalk, resin cannabis, and resin cannabis

¹² Available at: <https://www.astm.org/Standards/D8245.htm>

product in *ASTM D8245-19, Standard Guide for Disposal of Resin-Containing Cannabis Raw Materials and Downstream Products*. These updated definitions should also be included in Section 502 for the changes to Section 201 of the FFDCA.

Additional opportunities to expand restorative justice and access to capital for historically-disadvantaged entrepreneurs; and

NCIA's Diversity, Equity, and Inclusion Committee (DEIC) has put forth a proposal that we, as an organization, have not yet had the chance to fully analyze, but believes is worth sharing for others to consider. The DEIC found that authorization and appropriation provisions located within CAOAs speaks to funds that have been allocated to Omnibus Crime Control and Safe Streets Act of 1968, however, maintain that this should be re-allocated in its entirety to the Cannabis Opportunity Program in order to more effectively facilitate repairing the harms for communities and individuals negatively affected by the enforcement of prohibition policies. Attention should be paid to ensure that the communities that have been harmed by the War on Drugs do not continue to be penalized via high barriers to entry and exorbitant licensing fees, essentially continuing the impact of those harms.

The DEIC understands the importance of state autonomy, but would also like to point out the unintended perpetuation of the War on Drugs that could result as an unintended consequence of protecting that autonomy. This could result from either states that legalize with unintended consequences, or from states that continue prohibition.

- If individual states impose potency caps that are not consistent with how some consumers actually use the products, this will likely drive efforts of diversion of products from states with high or no potency caps to states with stringent potency caps. The potential for continued targeting of communities that have been harmed by the War on Drugs will be exacerbated by potency caps.
- For states that choose to maintain prohibition, the War on Drugs will potentially continue in those states, with communities that have already been disproportionately impacted likely to continue to be disproportionately impacted. The Committee would like to suggest the Sponsoring Offices consider a way to respect state autonomy, while also ensuring that individuals in states with prohibition do not continue to be targeted in a discriminatory manner nor continue to be brought into the prison system. Search and seizure due to the presence of or the suspicion of the presence of cannabis should no longer be allowed in a country where it has been legalized.
- The Committee recommends an offer of one-time amnesty for legacy operators to bring products from the illicit market into the regulated market, with strong consumer protection guidelines in place for doing so. This would include genetics as well as existing inventory. The goal is to curb unregulated market activity by providing a pathway to the legal market, while also acknowledging the need for restorative justice.

The DEIC would also like to draw attention to participant eligibility in the Cannabis Opportunity Program and the Equitable Licensing Grant Program; the proposed language is limiting and does not consider those who were impacted and subsequently able to prosper in spite of that negative impact. This criteria is potentially limiting, essentially penalizes those who were able to ascend to a certain socioeconomic status, and does not take into account the amount of capital that is needed and required by most

licensing processes to engage in the industry. The Sponsoring Offices may look to examples such as Virginia, where the inclusion of graduation from HBCUs and other institutions of higher education is included in their newly-passed cannabis legalization bill.

Additionally, the DEIC notes Sec. 3052 (Authorization– Section 301 of the CAO) speaks to “re-entry” services being offered under the Community Reinvestment Grant Program. For those who’ve already lost access to federal benefits (housing, education grants, etc.), the Sponsoring Offices should consider the implementation of expungement and retribution provisions. Coordination with other government agencies must be taken into account, and restoration of services must be implemented. For justice to truly be considered restorative, return of – or credit for – assets seized and rights removed, such as Second Amendment rights, as a result of efforts of the War on Drugs must be considered.

The DEIC also believes that the Sponsoring Offices may want to consider additional language regarding loans to cannabis-related legitimate businesses and service providers. Specifically, the Offices should contemplate language pertaining to the awarding of loans with the inclusion of “minimum percentages” and “set-asides” as is already practiced with the [awarding of government contracts for minority- and women-owned businesses](#). Additionally, going beyond job training to job placement which creates more accountability and expands deliverables to be more tangible should also be considered.

Lastly, the DEIC believes that in order for the bill to truly address restorative justice, the term bears definition in official language so that the public at large understands the necessary steps and impact sought. Telling the true story of what harms were done will further solidify this.

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

The Sponsoring Offices should consider incorporating protections for designations of origin that identify specific geographic regions where cannabis is uniquely cultivated based on the terroir, including environmental factors like climate and soil. Some states, like California, are already doing this on their own, but producers and consumers alike would benefit from national standards and protections for these designations