AmericansFor SafeAccess
Advancing Legal Medical Marijuana Therapeutics and Research

September 1, 2021

The Honorable Charles Schumer, Majority Leader
United States Senate
S-221, U.S. Capitol Building
Washington, DC 20510

The Honorable Cory Booker
United States Senate
717 Hart Senate Office Building
Washington, DC 20510

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

Re: The Cannabis Administration and Opportunity Act, Discussion Draft

Dear Senate Majority Leader Schumer and Senators Booker and Wyden:

Americans for Safe Access (ASA) respectfully submits these comments with regard to the Cannabis Administration and Opportunity Act. ASA is the nation's oldest and largest 501(c)(3) member-based medical cannabis advocacy organization with a mission to advance access to cannabis for therapeutic use and research. ASA was founded in 2002 and since then has led the way toward the enactment of numerous state medical cannabis laws.

ASA also created the Patient Focused Certification (PFC) program in 2014 as a way to address cannabis cultivation, processing, dispensing, and laboratory production and testing requirements, and is currently the only ISO 17065 accredited certifying body for a cannabis compliance program. Below are ASA's comments which are presented in responses to the specific questions provided by your offices for this solicitation.

Should you have any questions or need any additional information please contact Dustin McDonald at dustin@safeaccessnow.org and Heather Despres at heather@safeaccessnow.org.

Sincerely,

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ASA is the largest national nonprofit organization of patients, medical cannabis providers, medical professionals, scientists and concerned citizens promoting safe and legal access to cannabis for therapeutic use and research with over 100,000 advocates in all 50 states.

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.

There is much discussion amongst the scientific community about the best way to measure the potency of cannabis and cannabis products. Some of the first methods published were methods which used gas chromatography (GC). This method was flawed because the conversion of THCA to THC was incomplete, making the quantification of THC unreliable. The cannabis plant produces cannabinoids, which are responsible for many of the physical responses in the body, in their acidic forms, which must generally be converted into their neutral forms to achieve many of the desired physiological responses. Studies now show that the acidic cannabinoids may also achieve desired physiological responses and it is important for laboratories to be able to differentiate between the acidic and neutral forms.

Many states Departments of Agriculture utilize a GC method, which, for a department that would have historically been tasked with identifying the plant or product as cannabis or cannabis-containing to identify if something was illegal or not, only the presence of THC mattered, not necessarily how much of it was there. The incomplete conversion of THCA into THC would not matter for that type of analysis, whereas in order to accurately quantify both the acidic and neutral cannabinoids a liquid chromatography (LC) method is more appropriate. The American Herbal Pharmacopeia's Cannabis Inflorescence Monograph and recent publication from the United States Pharmacopeia (USP) both highlight GC and LC methods, however most cannabis testing laboratories opt for LC methods over GC methods.

High performance liquid chromatography (HPLC) is the preferred analytical method for analysis of both the acidic and neutral cannabinoids. Additional consideration should be given to the methods used to extract the cannabinoids from extracts and derived products. Incomplete extraction of cannabinoids from a food or other infused product could result in a mislabeled product and lead to potentially adverse events. Laboratories conducting analyses of cannabis and cannabis products should be required to validate not only the testing method being utilized but also the extraction and sample preparation methods as well.

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

Americans for Safe Access respectfully submits the following nomenclature to identify and differentiate between cannabis and hemp. The principal difference between cannabis and hemp is regulatory in nature in that hemp is permitted as long as the total amount of THC present is less than 0.3% by weight whereas in cannabis products the total amount of THC present may exceed 0.3% by weight. When talking about the plant and only its taxonomic features, it should be referred to as either *Cannabis sativa* or simply *Cannabis* whereas if a specific cannabis or hemp product is being referred to they may be called cannabis or hemp products, based on their THC content, and to identify products according to the regulations they fall under.

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

With the use of consistent nomenclature the differences in product type and origin may be ascertained.

The following terminology is recommended to identify product types and origins:

- *Cannabis* - plant of the species *Cannabis sativa* whose inflorescences may contain greater than 0.3% THC by weight.
- Cannabis product - product made from the cannabinoids contained in the plant *Cannabis sativa* which may contain greater than 0.3% THC by weight.

- Hemp - plant of the species *Cannabis sativa* whose inflorescences must contain less than 0.3% THC by weight per USDA requirements.
- Hemp product - product made from the plant *Cannabis sativa* which may or may not contain cannabinoids and, if so, must contain less than 0.3% THC by weight.
- Medical cannabis (product) - *cannabis* products, including inflorescences, which are regulated under state medical cannabis programs.
- Pharmaceutical cannabis product - products derived from *Cannabis sativa* which are regulated under the FFDCA for which Food and Drug Administration (FDA) approval is required.

It should be noted that medical cannabis products may also be regulated under the FFDCA and be required to meet the standards for dietary supplements (21 CFR 111) and be distinguished and classified differently than pharmaceutical cannabis products which must adhere to more stringent regulations (21 CFR 211). This is principally due to the differences in access and product availability of medical versus pharmaceutical cannabis products. There are almost 5 million medical cannabis patients in the US who utilize their state's medical cannabis program to access medical cannabis products while there are only 3 pharmaceutical cannabis products that have been approved by the FDA. These 3 products (Marinol, Cesamet, and Epidiolex) have a limited scope of patients for whom the drug may be prescribed. In previous comments submitted to the FDA, ASA has encouraged FDA to work with Drug Enforcement Administration (DEA) to increase the number of researchers and research products available to researchers so that scientists can continue to identify products which prove medically beneficial. No matter which standard medical cannabis products must adhere to (21 CFR 111, 21 CFR 211, or state specifications), access for patients relying on this medicine must not be affected while the best way to set product specifications and regulations is determined.

Most state medical and adult-use cannabis programs have product specifications that products must meet prior to being permitted to be sold including specifications for potency, adulteration, and contamination along with labeling and disclosure requirements. ASA urges Senators Schumer, Wyden, and Booker to work with cannabis regulator groups, practicing cannabis researchers, cannabis testing laboratory operators and scientists to identify appropriate testing and product specification requirements. Currently each state maintains different testing requirements, leaving cannabis patients across 37 states without uniform medicine that maintains the same composition of plant compounds in the same proportions, or that is held to the same standards related to the volume of heavy metals, molds, pesticides and contaminants included in the cannabis medical products.

The appropriate classification and regulation of synthetically-derived THC.

At this time there are two different categories of synthetic THC products - those that have been banned by the DEA and those that have been approved by the FDA. The DEA has banned synthetic THC products, also known as Spice, K2, Black Mamba, etc. These "synthetic", or non-naturally derived, substances were banned because of the toxic effects within the body including increased heart rate, vomiting, agitation, and confusion along with a lack of manufacturing oversight and standardization. On a molecular level, these substances have a chemical structure similar to THC, but it is not identical and it is this altered structure that causes the litany of adverse effects. In contrast, the FDA has approved 2 pharmaceutical drugs that are synthetic THC: Marinol and Cesamet. The THC present in Marinol and Cesamet has a structure identical to THC which is derived through a series of chemical reactions and processes to be identical to naturally-derived THC.

Studies have shown that patients had better outcomes when taking whole plant medicine that included all the cannabinoids and terpenes present to Marinol, which is a single-compound drug. The reason for this is related to the Entourage Effect, which was first identified in 1998. Numerous studies have supported the Entourage Effect

that whole plant extracts increase the physiological activity of the cannabinoids as opposed to that of a single compound".

ASA supports those products which are approved by the FDA and a ban on those products which may cause adverse effects and unwanted harm to patients as it relates to synthetic cannabinoids. Additionally, ASA supports maintaining access to whole plant medicines and products for the almost 5 million medical cannabis patients and estimated 40.3 million adult-use consumers, many of whom may be using cannabis medicinally despite making a purchase in the adult-use marketplace.

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

Since the passage of the Controlled Substances Act (CSA), the conversation surrounding federal cannabis reform has always been tethered to cannabis' Schedule I status. This is because removing cannabis from the CSA entirely would create pathways for other federal departments and agencies to act and organize corollary reforms. However removing cannabis from Schedule I or from the schedule of controlled substances entirely does not facilitate an expedited pathway to federally sanctioned cannabis medicine, or address the effect of federal discriminatory policies on the lives of patients across the country, which are predicated on cannabis' CSA classification.

As federal departments and agencies have traditionally approached cannabis with a view consistent with cannabis' CSA Schedule I status – that the drug has a high propensity for abuse but no medical value – this view must be changed completely to meet those now held by 37 U.S. states, the District of Columbia, four U.S. territories, 47 countries across the globe, the United Nations and the World Health Organization who have reformed their laws to extend safe and legal cannabis access to patients. Beyond simply rescheduling or descheduling cannabis, what will be most critical to the successful establishment of federally-sanctioned cannabis medicine will be the reassignment of federal department and agency roles predicated on the value of cannabis as a medicine.

ASA urges federal departments and agencies to lead a comprehensive review of federal cannabis policies as they exist currently, how those policies affect the health of patients relying on cannabis to treat their health, and how changes to the federal scheduling of cannabis under the CSA and corollary reassignments of departments and agencies would improve health outcomes for all patients. From the Office of Personnel Management (OPM) and the Department of Housing and Urban Development (HUD0 to the Department of Veterans Affairs (VA), Health & Human Services (HHS) and the Department of Commerce (DOC), reforms must be made to facilitate a pathway to federally-sanctioned cannabis medicine and address federal policies that are harming cannabis patients.

HUD's policies provide an excellent case study of the impact of the Schedule I classification of cannabis under the CSA. HUDs mission to extend housing support to equity communities is compromised by this scheduling. And with millions facing the loss of housing security and economic instability stemming from the COVID pandemic, it is critical that HUD work to remove discriminatory policies pertaining to cannabis and housing. According to U.S. census data, there are nearly 4.6 million Americans who rely on federal support for housing. However, because federal law still classifies cannabis as a Schedule I substance under the CSA, any of the 4.6 million Americans who rely on federal support for housing, and who are also medical cannabis patients, are at risk of eviction even if they live in one of the 37 states where medical cannabis is legal. As a result, many of our nation's medical cannabis patients must choose daily between meeting their health and housing needs.

To address this and other policy challenges, ASA encourages the inclusion of key members of the medical community on the legislation's proposed Advisory Committee. Specifically ASA urges the inclusion of patients, caregivers, and senior physician, health and research professionals from key fields such as neurology, psychology,

pediatrics, palliative medicine, addiction and emergency medicine, who also possess experience in treating patients with cannabis. Together this group would provide recommendations to Congress and the administration on reorganization of federal department and agency jurisdictions and responsibilities to facilitate federally-sanctioned cannabis research, and address associated cannabis patient discrimination issues.

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.
ASA encourages the organization of a temporary or permanent office to lead all federal department and agency reforms related to cannabis following either a rescheduling or descheduling of cannabis. The purpose of the office would be to lead federal reforms and reconcile competing department and agency agendas. Such an office should include the leadership of key federal departments and agencies who currently maintain jurisdiction over cannabis, and be overseen by a new appointment unaffiliated with any federal department or agency. The head of this office would maintain a deep working knowledge of federal regulatory roles related to cannabis and the suite of U.S. state and foreign nation cannabis reforms implemented, and be dedicated to facilitating an expedited pathway for federally-sanctioned cannabis medicine that produces uniform, consistent, safe and affordable medicine for patients.

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.

Sufficient federal spending should be authorized and appropriated to facilitate federal regulatory reorganization related to oversight of the medical and adult-use cannabis industries, establish an expedited pathway to federally-sanctioned cannabis medicine, develop unifying federal regulations for laboratory testing requirements for cannabis medicine and organize guidance for insurance companies to subsidize the high cost of cannabis medical products for patients.

The Sponsoring Offices request comments on states' rights and anti-diversion provisions, including—

The appropriate quantitative thresholds regarding contraband cannabis.

Americans for Safe Access supports reasonable quantitative thresholds regarding contraband cannabis to ensure the safety of cannabis medicine as it is transported from one state to another. At present 37 states and 4 U.S. territories have implemented some form of medical and/or adult-use cannabis program. These programs stipulate personal possession limits for each type of product, with medical cannabis patients typically authorized to possess larger amounts of cannabis products than adult-use consumers. One of the many challenges with establishing this type of limit is the type of medicine each patient needs. For example, if a patient is inhaling cannabis for immediate relief of nausea they may not need to possess as much cannabis flower as a patient who is making extracts, consumable, or topical cannabis products as those products require a higher amount of plants to make the extracts that are used in making consumable and topical products. Setting a higher limit will prevent patients who need larger volumes of plants and extracts to make their medicine from being prosecuted under either state or federal law while allowing for the prosecution of those who violate threshold limits.

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.

The Advisory Committee should be composed of patients, caregivers, and senior physicians, health and research professionals from key fields such as neurology, psychology, palliative medicine, pediatrics, addiction and emergency medicine, who also possess experience in treating patients with cannabis.

Roles and responsibilities of the Advisory Committee.

The Advisory Committee should provide a comprehensive review of the scope of domestic and international research conducted on the application of cannabis to health conditions, as well as associated domestic and international policy reforms of countries and world organizations. The Committee should also assess the status of cannabis under the Controlled Substances Act and existing jurisdictional roles and responsibilities of federal departments and agencies related to cannabis and current federal processes for approval of proposed medicines and products demonstrating medicinal value.

Ultimately this commission should provide recommendations to Congress and the administration on:

- Optimal approaches to establishing federally-sanctioned cannabis medicine;
- The reorganization of federal department and agency jurisdictions and responsibilities pertaining to authorization of federally-sanctioned cannabis medicine research, medical cannabis researchers and cannabis material to be used in federally-sanctioned cannabis research;
- Appropriate consumer product testing and labeling standards for medical cannabis and cannabis products; and
- Appropriate recommendations for physician education and continuing education regarding the endocannabinoid system.

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

The Advisory Committee should be included in the rulemaking process and development of proposed rules, regulations and guidance on all federal cannabis policy reform items.

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

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.

There is a large volume of state-regulated cannabis products available and actively being produced and used by patients, which must be maintained and available to patients to treat their health during the integration of any federal regulations for these products.

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

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

Beyond the medical cannabis patient priorities covered in our responses to this questionnaire, ASA also requests clarity on Sec. 312 of the bill regarding non-discrimination of federal programs related to cannabis possession and use. Specifically, ASA would like this section to address HUD's practice of denying housing assistance to or forcing the removal of patients who use cannabis to treat their health. ASA would also like to see this legislation require HHS and the VA to collaborate with the ASA-recommended Advisory Committee to develop a cannabis physician education curriculum for VA and civilian physicians.