Getting it Right from the Start

Advancing Public Health & Equity in Cannabis Policy

August 30, 2021

The Honorable
Senator Cory Booker
Senator Chuck Schumer
Senator Ron Wyden
Sponsoring Offices of the Cannabis Administration & Opportunity Act
United States Senate
Washington, DC
Cannabis_Reform@finance.senate.gov

RE: Comments on the Draft Cannabis Administration & Opportunity Act

Dear Senators Booker, Schumer and Wyden,

On behalf of *Getting it Right from the Start*, a project of the Public Health Institute, a 501c3 that has served to promote public health in the United States and globally for the past 55 years, we write to respectfully suggest ways to improve the Discussion Draft of the Cannabis Administration & Opportunity Act. We have been working through research and advocacy for the past 4 years to bring key lessons from public health, tobacco control, and social equity to the regulation of cannabis where states have legalized, providing technical assistance to over 100 California jurisdictions and to policymakers and nongovernmental organizations in numerous states which have legalized or were discussing legalizing. Based on findings from extensive qualitative research with a wide range of experts and stakeholders, we developed model laws for retailing and marketing and for taxation for California local jurisdictions and principles of regulation for national use. These recommendations are being increasingly adopted in state and local laws as the health consequences of excessively lax legalization become clear. We are also funded by the NIH and other organizations to carry out research on effects of cannabis legalization on perinatal and adolescent health, on youth access and use, and on marketing to youth. We created and maintain the California Cannabis Local Laws Database and publish annual Cannabis Policy Scorecards inspired by the American Lung Associations scorecards for tobacco control policy.

Based on this growing body of experience we are submitting comments with goals of assuring that if a decision is taken to legalize cannabis, the laws are drafted in such a way as to reduce negative impacts on youth and on public health while harvesting the criminal justice benefits of decriminalization and expungement, to assure that the FDA has the full authority it needs to do the job, that the system is protected against conflicts of interest, and that it is designed to minimize the emergence of a predatory profit-driven tobacco-like industry such as that emerging today in California and some other states.

Cannabis legalization, including this Act, should include as stated principles of its policies the protection public health, reduction of youth use, and discouraging increases in consumption and cannabis use disorder.

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Congress can decriminalize, expunge and even potentially legalize in ways that the net balance of effects will be positive. Legalization of commerce is not essential to reap the benefits of decriminalization and expungement of criminal records. Yet if legalization is conducted in a way similar to California or several other states, the long term balance of harm may reach or even outweigh social justice benefits by exacerbating the toll of serious mental illness, with psychosis and schizophrenia being of greatest concern, of motor vehicle accidents, of youth whose full mental and educational development and well-being is impaired by cannabis effects and addiction, and of babies who are born with ill-effects of *in utero* exposure. The strong scientific evidence of these harms is consistently underplayed by the cannabis industry, just as the tobacco industry did for so many years. The trends of the industry to massive increases in potency, product diversification with products attractive to youth, and aggressive marketing all lead to exacerbation of these effects. Any Act to legalize cannabis must address these trends head on.

In response to specific questions posed:

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

*Potency should be measured in relation to the THC content, corrected for THCa. However, if products are allowed that artificially increase the content of other psychoactive cannabinoids such as Delta-8, (which we recommend **not** be allowed) formulas should used to take these into account.*

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

*The hemp market is increasingly becoming a back door to sale of neurologically active and psychoactive cannabinoids and their inclusion in food and supplements without age limited access. This breaks with the longstanding policy of the FDA not to permit substances licensed as pharmaceuticals to be used in food or supplements. The sale of hemp derived CBD supplements permitted in **SEC. 505** represents a violation of this principle and should not be allowed. Furthermore, hemp derived final products should not be allowed to be sold with more than trace quantities of psychoactive cannabinoids (for example <1 mg in a final product.) Today regulations sought by hemp manufacturers in California would allow more THC in hemp soda or cookie than in a licensed cannabis edible.*

• The appropriate classification and regulation of synthetically derived THC

Synthetically derived THC should be allowed only in approved pharmaceuticals. The cannabis and hemp markets should be limited to naturally present cannabis components.

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

We strongly believe that the authority of FDA should be more clearly and broadly defined. It should be the lead regulator not only on product standards, but also packaging, labelling, health warnings, marketing, advertising, controls for underage access, and information for consumers. This responsibility should primarily reside at the FDA, with the exception of packaging provisions specifically related to taxation or other TTB enforcement. Since the cannabis industry has specifically used the same strategies as the tobacco industry and alcohol industries known to attract youth, FDA should be required to develop product standards to reduce these risks.

Product standards should be specifically required to address prohibitions of flavored products. While we support the intent of the included section, these restrictions should not be limited to vaping but should cover all products for inhalation or combustion and beverages, and prohibit products that would cause a person to believe they are flavored through words or imagery, a common issue in the cannabis industry. For example Canada's recently proposed regulations call for restricting licensed producers "from producing or packaging and labelling inhaled cannabis extract products with any flavour, other than the flavour of cannabis. It would also restrict the promotion of inhaled cannabis extracts in a manner that could cause a person to believe that the product has a flavour other than one that is typical for cannabis. The proposed amendments would apply to all inhaled cannabis extracts (e.g. cannabis vaping products, hash, shatter) to avoid incentivizing licensed processors to create subsets of flavoured inhaled cannabis products…"[1] Allowance of additives in products for inhalation or combustion should be minimal and require demonstrated safety for inhalation, and not be based just on whether they are botanically derived terpenes, synthetic copies, or artificial additives.

Manufacture and sale of cannabis beverages, like cannabis orange soda and root beer, inspired by alcopops which are well documented to be initiation drinks for teens, should not be allowed.

FDA should be required to develop clear product standards limiting the potency of flower and of cannabis products and requiring standardized metered dosing for inhaled products. Quebec for examples limits concentrates to no more than 30% THC.

FDA should be required to develop rigorous packaging, labelling and marketing standards to avoid attractiveness to children and youth.

[1] Health Canada. Canada Gazette, Part I, Volume 155, Number 25: Regulations Amending the Cannabis Regulations (Flavours in Cannabis Extracts) https://gazette.gc.ca/rp-pr/p1/2021/2021-06-19/html/reg4-eng.html

FDA should be required to develop specific requirements for rotating graphic health warnings covering at least 30% of the front panel of cannabis and cannabis products, based on the best evidence from tobacco regulatory science and emerging cannabis evidence within one year.

• Appropriations requests for various agencies involved in cannabis administration in order to ensure that those agencies have the necessary tools and resources to effectively carry out new responsibilities; and • Whether FDA regulation of cannabis products should be funded through a user fee program or other funding model.

FDA should be funded through a dedicated portion of the cannabis excise tax at a generous and sufficient level to cover regulatory expenses, including pre-market review, as well as funding of educational counter-advertising similar to those supported for tobacco. This will reduce any potential risk of regulatory capture potentially attributable to user fee systems and reduce expenditures for small business applicants.

The Sponsoring Offices request comments on states' rights and anti-diversion provisions, including—
• Effective coordination between federal and state law enforcement and tax administrators relating to diverted cannabis
• The interaction between state primacy regarding cannabis regulation, and the need for interstate consistency for product standards and regulation, including any responsibilities that should be reserved explicitly for states or the federal government

The right of states to regulate more stringently than the Federal government should be protected. As Justice Brandeis noted, the state are our laboratories of innovation. If the FDA fails to adequately protect consumers, it will fall to the states and local government to set the example, as occurred in the case of trans fats for example and many tobacco regulations. The right of a state to prohibit the sale of specific product types should not be abridged. Nor should their right to prohibit the manufacture of those products in their state.

FDA product, packaging, labelling, and health warning requirements, should constitute a mandatory national floor. However, states can impose additional requirements for sale in their state.

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

State and local taxation of cannabis should not be pre-empted in any fashion. We strongly support the provisions for taxation based on potency and have advanced those in CA where they were adopted by two jurisdictions in different forms.[2] The California Legislative Analyst's office also recommended potency-based taxation[3] although it has not yet been implemented in the state.

[2] Measure N. City of Grass Valley November 3, 2020.

[3] Petek G. How High? Adjusting California's Cannabis taxes. Legislative Analyst's Office. Sacramento. 2020. https://lao.ca.gov/reports/2019/4125/cannabis-taxes-121719.pdf

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

Yes, some portion of taxes should support enforcement of age limits and product sale limits.

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

Weak medical cannabis systems have been a major avenue of access for underage youth. At the same time a small number of youth may have valid reasons to use medical cannabis. Systems which assure that any underage access to medical cannabis respects true medical need and real medical care are essential. In California, despite strong guidance from the medical board, it is still easy to obtain a medical card without being seen, examined or truly treated for a medical condition. We recommend maintaining the 21+ approach for federal law.

• Guidance on existing best practices by cannabis-legal states regarding minimum age enforcement & the interaction between state minimum age laws and limitations regarding non face-to-face transactions (discussed further in Sec. 501 of the draft), and

We strongly recommend providing FDA with authority to regulate and enforce age access requirements. These should include requiring third party independent age verification for face to face sales, delivery, and access to any cannabis related websites or ordering platform. While dispensaries in general have been fairly consistent at verifying age, delivery services have been less so, as evidenced in one small study in San Mateo County, CA and in our preliminary research cannabis related website age-gating is grossly inadequate. Cannabis specific research on this issue is new but research from alcohol exists.

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

Limits should also be established for cannabis products based on total milligrams of THC.

The Sponsoring Offices request comment on research, training, and prevention, including—
• Additional areas that may benefit from research, including agriculture, environmental protection, worker health and safety, and other areas.

Important areas for research and regular surveillance that appear missing include:

Surveillance of incidence and hospitalizations for psychosis and schizophrenia in general and specific cannabis related episodes should be required. A rapidly increasing volume of scientific literature demonstrates significant and growing attributable risk of psychosis to cannabis, especially when potent and consumed frequently, and associations with higher rates of population incidence of these serious mental illnesses.[4] These may be the most serious

[4] Di Forti M, Quattrone D, Freeman TP, et al. The contribution of cannabis use to variation in the incidence of psychotic disorder across Europe (EU-GEI): a multicentre case-control study. *Lancet Psychiatry*. 2019;6(5):427-436. doi:10.1016/S2215-0366(19)30048-3

consequences of legalization from a population health and healthcare and social services expenditure viewpoint.

Surveillance of perinatal use and impact of perinatal use on neonatal outcomes and on long term child development should be required. Cannabis use during pregnancy is increasing, has been found to be related to the density of retail outlet, [5] and is clearly related to the occurrence of low birth weight. Early results from NIH's landmark study of cognitive development of children is also finding significant negative impact on child cognitive development in children exposed in utero by age 9. [6]

Surveillance of rates of cannabis use, frequent use, and cannabis use disorder in all age groups and by race/ethnicity should be required.

Changes post legalization in specific health or educational disparities that may be affected by cannabis use including low birth weight, mental health outcomes for psychoses and for suicide, and high school graduation by race/ethnicity.

High school drop-out is mentioned but other academic and mental health impacts on cannabis consuming youth should be assessed.

Surveillance of market characteristics including the potency distribution of product sales and the growth of high potency products in the market, and sales of flavored products if allowed should be required research.

These suggestions should be required research and reporting not only at 2 years post-legalization but every 3 years thereafter.

As a nation we have a collective responsibility to protect youth, who are particularly vulnerable to the neurological effects of cannabis. Cannabis tax revenue should also be invested to create nationwide investments in cannabis control similar to the infrastructure for national tobacco control, to promote both education to reduce use and state and local advocacy for policy and systems to minimize harmful cannabis use and youth use. These funds could be appropriately channeled through the CDC.

• 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

We support and appreciate the idea that Federal dollars should go to support socially and economically disadvantaged business owners engaged in healthier business activities than the cannabis industry. While if for-profit businesses are to be allowed, we believe all of them should

[5] Young-Wolff KC, Adams SR, Padon A, Silver LD, Alexeeff SE, Van Den Eeden SK, Avalos LA. Association of Cannabis Retailer Proximity and Density With Cannabis Use Among Pregnant Women in Northern California After Legalization of Cannabis for Recreational Use. JAMA Netw Open. 2021 Mar 1;4(3):e210694. doi: 10.1001/jamanetworkopen.2021.0694. PMID: 33662131; PMCID: PMC7933995.

[6] Paul SE, Hatoum AS, Fine JD, Johnson EC, Hansen I, Karcher NR, Moreau AL, Bondy E, Qu Y, Carter EB, Rogers CE, Agrawal A, Barch DM, Bogdan R. Associations Between Prenatal Cannabis Exposure and Childhood Outcomes: Results From the ABCD Study. JAMA Psychiatry. 2021 Jan 1;78(1):64-76. doi: 10.1001/jamapsychiatry.2020.2902. PMID: 32965490; PMCID: PMC7512132.

be equity licensees, we do not recommend prioritizing public funds to promote cannabis sales even by equity licensees.

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

Fee deferrals or waivers may be a more appropriate way to attain this goal.

• 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

It is perfectly appropriate and highly desirable from a public health standpoint to tax THC in linear proportion to its presence and support the proposed approach. This approach should be applied to all cannabis and cannabis products.

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

We appreciate and support the use of an approach that will continuously update for prevailing price, which will help avoid reductions over time that have characterized excise taxes not adjusted for inflation.

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

We strongly support the use of the "alcohol monopoly" approach to allowing legal sale of harmful products. This approach has been successfully used in many US states and other countries. Quebec implemented its legalized cannabis system piggybacking on its alcohol monopoly and creating a public retail monopoly – the Societé Quebecois du Cannabis. The former Governor of the State of Rhode Island previously recommended this approach. Preliminary data supports this approach leading to lesser increases in use. All sections of this law should be written in such a way as to encourage, and at a minimum not obstruct, efforts by states or localities to use a public monopoly or nonprofit monopoly approach to reduce profit driven increases in cannabis consumption. Any provisions regarding anti-competitive behavior or licensing approaches that would restrict this important public health approach should be adjusted.

Federal regulation should also encourage reasonable limits on the number of retail licensees (both storefront and dispensary) to allow reasonable access without encouraging consumption. In California jurisdictions which regulate the number of storefront retailers average approximately 1 outlet per 19,000 residents.[7]

[7] Silver LD, Naprawa AZ, Padon AA. Assessment of Incorporation of Lessons From Tobacco Control in City and County Laws Regulating Legal Marijuana in California. JAMA Netw Open. 2020 Jun 1;3(6):e208393. doi: 10.1001/jamanetworkopen.2020.8393. PMID: 32558915; PMCID: PMC7305525.

Other restorative justice issues: *We strongly supports the steps to decriminalize, expunge criminal records and facilitate resentencing. It seems that the provisions assuring automatic expungement of non-violent Federal cannabis offenses were limited to juvenile offenses, although my pediatrician's reading may be defective. These should also apply to appropriate non-violent offenses committed as an adult, if that is not already the case. Our experience in California was that very few individuals were able to proactively avail themselves of the expungement process, whereas the later approved automatic expungement process offers great social benefit.*

We also strongly support the proposed elimination of cannabis as a reason for immigration actions, an important social justice measure.

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

We recommend that any mechanism to prioritize or favor public or nonprofit publicly regulated cannabis monopolies be facilitated. Where for profit licenses are allowed, equity licenses should be prioritized, for example, by only having equity candidates be eligible for licenses in the first three years. The effectiveness of current approaches to equity licensing in most communities has generally been limited and equity licensees have been out-funded and outgunned by external investors.

- **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**

We strongly support a requirement for premarket review of all cannabis products. This review should include full product composition, and the safety of all ingredients under the intended use, safety of any associated devices such as vape pens, testing results, product packaging and labeling, any associated claims. The absence of such review in many states has allowed widespread marketing of products and packaging attractive to kids, packaging mimicking established foods, and use of additives in inhalation products known to be unsafe or of unknown safety profile. In states which have engaged in product review some such problems have been caught early. This process requires adequate funding to the FDA for the needed staff and infrastructure to review large numbers of products. Criteria should include toxicity of intended ingredients, contamination or adulteration, attractiveness to children and youth of products, packaging and labeling, impact of product design on risk of youth initiation, cannabis use disorder, psychosis or other adverse effects. Compliance with warning language and other labeling requirements should be assessed. These considerations will require development of clear standards for pre-market review.

We also strongly recommend that health and therapeutic claims or functional statements for cannabis not be allowed outside of the approved pharmaceutical pathway. Federal and State agencies have shown limited capacity for enforcement of provisions based on absence of deception and false and misleading cannabis claims are rampant. Outside of the licensed pharmaceutical track there is little structure for requiring the submission of the scientific

evidence that would be needed to affirm or deny if a claim or functional statement is accurate or deceptive, and each statement would essentially require a Federal or local research project to assess veracity.

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 is a cannabis products advisory committee. It should be primarily a scientific body, and should be fully exempt from conflicts of interest. While it seeks to advise in regard to the creation of a legal industry, like tobacco, it is a legal industry producing a harmful and addictive product. While the advisory committee should be able to receive input from all stakeholders including the cannabis industry, it should not represent the interests of that industry. Just as we would not today allow the tobacco industry to directly guide its regulation, we should not do so with the cannabis industry. The heavy presence of industry stakeholders on advisory committees in several legalizing states has paralyzed public health and equity considerations. The committee should include experts in substance abuse, psychiatry and addiction medicine, youth development, cannabis pharmacology and pharmacoepidemiology, pediatrics, pediatric neurology, public health, tobacco regulatory science including regarding warning labels, cannabis agricultural economics or agricultural production, and cannabis environmental impacts. Depending on the scope of work, other social science areas or civil rights experts may be relevant.

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

The advisory committee should have the opportunity to suggest principles and guidance for product standards and other rule-making, and to review proposed rules. Their scope should include product standards including composition, product design, associated devices, contamination, potency, packaging, labeling, warning labels, claims or functional statements if allowed, controlling age access, marketing and priorities for educational investments and consumer information.

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

As noted above, we strongly support the use of the "alcohol monopoly" approach to allowing legal sale of harmful products. All sections of this law should be written in such a way as to encourage, and at a minimum, not obstruct, efforts by states or localities to use a public monopoly or nonprofit monopoly approach to reduce profit driven increases in cannabis consumption. Any provisions regarding anti-competitive behavior that would restrict this important public health approach should be adjusted.

Federal regulation should encourage reasonable limits on the number of retail licensee (both storefront and delivery) to allow reasonable access without encouraging consumption. In California jurisdictions which regulate the number of storefront retailers average approximately 1 outlet per 19,000 residents.[8] Large scale overproduction is also creating a strong incentive to push more cannabis onto the market. No provision should impede the ability of state or local government to limit the number of licensees or the volume of cannabis production.

Consumers should benefit from strong rotating graphic warning labels and other consumer information, and should be rigorously protected from misleading or unfounded statements.

• 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

Because extensive product diversification by the industry has launched such a large volume of dangerously formulated and designed products and products attractive to youth, all currently marketed products should be subjected to a product review to verify compliance with the regulations established by the FDA within three years of their publication. FDA should have clear authority to prohibit products which do not comply with new standards. No grandfathering provisions should protect existing state-licensed products. Manufacturers should be provided a reasonable period to modify their products to come into compliance, such as one year unless the product is considered excessively high risk.

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

Whatever the approach taken, we would request that all data from the track and trace system by subject to the Freedom of Information Act and publicly available.

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

A single, transparent Federal system would be preferable and facilitate national understanding, research and surveillance of industry trends and public health risks. It should however retain the maximum degree of geographic resolution and permit analyses at the state and local level, by product types, potency, price, flavors if allowed, and other characteristics

The Sponsoring Offices request comment on additional, general, and unspecified items, including—
• Interactions with state and local laws

A principle of not preempting state or local laws more stringent then the Act should be maintained.

[8] Silver LD, Naprawa AZ, Padon AA. Assessment of Incorporation of Lessons From Tobacco Control in City and County Laws Regulating Legal Marijuana in California. JAMA Netw Open. 2020 Jun 1;3(6):e208393. doi: 10.1001/jamanetworkopen.2020.8393. PMID: 32558915; PMCID: PMC7305525.

• Interactions and additional considerations regarding hemp

We strongly encourage deleting the allowance for CBD as a supplement, given that it violates the current separation between approved pharmaceuticals and supplements or foods, and that it is has numerous well documented (See Epidiolex approval process) adverse effects and medication interactions.[9],[10] Hemp derived cannabinoids should not be permitted for use in food or supplements.

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

A key concern of ours is the need for the Act to have as part of its key principles not resulting in increased consumption of cannabis or cannabis use disorder. This principle is present in parts of New York's law and Quebec's, for example. Protection of youth and of public health should also be a stated aim.

Second the law should expressly extend all federal smoke-free air provisions to consistently include smoking, vaporizing or dabbing cannabis indoors and outdoors.

Third, the law should require that all cannabis licensees be specialized businesses. Supermarkets, pharmacies and restaurants should not be cannabis businesses.

Fourth, restrict cannabis marketing to the maximum extent allowable under US Law. To the extent allowed, do not permit marketing where audiences will be less than 85% over age 21.[11] The current widely used voluntary standard from the alcohol industry is ineffective and does not adequately protect children.

Fifth, a greater specific portion of the tax revenue should be directed towards substance abuse prevention programs and mass and social media education campaigns on harms of cannabis use, not limited to driving under the influence.

[9] Huestis MA, Solimini R, Pichini S, Pacifici R, Carlier J, Busardò FP. Cannabidiol Adverse Effects and Toxicity. *Curr Neuropharmacol*. 2019;17(10):974-989. doi:10.2174/1570159X17666190603171901

[10] Yamaori S, Ebisawa J, Okushima Y, Yamamoto I, Watanabe K. Potent inhibition of human cytochrome P450 3A isoforms by cannabidiol: Role of phenolic hydroxyl groups in the resorcinol moiety. *Life Sciences*. 2011;88(15-16):730-736. doi:10.1016/j.lfs.2011.02.017

[11] National Research Council and Institute of Medicine (2004). Reducing Underage Drinking: A Collective Responsibility. Committee on Developing a Strategy to Reduce and Prevent Underage Drinking, Richard J. Bonnie and Mary Ellen O'Connell, Editors. Board on Children, Youth, and Families, Division of Behavioral and Social Sciences and Education. Washington, DC: The National Academies Press.

We respectfully request that you consider the evidence in support of these considerations and proceed with an appropriate balance of caution, to reduce the burden of injustice while protecting against the consolidation of a new tobacco-like industry.

Sincerely,

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