COMMENTS OF THE GLOBAL ALLIANCE FOR CANNABIS COMMERCE REGARDING THE CANNABIS ADMINISTRATION AND OPPORTUNITY ACT DISCUSSION DRAFT

EXECUTIVE SUMMARY

The Global Alliance for Cannabis Commerce (GACC) appreciates the opportunity to comment on the "Cannabis Administration and Opportunity Act" (the CAOA or Discussion Draft) draft text. The Discussion Draft is an important and constructive step forward toward our shared goal of ending the criminalization of cannabis and establishing a safe, equitable, and productive cannabis market. To help advance that shared goal, we provide comments and recommendations addressing many of the Sponsoring Offices' specific requests for comment. For clarity, the headings and bullet points mirror the specific sections, subsections, and requests in the Discussion Draft.

We discuss our recommendations in greater detail below as well as in the Appendix, but we highlight the following key overarching recommendations:

- Expressly authorize introduction of existing state-lawful cannabis products into interstate commerce upon enactment.
  - Authorize interstate commerce of all state-lawful cannabis and cannabis products, including medical products, in cultivation, production, and distribution as of enactment of the CAOA, but subject to the laws of the states, including any prohibitions on cannabis products.
  - Subject all cannabis products that are not in production as of enactment of the CAOA and new productions of existing products to the CAOA's rules.
  - Reduce the deadline for FDA to issue final rules regulating non-in-person sales of cannabis and cannabis products from two years to one year.
  - Promote comity between state licenses and permits issued by the TTB.

- Further amend the FFDCA to authorize and facilitate the interstate commerce of cannabis foods, cosmetics, and "cannabis products."
  - Exclude cannabis from Sections 301(ll) and 201(s) of the FFDCA to enable the sale of cannabis foods.
  - Adopt a non-exhaustive statutory list of pre-approved structure-function like claims and permit the sale of cannabis products that make such claims to facilitate the sale of cannabis products.
  - Designate USDA as the primary regulator of raw cannabis.
  - Provide TTB primary labeling and product recall authority over cannabis products, and establish a uniform federal track-and-trace system that preempts state law.

- Fund programs and institutions that provide capital and technical assistance to socially and economically disadvantaged companies and direct the federal financial regulators to implement initiatives to support such businesses.
  - Support increased capital for minority depository institutions and further fund the Minority Business Development Agency.
  - Leverage the Community Reinvestment Act to encourage financial services for socially and economically disadvantaged cannabis businesses.

- Require the federal financial regulators to implement initiatives to encourage financial services for socially and economically disadvantaged cannabis businesses.
- Fund programs that provide technical, trade, and export assistance to socially and economically disadvantaged companies, and provide research funding for minority-serving post-secondary educational institutions.

We have not addressed every question in the Discussion Draft, but we would be pleased to consider and discuss any specific questions you have that we have not addressed. We look forward to discussing these comments and recommendations with you and continuing to work together on comprehensive federal cannabis reform.

GLOBAL ALLIANCE FOR CANNABIS COMMERCE

The Global Alliance for Cannabis Commerce is a 501(c)(6) cannabis trade organization and industry voice advising policymakers on sound policy solutions to support the legalization and regulation of the cultivation, manufacture, distribution, sale, and use of medical and adult-use cannabis products. GACC represents a major, multi-billion dollar cross-section of United States cannabis industry interests, from small businesses to single-state operators to international companies. We support a vibrant, diverse, equitable, competitive, and open cannabis industry for all Americans, but especially for Americans most harmed by the federal prohibition on cannabis.

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COMMENTS AND RECOMMENDATIONS

I. Decriminalization of Cannabis, Recognition of State Law Controlling Cannabis

a. Comments Addressing Removal from Controlled Substances Act, Transfer of Federal Agency Function

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

Recommendation:

1. **Exclude all seeds, not just sterilized seeds, from the definition of "cannabis" so the definition is consistent with international treaties.**
2. **Further clarify that any undiscovered or unidentified cannabinoids are included in the definition of cannabis.**

GACC supports the Discussion Draft's language moving the definition of "cannabis" from the Controlled Substances Act (CSA) into the Federal Food, Drug, and Cosmetics Act (FFDCA) because it helps ensure that the definition is clear and will be interpreted consistently with over fifty years of judicial understanding of the term. We also appreciate that the change may be intended to promote consistency between federal cannabis regulation and cannabis regulation under international treaties.[1] However, to ensure such consistency, GACC recommends that the definition of cannabis exclude all seeds, not exclusively sterilized seeds.

The CAOA's definition of cannabis includes all cannabis seed (except for sterilized seeds) as cannabis,[2] whereas international treaties exclude all seeds as long as they are not actually germinated (germinated seeds are considered plants under international treaties). For instance, the 1961 Narcotics Convention treaty defines cannabis as "the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated."[3] The CSA included non-sterilized seeds in the definition of cannabis to further limit production. Accordingly, including non-germinated seeds in the definition of cannabis is inconsistent with the international treaties and does not help further the Sponsoring Offices' goal of reforming federal prohibitions on cannabis.

The more restrictive definition will harm U.S. farmers in particular by raising barriers to entry into the lawful global market for non-sterilized cannabis seeds. Currently, there is a lawful global

[1] Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol; Convention on Psychotropic Substances of 1971; United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988.

[2] Cannabis would be defined to include "the seeds thereof…every compound, manufacture, salt, derivative, mixture, or preparation of…its seeds….[**but not] the sterilized seed of such plant which is incapable of germination**."[2] (emphasis added).

[3] Single Convention on Narcotic Drugs of 1961, Art. I, Sec. 1(b).

marketplace for non-sterilized cannabis seeds to produce crops for industrial and medical purposes because international treaties do not include non-germinated seeds in the definition of cannabis. Including non-germinated cannabis seeds within the meaning of cannabis would raise barriers to agricultural production of cannabis crops in the U.S. by subjecting such production to primary FDA oversight rather than primary oversight by USDA. We recommend reconciling the CAOA's definition of cannabis with international treaties' definition so U.S. farmers can more effectively compete in the global market for non-sterilized cannabis seeds and to minimize inconsistencies between federal law and the international treaties to which the U.S. is a party.

We also recommend including a parenthetical within the definition of cannabis specifying that unidentified and undiscovered cannabinoids within cannabis sativa L. are within the definition of cannabis. Delta-9 THC was first identified in 1964. Since then, more than 100 cannabinoids have been identified but many cannabinoids and associated synergistic compounds have yet to be discovered or identified. As innovations in separation and analytical techniques are currently being developed to further differentiate the total number of cannabinoids, there could be more undifferentiated cannabinoids that need to clearly be classified under the definition cannabis. In fact, many cannabinoids and associated synergistic compounds that have yet to be discovered, likely already exist in the heavily hybridized plants used for medical cannabis production. Accordingly, specifying expressly that such cannabinoids fall within the definition of cannabis will help preclude any confusion.

We propose the following amendment to make this change:

(ss)(1)(A) The term 'cannabis' means—

''(i) all parts of the plant Cannabis sativa L., whether growing or not and including any germinated seeds;

~~''(ii) the seeds thereof;~~

''(iii) the resin extracted from any part of such plant; and

''(iv) every compound, manufacture, salt, derivative, mixture, or preparation (including any unidentified or undiscovered cannabinoid) of such plant, ~~its seeds~~ or its resin.

''(B) The term 'cannabis' does not include—

''(i) hemp, as defined in section 297A of the Agricultural Marketing Act of 1946; or

''(ii) the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the ~~sterilized~~ seed of such plant unless it is germinated ~~which is incapable of germination~~.

ii. The appropriate way to measure the potency of cannabis and cannabis products

Recommendation:

1. **Require use of testing standards that are widely accepted by the scientific community and are available at a reasonable cost.**
2. **Require disclosure of Total THC.**

To promote accuracy and consistency of testing across cannabis and cannabis products, we recommend greater specificity regarding the appropriate methods by which the potency of cannabis and cannabis products are tested as well as more details on the appropriate measurement of potency.

Methodology: The CAOA should require the use of protocols that (a) meet widely accepted laboratory testing standards established by the scientific community and (b) are widely available at reasonable costs so as not to become a *de facto* barrier to entry for small and/or socially and economically disadvantaged businesses. The experience of the hemp industry with the USDA mandating that analytical labs testing hemp comply with the Drug Enforcement Agency's laboratory standard requirements demonstrates the need to thoughtfully consider small businesses' ability to participate.[4]

One set of laboratory testing protocols that meets these criteria is ISO/IEC 17025.[5] This standard enables laboratories operating in the government, industry, university or other contexts to demonstrate that they operate competently and generate valid results. Moreover, testing results by laboratories that meet this standard are generally accepted both within the United States and by other nations without further testing.

One way to clearly require such standards and provide FDA flexibility is to amend the FFDCA's existing provisions regarding the recognition of testing standards to apply to cannabis products. For instance, the United States Pharmacopeia and National Formulary (USP/NF) is the standard for testing of drugs and is incorporated into the FFDCA's definition of "drug." Moreover, Section 514(c) of the FFDCA contains a process for FDA to "recognize" a "nationally or internationally recognized standard." FDA uses this provision extensively to recognize standards that device manufacturers use to demonstrate compliance with preapproval requirement. The CAOA could include a provision similar to Section 514(c) and further specify that laboratories must use any

[4] The requirements to become a DEA-registered lab are onerous. As a result, very few labs are DEA-registered and thus authorized to conduct testing on hemp. Although legal risks surrounding inadvertent testing of cannabis, rather than hemp, are another reason why many labs have decided not to become DEA-registered, we believe the registration requirements are a material factor. For further discussion, see Ashley Brandt, "Win for hemp producers," LIBATION LAW BLOG (Feb. 28, 2020), available at https://libationlawblog.com/2020/02/28/win-for-hemp-producers-usda-backs-off-requiring-hemp-testing-at-only-dea-registered-labs-and-certain-hemp-disposal-requirements-it-had-made-in-the-interim-final-rule-on-the-domestic-hemp-production-p/ and Justin M. L. Stern, USDA Delays DEA Registration Requirement for Hemp Testing Laboratories, Duane Morris (Feb. 27, 2021), https://blogs.duanemorris.com/cannabis/2020/02/27/usda-delays-dea-registration-requirement-for-hemp-testing-laboratories/.

[5] https://www.iso.org/ISO-IEC-17025-testing-and-calibration-laboratories.html.

standard for laboratory testing that FDA recognizes under this new provision, unless the laboratory is using an appropriate standard previously recognized by FDA. Currently, FDA recognizes the ISO/IEC 17025 standard in its cooperative agreement program with states so, under this option, cannabis testing laboratories could use whatever new standard FDA recognizes or ISO/IEC 17025, unless FDA determined otherwise.[6]

Most of the domestic and international cannabis industry, and most state laboratory systems that conduct cannabis testing comply with this this standard. However, by further requiring the use of such standards, the CAOA could further promote safe cannabis products for an informed consuming public.

Potency: We propose including a required measurement of "Total THC". This measurement would include (and describe in isolation) all forms of intoxicating THC (and any other intoxicating cannabinoid) in the plant, but would exclude non-intoxicating forms of THC (and other non-intoxicating cannabinoids). For example, it is recognized that delta-9 and delta-8 THC are both intoxicating cannabinoids present in cannabis. Accordingly, both should be included in the measurement of THC. THC-A, in contrast, is a precursor acid that has no intoxicating effect and, thus, should not be included in a measurement of THC.[7] The label for cannabis and cannabis products, therefore, should include a measurement of Total THC representing a combined total percentage of the delta-8 and delta-9 THC in the product, as well as those individual percentages, but not THC-A.

We also recommend that the statute provide the FDA the discretion to issue rules determining whether additional isomers of THC are intoxicating and to define the meaning of intoxicating in order to give consumers and the industry greater clarity. As other cannabinoids are discovered and identified, FDA should issues similar rules, or require any cannabinoid that meets the definition of intoxicating to be included in the Total THC disclosure.

iii. The interaction between the definition of "cannabis" and the definition of "hemp"

Recommendation:

1. **Maintain the proposed language regarding hemp.**

GACC agrees that the definitions of cannabis and industrial hemp should remain differentiated.

iv. The interaction between the definition of "cannabis," "cannabis product," and FFDCA drugs containing cannabis

Recommendation:

1. **Amend the FFDCA to permit the sale of cannabis food and cosmetic products.**
2. **Adopt a non-exhaustive statutory list of pre-approved structure-function like claims.**

[6] https://www.fda.gov/media/107725/download.
[7] See https://www.leafly.com/news/cannabis-101/what-is-thca-and-what-are-the-benefits-of-this-cannabinoid.

3. **Clarify that cannabis product delivery systems cam include the natural flavors of cannabis.**
4. **Allow the export of cannabis products that contain alcohol, nicotine, and tobacco.**

The CAOA, as currently written, would continue the current prohibition on the interstate sale or distribution of existing cannabis food products because it does not address the FFDCA's prohibition on including drug active ingredients, such as THC, in food. Accordingly, the CAOA would prohibit the sale of cannabis food products that comply with the laws of the state in which they are sold and enable the FDA and other agencies to sanction businesses that produce, distribute, and sell such products. Moreover, many existing and new cannabis businesses would face significant challenges in accessing bank and other financial services because they would be unable to represent that they operate in compliance with federal law.

To address this issue, we recommend including language amending the FFDCA to allow for the introduction of food products that contain cannabis into interstate commerce. To do so, the Discussion Draft can include specific exceptions for cannabis and cannabis products in Sections 301(ll) and 201(s) of the FFDCA to permit cannabis to be used in food at acceptable levels without the requirement for an FDA-approved food additive petition. This amendment should be applied retroactively as well to cover existing cannabis food products that are produced, distributed, and sold in compliance with state law.

Additionally, the FFDCA's cosmetic provisions should be amended to ensure that a cosmetic is not deemed unlawful merely because it contains "cannabis" as an ingredient, and again, authorize the continue manufacture, distribution, and sale of these products to the extent they are legal under current state law. These changes will prevent a major disruption to the existing cannabis market that services millions of consumers every day.

To provide further clarity as to what claims cannabis products may make, we recommend that the CAOA a non-exhaustive statutory list of pre-approved acceptable "structure-function like" claims that may be made on cannabis products in interstate commerce. Cannabis and cannabis extract were regulated as medical products in interstate commerce from 1850 to 1936 under the *U.S. Pharmacopeia* and every predecessor statute of the FFDCA until the passage of the 1937 Marihuana Tax Act and 1938 FFDCA itself. There are well-understood historical uses of the products that can be listed as structure-function-type claims (e.g., helps maintain a healthy digestive system; helps elevate mood; helps maintain a healthy sleep pattern) without detriment to FDA's authority or scientific integrity. This proposal is critical for small businesses. As we learned from applying similar statutory language to vaporizer products with the Tobacco Control Act, small businesses struggle to afford studies to substantiate claims. The Tobacco Control Act resulted in the substantial and immediate concentration of the market by a few large producers because of the compliance burdens it raised.

We also recommend that the prohibition on "flavored electronic cannabis product delivery systems" under Section 1109 of the Discussion Draft be slightly amended to avoid any confusion between the ban on adding natural characterizing flavors and the parenthetical allowing for "cannabis" to retain its natural characterizing flavor. The Discussion Draft currently states that "any flavored electronic cannabis product delivery system shall not contain an artificial or natural

flavor *(other than cannabis)* that is a characterizing flavor…" (emphasis added). Accordingly, we understand the text to allow a flavored electronic cannabis product delivery system to contain natural flavors that "are cannabis." However, cannabis, like wine, contains many natural flavors and terpenes (aromatic compounds), including some that may also be listed as examples of prohibited natural flavors that are a characterizing flavor. To avoid any confusion, we recommend further clarifying the parenthetical.

We propose the following amendment to make this change:

> "(a) IN GENERAL.—Any flavored electronic cannabis product delivery system shall not contain an artificial or natural flavor (other than cannabis, including its naturally occurring flavors) that is a characterizing flavor, including menthol, mint, mango, strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee.

Finally, we recommend that the prohibition on the sale or distribution of cannabis products that contain alcohol, nicotine, or caffeine be modified to allow for the export of such products to other countries where such products are legal. Numerous foreign markets allow for or will allow for such products. The Discussion Draft should not prohibit U.S. cannabis companies from competing in those markets. The track-and-trace regulations and enforcement by the Treasury Department, as well as the other anti-diversion measures included in the CAOA, are adequate to address diversion, so such products can be exported to foreign markets safely. Competing in those markets will generate tax revenues and create jobs in the U.S.

To allow for the export of such products, the current prohibition in Section 1111 should be deleted and Sections 1102 and 1103 (which address adulterated and mislabeled cannabis products, respectively) should be amended to include cannabis products that contain alcohol, tobacco, or caffeine. This change would allow such products to be exported pursuant to Section 801(e)(1) of the FFDCA, provided the other provisions of that section are met.

v. The appropriate classification and regulation of synthetically-derived THC

Recommendation:

1. **Maintain FDA's current regulation of synthetic THC.**

We believe that the current regulatory structure for synthetic THC should remain in place. Currently, synthetic THC is an approved drug by FDA and is subject to the various FFDCA and FDA rules governing approved drugs.

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

Recommendation:

1. **The descheduling of cannabis should be effectuated in the statute, and the Attorney General's role should be the ministerial correction of relevant regulations.**
2. **Retroactivity of descheduling cannabis should apply to administrative enforcement, non-violent criminal activity and forfeiture actions as well.**

To avoid confusion, delay, and any inconsistency in effective dates and their application to prior offenses, we recommend that the act of descheduling cannabis be executed in the statute (as the Sponsoring Offices have done) and that the Attorney General's role be limited to the ministerial role of conforming outdated rules to the CAOA. We believe that upon enactment, any regulation that is inconsistent with the CAOA, including with respect to the status of cannabis as a controlled substance, would be void automatically as a matter of law. Accordingly, requiring the Attorney General to conduct a rulemaking to deschedule cannabis would thus be result in unnecessary confusion and delay. Instead, the Attorney General can execute whatever ministerial functions are needed to remove the regulations invalidated by the CAOA. This process can and should be executed quickly after enactment of the CAOA.

We propose the following amendment to make this change:

> REMOVAL FROM SCHEDULE.—Not later than 30 days after the date of the enactment of this Act, the Attorney General shall administratively revise the current regulations at 21 C.F.R.1308.11 and _____ rulemaking ~~under section 201(a)(2) of the Controlled Substances Act (21 U.S.C. 811(a)(2))~~ removing marihuana and tetrahydrocannabinols from the schedules of controlled substances to clarify that ~~F~~for the purposes of the Controlled Substances Act and related statutes, in light of the Cannabis Administration and Opportunity Act, marihuana and tetrahydrocannabinols ~~shall~~ are each ~~be~~ deemed to be a drug or other substance that does not meet the requirements for inclusion in any schedule. ~~A rulemaking under this paragraph shall be considered to have taken effect as of the date of enactment of this Act~~ Such administrative rulemaking amendments shall not be subject to the requirements of Administrative Procedures Act other than notice of changes in the Federal Register. Any regulations inconsistent with this Act shall be deemed invalid on the date of enactment of this Act for all purposes including but not limited to any offense committed, case pending, conviction entered, and, in the case of a juvenile, any offense committed, case pending, and adjudication of juvenile delinquency entered before, on, or after the date of enactment of this Act.

Additionally, we note that the Discussion Draft's retroactivity provisions do not apply to administrative enforcement, related non-violent criminal activity, or forfeiture actions. If the retroactivity provisions do not apply to these areas, there will be substantial risk of legal liability for employees, consumers, and businesses.

vii. 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

Recommendation:

1. **Designate USDA as the primary regulator of raw cannabis.**
2. **Provide TTB primary labeling and product recall authority over cannabis products.**

First, we believe it would be constructive to designate the Department of Agriculture (USDA), rather than FDA, as the primary regulator of raw cannabis that has not yet been made into a finished good or delivered at the facility of a producer. As written, the Discussion Draft authorizes FDA to regulate raw cannabis but we believe primary USDA oversight would be more efficient and consistent with the regulatory framework for other crops. Folding raw cannabis into the existing crop management regulatory framework would be efficient and facilitate the cannabis cultivation market quickly under an experienced regulator. Moreover, we recommend explicit statutory language designating raw cannabis as a full federal crop so that it is subject to similar rules and protections as other crops.

Second, we recommend that TTB have primary responsibility for labeling requirements and recall authority. With respect to labeling, TTB is well suited to this role given its authority over alcohol labeling. With respect to product recall, there will be efficiency gains because the CAOA designates ATF and TTB as the administrators of the track-and track system. The track-and-trace system will be critical to facilitating recalls of non-conforming cannabis products. TTB, thus, is best positioned to direct recalls. Moreover, TTB has had primary authority over seeking and monitoring voluntary recalls of alcoholic beverages for decades (and it consults with FDA) so it has the requisite experience.

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

Recommendation:

1. **Do not impose a user fee; use excise taxes and other revenues to fund FDA's oversight.**

A user-fee model would disadvantage small businesses by significantly increasing the cost of developing and introducing new products. Large businesses can absorb these costs but small businesses will lose material margin that they need to compete. To avoid this inadvertently inequitable outcome, we recommend that Congress appropriate funds to FDA to exercise its cannabis regulatory authority and impose an excise tax rate comparable to the rates proposed in the "Marijuana Opportunity and Reinvestment Act". To the extent any user or application fees are imposed, they should be low to enable small businesses to compete.

b. Recognition of State Law Controlling Cannabis, Establishment of Public Safety and Enforcement.

i. The appropriate quantitative thresholds regarding contraband cannabis

Recommendation:

1. **Maintain the diversion limit at 10 pounds.**

We share the Sponsoring Offices' concerns regarding risk of diversion of lawful cannabis and cannabis products. Given the current and projected size of the US and global cannabis market, we are agree that the proposed diversion limit of 10 lbs is appropriate to meet our shared goal.

ii. The appropriate penalties for violations of anti-diversion provisions

Recommendation:

1. **Remove criminal penalties and replace them with significant civil fines.**

GACC opposes criminal penalties for cannabis diversion. Our board members have personally suffered from the criminalization of cannabis and thus oppose any vestige of the War on Drugs. Instead, civil penalties would appropriate and effective to punishing and deterring diversion. Specifically, a civil fine equivalent to the prevailing market value of the diverted cannabis or cannabis product, as applicable (based on the Treasury Department's determination of the prevailing price), plus a triple excise tax due to the Treasury would be effective.

iii. 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

Recommendations:

1. **Reduce the deadlines by which FDA and TTB issue their rules.**
2. **Provide robust judicial remedies to enforce the rulemaking deadlines.**
3. **Promote comity between state licenses and permits issued by the TTB.**

The federal government should establish as much interstate consistency for product standards, labeling requirements, and other regulation as possible by creating federal baselines that the states may choose to exceed. Moreover, it should authorize and facilitate interstate commerce as quickly as possible. Doing so will promote a competitive, diverse, and consumer-driven market in the U.S. and enable U.S. businesses to compete in the global cannabis market. Furthermore, a federal baseline in labeling, product standards, and interstate commercial regulation will help small businesses thrive in a manner similar to the craft beer revolution.

We support the Discussion Draft's inclusion of the Webb-Kenyon and Wilson Acts, fully in line with recent Supreme Court precedent in *Tennessee Wine and Spirits*, and the requirement that rules governing the promotion, sale, and distribution of cannabis products through e-commerce (and similar, non-in-person channels) be implemented by a specified time (two years in the Discussion Draft).

To build upon this excellent framework, we suggest the following:

First, reduce the deadline for issuing final rules regulating non-in-person sales of cannabis and cannabis products from two years to one year. We believe that the regulators can issue appropriate rules within one year. Moreover, we are concerned that a two year delay will primarily disadvantage small businesses and will significantly undermine their ability to compete in the long-term. Small businesses need to be able to sell their products to consumers all over the country in order to generate the revenues and customer base needed to survive and compete with large incumbent multistate operators who already dominate markets within states. Access to ecommerce is critical reaching their consumers. A two year delay will further weaken their position to the benefit of large incumbents.

Second, ensure robust judicial remedies are available under both the Administrative Procedure Act and the Mandamus Act to require the agencies to issue their rules quickly if they miss their deadlines. If rulemaking takes longer than the anticipated timelines, small businesses will suffer the most, as evidenced by the lack of FDA rulemaking in the hemp/CBD space. The Discussion Draft already includes partial remedies but we urge the more comprehensive and efficient remedies that apply to FDA and TTB. APA litigation for undue delay can take years, so the most cost-effective and time-efficient remedy is authorizing relief under the Mandamus Act with a "shall issue" directive to the judicial official upon demonstration of delay past deadlines. This tool will give small businesses access to an efficient judicial remedy in addition to ensuring the agencies create a marketplace consistent with congressional intent in a timely manner. Moreover the Discussion Draft should expressly provide payment of legal fees to any party that prevails in a mandamus suit, since it is small businesses that are most likely to need this relief.

Third, ensure comity of state licenses and grandfather existing state licenses. A state-licensed cannabis company that engages in the activities for which a permit from the TTB would be required should be entitled to such a permit as a matter of law and be issued upon proof of a valid license. Such comity will help ensure that such entities (especially wholesalers) are incentivized to compete in interstate commerce, thereby facilitating interstate trade; minimizing disruption to existing markets; and lowering costs for existing businesses, especially small businesses. Doing so would also respect states' rights to regulate cannabis as they see fit (for instance, a license could not distribute cannabis in a state where doing so is illegal). It also would vastly speed up the federal permitting process.

c. Establishing Minimum Age, Restriction on Retail Sale

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

Recommendation:

1. **Explicitly clarify that any age limit for purchase or use of cannabis products does not apply to patients purchasing or using products pursuant to a doctor's recommendation.**

We agree with the Sponsoring Offices that the minimum age to purchase adult use cannabis products should be 21. However, we urge the Sponsoring Offices to revise the Discussion Draft to use federal funding incentives to persuade states to adopt a 21 adult-use age limit (as is done with highway funding and the age for alcohol consumption) rather than mandate a 21 year old age requirement. We believe this funding model is tried-and-true, and is constitutional.

We also believe it is important to explicitly protect patients, including patients under the age of 21, to use medical cannabis products under advisement of their doctor. Accordingly, we recommend that the CAOA include an explicit provision authorizing persons of any age to purchase and use medical cannabis products if recommended by a doctor, and preventing the federal government from withholding or clawbacking any federal funding to states that do not impose an age cap on medical cannabis usage.

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

Recommendation:

1. **Limit retail sales to 5 pounds.**

The retail sale limit to a single consumer or patient in a specific transaction should be increased to 5 lbs. Many medical patients, particularly the ones suffering from the most severe illnesses, purchase product in bulk and in excess of 10 ounces. Many states, such as Oregon, recognize this issue and thus limit retail sales to significantly large amounts, such as 72 ounces of medical cannabinoid extract, or 42 ounces (as in Washington). With respect to adult use products, we believe that 5 lbs is a reasonable threshold to enable consumers to make decisions that are best for them.

II. Research, Training and Prevention

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

Recommendation:

1. **Provide additional funding to support undergraduate and graduate programs in a wide-range of cannabis studies at HBCUs and other minority-serving institutions.**

We suggest that the Sponsoring Offices consider amendments to 20 U.S.C. § 1067q to include funding for cannabis research and education for historically black colleges and universities (HBCU) as well as all minority-serving institutions (MSI) included in Section 1067q. To do so effectively, we recommend appropriating additional amounts to the annual funds allocated under this provision. Funding should be focused on developing wide-ranging curricula including undergraduate and graduate courses focused on entrepreneurship, agriculture, marketing, finance, biotechnology, health, etc.

We understand the Minority Cannabis Business Association, among other groups, are drafting recommendations for facilitating such research investment. We look forward to working with and supporting their recommendations.

III. Restorative Justice and Opportunity Programs

a. *Opportunity Trust Fund Programs and Small Business Administration Programs*

i. 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.

Recommendation:

1. **Provide funding for large scale loans or seed capital to Minority Cannabis Companies and increase funding for the Minority Business Development Agency.**

We support the CAOA's provisions extending access to SBA loans, including the microloan program, to cannabis businesses. However, these programs, especially the microloan program, may not be sufficient to meet minority entrepreneurs' need for capital. Accordingly, we support efforts to create programs that give minority entrepreneurs seed capital to start a business or allow them to tap into additional dollars to scale an existing company.

Additionally, we support funding for the Minority Business Development Agency (MBDA) and MBDA business centers to offer industry-focused services that enable minority businesses to tap into sources of capital, contracts, and markets. We also support funding for state Small Business Development Centers to assist minority companies in their states. These programs can help make programs designed to connect minority entrepreneurs to seed capital more effective.

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

Recommendation:

1. **Provide funding to state and local governments for technical assistance to socially and economically disadvantaged cannabis businesses, especially those located in federally**

recognized HUBZones, Empowerment Zones, Enterprise Zones, and Opportunity Zones.

We are supportive of expanding the Opportunity Trust Fund and/or appropriating additional revenues to fund grants to state and local governments to establish and operate technical assistance programs to help minority entrepreneurs enter and grow in this space. Currently, complying with state and local rules, including zoning and security requirements as well as licensing application processes, is expensive, time-consuming, and require technical expertise. Small businesses are the least equipped to comply with such requirements because they often lack the technical expertise necessary to comply in a cost-effective manner. State and local agencies should be available to help small businesses, especially socially and economically disadvantaged businesses, complete applications and comply with technical operating requirements. Federal funding for such programs via grants could help create and sustain such services throughout the United States, thereby helping thousands of small and socially and economically disadvantaged businesses. To be most effective, these grants should be open-ended to enable state and local government to design technical assistance programs that best work for the minority entrepreneurs in their districts. Moreover, funding should incentivize state and local governments to work with cannabis businesses located in HUBZones, Empowerment Zones, Enterprise Zones, and Opportunity Zones to leverage the benefits of those policies.

IV. TAXATION OF CANNABIS AND ESTABLISHMENT OF TRUST FUND

a. Imposition of Tax on Cannabis Products

i. The appropriate sales or production threshold for the small producer credit

Recommendation:

1. **Impose a $25 million annual gross revenues threshold for phasing out the credit.**

Similar to the policy behind reduced rates of excise tax on craft brewers, a reduction in the excise tax rate or a credit against the excise tax rate on cannabis products would encourage and facilitate ownership of cannabis businesses by small business owners, including women and minority-owned businesses, by reducing the cost of participating in the market. To ensure that small businesses benefit, reduced rates or credits against the rate could be phased out based on a gross receipts threshold. There is precedent in the tax code for a $25 million gross receipts threshold. For example, businesses averaging $25 million in annual gross receipts may use the cash method of accounting, even if they have inventories. Applying the same threshold for an excise tax reduction would provide certainty and simplicity for small cannabis businesses. Using a phase out approach would also prevent creating an artificial cliff and disruption to growing small businesses.

Regulatory authority should be granted to the Secretary of the Treasury to promulgate rules in the event that a business moves slightly above or below the threshold from year to year.

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

Recommendation:

1. **Include clear statutory language prohibited a producer from taking duplicative deductions.**

The tax code generally prohibits "double dipping," i.e., if an activity qualifies for one special tax benefit, it generally may not take advantage of another special tax benefit. Appropriate language should be inserted into the statute to clarify this point and to address whether, once elected, a business must continue to use a certain benefit or if it would be allowed to use the most advantageous benefit from year to year.

iii. 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

Recommendation:

1. **Tax all products based on weight and ensure the methodology provides certainty and is easy to administer.**

Determining the proper manner to measure potency is not a tax question, per se. This is a question that could be addressed through a grant of regulatory authority to Treasury. Whatever manner is determined, it should be clearly described and defined to provide certainty and ease of implementation and compliance for cannabis taxpayers, and certainty and ease of administration and enforcement for Treasury, whether the TTB or the IRS. Such features will reduce the need for compliance checks and audits, and reduce the cost of compliance for taxpayers. Rules should be drafted to avoid migration from one category, i.e., tax determined by potency versus weight versus cost, to prevent abuse.

We caution against subjecting any cannabis products to the per-THC context rather than the weight-based tax to discourage production of products that contain lots of additives and low quality production value as a means of reduces taxes.

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

Recommendation:

1. **Designate the Treasury Department as the appropriate entity.**

Treasury should be responsible for establishing the methodology to administer a cannabis excise tax regime. To the extent necessary and practicable, Treasury and other agencies, including the FDA, should coordinate, but to avoid unnecessary and inconsistent policies and procedures, the primary responsibility should be housed in one department. Since Treasury is responsible for collecting and enforcing excise taxes, Treasury is the logical choice.

Treasury could draw from industry or governmental sources of data regarding the industry to determine prevailing prices. To provide more certainty and to simplify the process, prices could be tied to a consumer price index or inflationary index to reset the price each year. However, since cannabis is an evolving industry the rate of inflation may not be a reliable measure for the first few years. Relying on an index could be postponed until the industry stabilizes.

It may be valuable to explore a federal sales tax based on the sales price of a cannabis good that is levied at the point of retail sale as a potential alternative to a federal excise tax levied on manufacturers. We are aware that proponents of such a tax believe it may raise comparable sums as an excise tax on manufactures, and may interact more neatly with the existing state tax regimes. If interested, we would be available to further expand on such a policy proposal with the Sponsoring Offices.

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

Recommendation:

1. **Allow for quarterly or annual filings.**

To reduce costs and for ease of compliance, small cannabis producers should be allowed to file tax returns/payments on a quarterly or annual basis. The frequency could be tied to the size of the payments.

vi. 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

Recommendation:

1. **Allow cannabis businesses to access the same deductions as other lawful businesses.**

The role of the cannabis taxpayer in the industry will impact the transition to a "regular" taxpayer able to enjoy the benefits of below the line deductions. For example, rules for farmers may apply to growers and rules for retail businesses will apply to storefronts. The IRS and the SBA should partner with the industry to educate cannabis taxpayers about tax rules so they are able to comply with the tax laws and not fall into a pattern of noncompliance that is difficult to reverse, especially if delinquent taxes accumulate. Penalties for noncompliance could be waived as part of this transition.

Particular tax incentives that the cannabis taxpayer might have been entitled to but for 280E, such as 100% bonus depreciation, could be allowed on a pro-rated basis. For example, the remaining cost of a 5 year depreciable asset that is 2 years old when 280E becomes moot could be written off.

Although 280E allows for the cost of inventory, courts have ruled that small cannabis businesses, i.e, those with gross receipts under $25 million, have not been able to take advantage of the cash accounting rules (see IV(a)(i), above). With the non-application of 280E, these taxpayers should be able to deduct the cost of inventory as purchased rather than account for inventory using a conventional method, such as LIFO or FIFO.

vii. 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

To the extent that cannabis products are mingled with other products, like alcohol, conforming amendments should be drafted or regulatory authority granted to coordinate the two regimes in order to avoid double taxation and to avoid uncertainty and potential inadvertent noncompliance. Rules for rolling papers and other products used for tobacco products should be coordinated so one industry is not advantaged or disadvantaged and to avoid abuse.

Statutory or regulatory authority for coordination between Treasury and the FDA should be established to account for special considerations in the case of medical cannabis. For example, a drawback of excise taxes paid on medical cannabis could apply if FDA-related fees apply to the product.

b. Operations

i. 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.

As a general proposition, we believe that the CAOA should maximize the extent to which the Regulatory Flexibility Act, and the Paperwork Reduction Act can be used to ensure that implementing regulations do not become *de facto* barriers to entry for small business. Accordingly, we recommend that the Regulatory Flexibility and Paperwork Reduction Acts be explicitly applied to FDA and TTB regulation implementing the CAOA.

V. PUBLIC HEALTH, CANNABIS ADMINISTRATION, AND TRADE PRACTICES

a. Food and Drug Administration Regulation of Cannabis

i. 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

Please see our comments in Sections I(a)(iv), (xi-xiii).

b. Establishment of Cannabis Products Regulatory Advisory Committee

i. Roles and responsibilities of the Advisory Committee; and

We believe the proposed role of the Advisory Committee as currently defined is appropriate.

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

We believe it may be helpful, as is currently drafted, for the Advisory Committee to provide comments to FDA before issuing final rules. However, the process of soliciting and reviewing feedback from the Advisory Committee should not be allowed to cause any meaningful delay to the rulemaking process. Moreover, the Advisory Committee should not be folded into the APA process; doing so, would create unnecessary delays and bottlenecks to the already lengthy rulemaking process.

c. Cannabis Administration and Trade Practices Enforcement

i. 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

Recommendation:

1. **Exempt state-lawful products in the marketplace at the time of enactment of the CAOA, and only such products, from the CAOA.**
2. **Transition to FDA Manufacturing Rules in a Manner to Preserve Small Business Competitiveness.**

An orderly and timely transition to the CAOA's rules is necessary to promote a safe and productive marketplace that empowers consumers and gives them choice. Thus, to minimize disruption to consumers and businesses while respecting states' rights to implement their own regulations, we recommend that the CAOA expressly authorize the interstate trade of cannabis and cannabis products that exist in the marketplace, including products in cultivation (to the extent not already covered by the CAOA's transition provisions) and production, at the time of enactment of the CAOA, subject to existing state laws. Such cannabis and cannabis products should be excluded from the CAOA's other regulatory provisions, with the key exception of the rules prohibiting interstate trade that violates the laws of any given state. All subsequently cultivated, produced, distributed, and sold cannabis and cannabis products should be subject to the CAOA and any implementing regulations by the FDA and TTB (in a manner consistent with our previous recommendations to update the FFDCA).[8]

[8] We encourage the Sponsoring Offices to take legislative notice of the multitude of studies on medical cannabis products and the many years of widespread use of medical cannabis products by millions of patients throughout the United States pursuant to state regulated medical regimes. The data and experience that these markets provide on a multiplicity of products provide a rich potential source of information about medicinal cannabis and should be incorporated into the medicinal cannabis regulatory regime. Notably, studies and widespread market experience have

This recommendation would allow consumers to continue to purchase products that are lawful under state law, and only such laws; enable businesses to deplete rather than abandon their pre-CAOA inventory; give businesses time to comply with the CAOA's new rules; and respect states' authority to regulate cannabis products within their borders (provided no undue burden is imposed on interstate trade). Importantly, this recommendation does not impose an artificial time-based delay on compliance with the CAOA. The fundamental issue to be addressed is ensuring that state-lawful products that are already in the market can continue to be bought and sold, rather than deemed illegal immediately. A time-based solution is not necessary to achieve this goal.

One overriding area of concern is the barrier to entry created by the application of FDA GMP facilities requirements to all cannabis producers.[9] These requirements impose substantial costs that many small and medium businesses as well as socially and economically disadvantaged businesses will be unable to afford. Many of these businesses operate consistent with the TTB's manufacturing specifications because the TTB's rules are not cost prohibitive. We propose that the Sponsoring Offices include a tax deduction up to 100% of the cost of converting non-compliant manufacturing facilities for currently-state-licensed cannabis manufacturers that obtain federal permits under the CAOA to FDA GMP compliant ones.

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

Recommendation:

1. **A federal track-and-trace system should replace the state-based seed-to-sale tracking systems.**

We believe that the federal track-and-trace system contemplated by the Discussion Draft should, when fully operational, become a uniform system that would ultimately preempt state-based seed-to-sale tracking systems, but with respect to which states will have full access. Implementing one uniform tracking system that provides the relevant information to one regulator is more effective, efficient, secure, and affordable than a 50 state system. We are concerned that there would be significant operational challenges to sharing data between the states and the federal government if state-based seed-to-sale is maintained. Many states do not even have such a system and there are meaningful differences between the states that do have such systems, so there is not a meaningful efficiency gain to preserving them. Compliance with one system will be far more simple and affordable, and designating the Treasury Department as the authority over the system and the recipient of the data will minimize data security breach risks while giving Treasury the visibility

never produced data demonstrating an LD_{50}. In other words, there is no data demonstrating that any amount of cannabis is lethal. Cannabis policy can build upon the extensive, positive real world user experience in state markets in a unique way relative to other medical or adult-use products.

[9] The cost of FDA manufacturing compliant construction compared to TTB compliant is a substantial cost (industry standard understanding is $250/sq foot for TTB facilities, $450/sq foot for FDA facilities; even more to retrofit facilities to FDA). And many, many businesses nationwide, particularly small ones, have elected for TTB construction due to capital scarcity. This cost differential will cause many small businesses to close immediately and discourage industry diversification, akin to the vaporizer small business market disappearing after the 2009 Tobacco Control Act and the subsequent industry concentration.

it needs in the market. During the interim period before a federal tack and trade program can be created and implemented, we suggest that that the states be encouraged to share their current tracking programs and that Congress fund such efforts with a small portion of the revenues generated by federal cannabis taxes. Their coordination will help facilitate the development of a national market.

VI. COMPTROLLER GENERAL REVIEW AND MISC. PROVISIONS

a. ADDITIONAL ISSUES AND GENERAL ITEMS

i. Consideration of transition rules and effective dates

We reiterate our recommendations throughout, but specifically in sections I(a)(ii), I(b)(ii), (iii), and IV(a)(vii).

b. Interactions with state and local laws

Recommendation:

1. **Federal law should establish a clear foundation facilitating interstate commerce and minimum standards for public safety and consumer protection, and states should regulate on top of and consistent with this foundation.**

To create a successful, equitable, and diverse cannabis market where consumers have access to safe products at affordable prices, we believe that Congress needs to create a clear and strong legal foundation facilitating interstate commerce as well as regulations establishing the baseline rules for public health and operations. On top of that foundation, each state should be allowed to exercise its existing authorities to regulate cannabis within its own borders as its citizens deem appropriate. Local governments should implement their own rules as long as they are appropriate under their state's law and do not conflict with federal law. This layered approach will provide clarity and consistency for consumers and businesses while allowing states to be the primary regulator of cannabis within its borders.

Accordingly, we believe that federal laws regulating cannabis should preempt any state law that conflicts with them, but federal law should not categorically preempt state cannabis laws. We applaud the Sponsoring Offices for taking this approach in their Discussion Draft and we urge them to maintain it.

c. Interactions with international obligations and treaties

Recommendation:

1. **Develop a comprehensive trade policy focused on enabling U.S. businesses to compete in the global market.**

To facilitate fair international trade that enables U.S. cannabis companies to compete, we suggest the Sponsoring Offices consider including language authorizing the President to send trade delegations, establish as U.S. policy the objective to remove unreasonable foreign barriers to international cannabis commerce, and clarify that Congress retains the power to alter any particular substance's status as a controlled substance regardless of that substance's designation per an international treaty to which the U.S. is a signatory.

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

Recommendation:

1. **Increase MDIs' Capital.**
2. **Leverage the Community Reinvestment Act to encourage financial services for small and historically disadvantaged cannabis businesses.**
3. **Require the federal financial regulators to implement initiatives to encourage financial services for small and historically disadvantaged cannabis businesses.**
4. **Require the federal financial regulators to issue guidance to encourage financial services for small and historically disadvantaged cannabis businesses.**
5. **Provide a safe harbor for financial institutions to accept the proceeds of cannabis sales by state-lawful cannabis companies and service providers that occurred prior to the CAOA's effective date.**
6. **Fund trade and export assistance for minority cannabis businesses.**

To help expand access to capital for historically-disadvantaged cannabis companies, the Sponsoring Offices should build on recent legislative and administrative efforts to create more minority depository institutions (MDIs) and to increase MDIs' available capital. Minority cannabis companies often lack sources of inexpensive capital and credit to expand business operations. MDIs, including minority-owned CDFIs, play an important role in extending credit to minority-owned businesses but these institutions lack adequate capital to meet demand. We believe that increasing capital available to MDIs will expand the flow of credit into these communities and will also serve as a means to increase the flow of credit to minority businesses.

The Sponsoring Offices should also consider leveraging the Community Reinvestment Act (CRA). Among other things, the Sponsoring Offices could consider directing the federal banking regulators to update their CRA performance criteria to consider a bank's services to otherwise "CRA-eligible" cannabis businesses or amend the CRA (or its implementing regulation) to afford additional CRA credit for providing qualifying services to cannabis businesses that are otherwise CRA-eligible.

Additionally, the Sponsoring Offices should consider directing the federal financial regulators (the federal banking regulators, FinCEN and the SEC, as well as the Office of the Advocate for Small Business Capital Formation) to develop a strategic plan to encourage financial institutions to provide financial services to socially and economically disadvantaged cannabis businesses. These regulators, both individually and collectively, have launched several initiatives designed to

promote financial inclusion for a wide-range of businesses and consumers.[10] Any such strategic plan should be developed and implemented quickly, ideally within one or two years of enactment. Leveraging their expertise, and mandating that they act in a timely manner, would help close the gap in financial services for small and historically disadvantaged cannabis businesses.

To further leverage strategic initiatives by the federal financial regulators, the Sponsoring Offices should consider directing the regulators to issue guidance designed to encourage access to capital for such businesses. These regulators have wide latitude to make adjustments in capital, liquidity, safety and soundness, disclosure, solicitation, and other requirements that can facilitate financial services and investment. They should use that authority to help small and historically disadvantaged cannabis businesses obtain the funds they need to prosper.

Absent affirmative steps to facilitate financial services to small and historically disadvantaged cannabis businesses, there is risk that the banking and traditional financial services industries will consider cannabis companies to be high-risk and thus, subject to more stringent oversight and costs, thereby reducing the availability and increasing the price of financial services. In this event, only the large companies will be able to access traditional bank and investor finance. Mandating the federal banking regulators update their examination and Bank Secrecy Act guidance with respect to cannabis businesses, and to do so in a manner that appropriately reduces the risk profile of such businesses will help encourage those institutions to provide more affordable financial services.

Aside from steps to encourage the financial services industry to work with small and historically disadvantaged cannabis companies, we are concerned that even after enactment of the CAOA, there will be at least two potential barriers to access to financial services:

First, even after the CAOA is enacted, there is risk that financial institutions would violate federal anti-money laundering laws by accepting the proceeds of cannabis sales that occurred before enactment. Although Section 101(d) provides for a "retroactivity" provision that would apply the changes to the status of cannabis under the Controlled Substances to "any offense committed, case pending, conviction entered" that occurred prior to enactment, this provision is unlikely to provide financial institutions the legal clarity they require to service purportedly "high-risk companies." Moreover, the retroactivity clause does not apply to any penalties that can be levied by the federal banking regulators (such as civil money penalties or loss of charter or deposit insurance, among others).

Second, financial institutions would still face risk under federal anti-money laundering laws if they accept proceeds from transactions involving cannabis products that violate the FFDCA. Many cannabis products sold prior to enactment of the CAOA were still sold in likely violation of the FFDCA so this risk would remain. It would also apply to the proceeds of any products that already exist in the market if there is no transition rule (as discussed in Section V(b)(ii)). This is already a serious concern in the hemp-derived CBD industry.

To address these issues, we ask the Sponsoring Offices to adapt at least sections 2–7 from the "Secure and Faire Enforcement Banking Act of 2021."

[10] For instance, the OCC has launched Project REACH and the FDIC is completing its FDITECH Sprint program.

Finally, we also support efforts to connect minority cannabis businesses with U.S. Export Assistance Centers to develop potential opportunities for new markets overseas (and to help navigate through with the myriad of rules and regulations that currently hamper the international trade of cannabis products).

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

As we have discussed throughout our recommendations, we believe that clear and consistent rules facilitating interstate commerce are critical to creating a successful, equitable, and diverse cannabis industry that provides consumers safe, effective, and affordable products. Minimizing barriers to entry for small businesses; enabling consumers and patients to access the products they want and need; and establishing an equal playing field by imposing baseline requirements on testing, operations, and safety are key elements to a competitive, consumer-focused market. Implementing clear federal rules quickly and transitioning existing businesses and products to those rules quickly and orderly is an important component of reform. We encourage the Sponsoring Offices to ensure that existing products can continue to be offered so to avoid a regulatory cliff, but we caution against any long delays in normalizing cannabis use and its sale.

Cannabis reform as the Sponsoring Offices well-recognize, is also a matter of civil rights, so we applaud the Sponsoring Offices for including important provisions regarding expungement of cannabis-related convictions and taking steps to ensure that people, like us, who were harmed by the War on Drugs, can participate in this market. To further that shared goal, we urge you to use civil, rather than criminal, penalties to deter and punish unlawful behavior

APPENDIX
SUMMARY OF QUESTIONS AND RECOMMENDATIONS

Questions Posed by Sponsoring Offices	Summary of Proposed Recommendations
Comments Addressing Removal from Controlled Substances Act, Transfer of Federal Agency Function	
Conforming amendments and interactions relating to the descheduling of cannabis and establishing a new definition outside of the Controlled Substances Act.	Exclude all seeds, not just sterile seeds, from the definition of "cannabis" so the definition is consistent with international treaties.
The appropriate way to measure the potency of cannabis and cannabis products.	Require use of testing standards that are widely accepted by the scientific community and are available at a reasonable cost. Require disclosure of Total THC.
The interaction between the definition of "cannabis" and the definition of "hemp."	Maintain the proposed language regarding hemp.
The interaction between the definition of "cannabis," "cannabis product," and FFDCA drugs containing cannabis.	Amend the FFDCA to permit the sale of existing cannabis foods and cosmetics. Clarify that cannabis product delivery systems cam include the natural flavors of cannabis. Allow the export of cannabis products that contain alcohol, nicotine and tobacco.
The appropriate classification and regulation of synthetically-derived THC.	Maintain FDA's current regulation of synthetic THC.
Conforming amendments and interactions relating to the descheduling of cannabis and establishing a new definition outside of the Controlled Substances Act.	The descheduling of cannabis should be effectuated in the statute, and the Attorney General's role should be the ministerial correction of relevant regulations.

Questions Posed by Sponsoring Offices	Summary of Proposed Recommendations
	Retroactivity of descheduling cannabis should apply to administrative enforcement, non-violent criminal activity and forfeiture actions as well.
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.	Designate USDA as the primary regulator of raw cannabis. Adopt a non-exhaustive statutory list of pre-approved structure-function like claims. Provide TTB primary labeling and product recall authority over cannabis products.
Whether FDA regulation of cannabis products should be funded through a user fee program or other funding model.	Do not impose a user fee; use excise taxes and other revenues to fund FDA's oversight.
Recognition of State Law Controlling Cannabis, Establishment of Public Safety and Enforcement	
The appropriate quantitative thresholds regarding contraband cannabis.	Maintain the 10 lbs limit
The appropriate penalties for violations of anti-diversion provisions.	Remove criminal penalties and replace them with significant civil fines.
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.	Reduce the deadlines by which FDA and TTB issue their rules. Provide robust judicial remedies to enforce the rulemaking deadlines. Promote comity between state licenses and permits under TTB.
Establishing Minimum Age, Restriction on Retail Sale	
The interaction between state minimum age laws and use of medication containing cannabis by minors.	Explicitly clarify that any age limit for purchase or use of cannabis products does not apply to patients using products pursuant to a doctor's recommendation.
The appropriate quantitative thresholds regarding the limit on retail sales of cannabis.	Limit retail sales to 5 lbs.
Research	

Questions Posed by Sponsoring Offices	Summary of Proposed Recommendations
Whether programs can be designed to steer research dollars to Historically Black Colleges and Universities and other institutions associated with historically disadvantaged communities.	Provide additional funding to support undergraduate and graduate programs in a wide-range of cannabis studies at HBCUs and other minority-serving institutions. Amend 20 U.S.C. § 1067q to include cannabis research funds for minority-serving institutions.
Opportunity Trust Fund Programs and Small Business Administration Programs	
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.	Provide funding for large scale loans or seed capital to Minority Cannabis Companies and increase funding for the Minority Business Development Agency. Provide funding to state and local governments for technical assistance to socially and economically disadvantaged cannabis businesses.
Imposition of Tax on Cannabis Products	
The appropriate sales or production threshold for the small producer credit.	Impose a $25 million annual gross revenues threshold for phasing out the credit.
Appropriate anti-double-benefit rules regarding the small producer credit, including rules related to substantial processing.	Include clear statutory language prohibited a producer from taking duplicative deductions.
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.	Tax all products based on weight and ensure the methodology provides certainty and is easy to administer.
The appropriate entity and methodology for measuring the prevailing price of cannabis for purposes of setting annual rates of tax.	Designate the Treasury Department as the appropriate entity.
Whether certain small producers should be eligible for quarterly or annual tax payments, similar to the rules applicable to small alcohol producers.	Allow for quarterly or annual filings.
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.	Allow cannabis businesses to access the same deductions as other lawful businesses.

Questions Posed by Sponsoring Offices	Summary of Proposed Recommendations
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.	Make conforming amendment to coordinate taxation of products that include cannabis products.
Operations	
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.	Apply the Regulatory Flexibility and Paperwork Reduction Acts to FDA and TTB regulation implementing the CAOA.
Food and Drug Administration Regulation of Cannabis	
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.	Please see our prior comments.
Establishment of Cannabis Products Regulatory Advisory Committee	
Roles and responsibilities of the Advisory Committee.	The role as outlined in the Discussion Draft is appropriate.
The role of the Advisory Committee in agency consultation, including the administrative and rulemaking process.	To provide comments in advance of rulemaking proposals.
Cannabis Administration and Trade Practices Enforcement	
Ways to reduce compliance costs for small businesses while ensuring that market participants comply with necessary labeling and trade practice rules.	Provide a tax deduction up to 100% of the cost of converting non-compliant manufacturing facilities for currently-state-licensed cannabis manufacturers that obtain federal permits under the CAOA to FDA GMP compliant ones.
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.	Exempt state-lawful products in the marketplace at the time of enactment, and only such products, from the CAOA.
Whether and how a single federal track and trace regime could replace the various, complex, state-based seed-to-sale tracking systems.	A federal track-and-trace system should replace the state-based seed-to-sale tracking systems.
Additional Issues and General Items	
Consideration of transition rules and effective dates.	We reiterate our prior recommendations.

Questions Posed by Sponsoring Offices	Summary of Proposed Recommendations
Interactions with state and local laws.	Federal law should preempt state law with which it conflicts; states should be able to implement rules that are otherwise within their purview.
Interactions with international obligations and treaties.	Authorize the President to send trade delegations. Establish as U.S. policy the objective to remove unreasonable foreign barriers to international cannabis commerce.
Additional opportunities to expand restorative justice and access to capital for historically-disadvantaged entrepreneurs.	Increase MDIs' capital. Leverage the Community Reinvestment Act to encourage financial services for socially and economically disadvantaged cannabis businesses. Require the federal financial regulators to implement initiatives to encourage financial services for socially and economically disadvantaged cannabis businesses. Require the federal financial regulators to issue guidance to encourage financial services for socially and economically disadvantaged cannabis businesses. Provide a safe harbor for financial institutions to accept the proceeds of cannabis sales by state-lawful cannabis companies and service providers that occurred prior to the CAOA's effective date. Fund trade and export assistance for minority cannabis businesses.