Getting it Right from the Start
Advancing Public Health & Equity in Cannabis Policy

July 22, 2024

Drug Enforcement Administration
Attn: Administrator Ann Milgram
Drug and Chemical Evaluation Section
8701 Morrissette Drive
Springfield, Virginia 22152
nprm@dea.gov

RE: Request for Public Comment on the Proposed Rule Rescheduling Marijuana, Docket No. DEA-1362

Dear Administrator Milgram,

Thank you for the opportunity to comment on the Proposed Rule Rescheduling Marijuana, Docket No. DEA-1362. On behalf of the Prevention Policy Group's *Getting it Right from the Start*, a program of the Public Health Institute (PHI), we write to share our comments.

PHI is an Oakland, California-based 501c3 nonprofit organization with 60 years of experience working in the State of California, nationally, and across the globe to advance health equity, well-being, and quality of life for all people. Getting it Right from the Start has worked across California and nationally since 2017 to advance marijuana policies that better protect youth, public health, and social equity where sales have been legalized. We develop model local laws, annually analyze the laws and retail presence of marijuana, and carry out NIH- and state-funded research on marijuana policy and effects on populations vulnerable to the harms of marijuana. We have worked with over 100 local jurisdictions, the CDC, in 15 states, and with hundreds of community partners on their approaches to marijuana policy. We have also developed model hemp laws and briefs and are working with state and local governments on the issue of intoxicating hemp.

Briefly, our comments center on two key recommendations:

> **1) Different marijuana products should be rescheduled differently based on their composition and risk, including concentration and modes of administration; and**
>
> **2) All university and NIH-funded researchers should be allowed to purchase and possess any marijuana products available in states with legal medical and/or adult-use markets to conduct research.**

We are at a critical juncture in marijuana policy, with legalization spreading rapidly across the United States and globally. As this movement progresses, whether you support or

oppose it, there is a pressing need to ensure that policies prioritize the protection of youth and the reduction of harm.

Marijuana legalization, while bringing positive outcomes such as decreased arrests and expungement of criminal records, has also given rise to an aggressive industry working from the tobacco industry's playbook. The unfettered nature of legalization has led to a profit-driven legal industry that prioritizes driving up consumption over public health. This has, in turn, resulted in a complex market that bears little resemblance to the marijuana of the time when the Controlled Substance Act was passed or when marijuana was defined. The traditional low-potency botanical is hard to find today. Flower currently sold is now typically 20-25% THC in California, roughly five to eight-fold stronger.[1] A vast array of ultra-high potency vapes and other concentrates has emerged, up to and including products with over 95% THC.

Figure. Example of Flavored High Potency Concentrate and Marketing

These very high potency products are often marketed with flavors known to attract youth and packaging and marketing imitating brands commonly marketed to children.

A massive edible market has also emerged, often with high doses in a single small container (to cite just one example, Uncle Arnie's beverages with 100mg THC in a small energy shot size container accompanied by cartoons on the package). This has been compounded by the emergence of similar or even more hazardous products on the hemp market, with a wide array of synthetic intoxicating THC variants, as noted in FDA's recent joint enforcement letters with the FTC.

While a small number of evidence-based medical uses exist, as discussed in the National

[1] Geweda MM, Majumdar CG, Moore MN, Elhendawy MA, Radwan MM, Chandra S, ElSohly MA. Evaluation of dispensaries' marijuana flowers for accuracy of labeling of cannabinoids content. J Marijuana Res. 2024 Mar 9;6(1):11. doi: 10.1186/s42238-024-00220-4.

Academies of Science, Engineering and Medicine's landmark 2017 report,[2] a much larger number of poorly supported indications are actively promoted by the industry or erroneously recognized in state laws and regulations. Other helpful uses may emerge if research is allowed to proceed more effectively, as well as a deeper and more realistic product-specific understanding of the potential for abuse and harm. Provisions are urgently needed to ensure that this research can take place in the future. Decisions about the existence of acceptable medical uses should be based on high-quality research consistent with FDA standards, including dose and mode of administration, rather than on common practice, which may lack scientific support or be harmful.

Consumption by adults, especially young adults has skyrocketed, with over one in ten young American adults getting high daily or near daily,[3] triple past rates and 14.4% of of young adults aged 18 to 25 with a marijuana use disorder or 4.8 million people.[4] Rates of emergency room use, from infant and child poisonings[5] to seniors[6] have skyrocketed. Marijuana induced psychosis[7] is increasing. Between 2002-2003 and 2016-2017, use during pregnancy doubled and daily/near daily use tripled (quintupling in 3rd trimester),[8] with significant associated harms to both mothers and infants.[9,10] As use increases, marijuana associated cardiovascular disease,[11] may also be become more common.

[2] National Academies of Sciences, Engineering and Medicine. The Health Effects of *Marijuana* and Cannabinoids: The Current State of Evidence and Recommendations for Research. National Academies Press, Washington, DC (2017)
[3] Patrick ME, Pang YC, Terry-McElrath YM, Arterberry BJ. Historical Trends in Marijuana Use among U.S. Adults Aged 19-55, 2013-2021. J Stud Alcohol Drugs. 2024 Feb 27. doi: 10.15288/jsad.23-00169..
[4] Substance Abuse and Mental Health Services Administration. (2022). Key substance use and mental health indicators in the United States: Results from the 2021 National Survey on Drug Use and Health (HHS Publication No. PEP22-07-01-005, NSDUH Series H-57).Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. https://www.samhsa.gov/data/report/2021-nsduh-annual-national-report
[5] Edible Marijuana. America's Poison Centers. https://poisoncenters.org/track/edible-marijuana
[6] Han BH, Brennan JJ, Orozco MA, Moore AA, Castillo EM. Trends in emergency department visits associated with marijuana use among older adults in California, 2005-2019. J Am Geriatr Soc. 2023 Apr;71(4):1267-1274. doi: 10.1111/jgs.18180.
[7] D'Souza DC, DiForti M, Ganesh S, George TP, Hall W, Hjorthøj C, Howes O, Keshavan M, Murray RM, Nguyen TB, Pearlson GD, Ranganathan M, Selloni A, Solowij N, Spinazzola E. Consensus paper of the WFSBP task force on marijuana, cannabinoids and psychosis. World J Biol Psychiatry. 2022 Dec;23(10):719-742. doi: 10.1080/15622975.2022.2038797.
[8] Volkow ND, Han B, Compton WM, McCance-Katz EF. Self-reported Medical and Nonmedical Cannabis Use Among Pregnant Women in the United States. JAMA. 2019 Jul 9;322(2):167-169. doi: 10.1001/jama.2019.7982.
[9] Avalos LA, Adams SR, Alexeeff SE, Oberman NR, Does MB, Ansley D, Goler N, Padon AA, Silver LD, Young-Wolff KC. Neonatal outcomes associated with in utero marijuana exposure: a population-based retrospective cohort study. Am J Obstet Gynecol. 2024 Jul;231(1):132.e1-132.e13. doi: 10.1016/j.ajog.2023.11.1232..
[10] Young-Wolff KC, Adams SR, Alexeeff SE, et al. Prenatal Cannabis Use and Maternal Pregnancy Outcomes. *JAMA Intern Med.* Published online July 22, 2024. doi:10.1001/jamainternmed.2024.3270
[11] Jeffers AM, Glantz S, Byers AL, Keyhani S. Association of Marijuana Use With Cardiovascular Outcomes Among US Adults. J Am Heart Assoc. 2024 Mar 5;13(5):e030178. doi: 10.1161/JAHA.123.030178.

Marijuana induced psychosis and schizophrenia,[12] and long-term harms to children who have been exposed in utero,[13,14] represent two of the most significant and increasing risks to public health. While effects are typically less immediately lethal or severe than those of fentanyl or heroin, because use is so much more widespread, overall population health impacts are highly significant.

These trends all indicate the need to act prudently. As one of the most widely consumed substances of abuse, the potential for significant harm to population health cannot be treated lightly.

You share eight key points for analysis: 1. The drug's actual or relative potential for abuse; 2. Scientific evidence of its pharmacological effect, if known; 3. The state of current scientific knowledge regarding the drug or other substance; 4. Its history and current pattern of abuse; 5. The scope, duration, and significance of abuse; 6. What, if any, risk there is to the public health; 7. Its psychic or physiological dependence liability; and 8. Whether the substance is an immediate precursor of a substance already controlled.

Numerous studies, provided in the footnotes, find a detrimental direction of effect for

[12] D'Souza DC, DiForti M, Ganesh S, George TP, Hall W, Hjorthøj C, Howes O, Keshavan M, Murray RM, Nguyen TB, Pearlson GD, Ranganathan M, Selloni A, Solowij N, Spinazzola E. Consensus paper of the WFSBP task force on marijuana, cannabinoids and psychosis. World J Biol Psychiatry. 2022 Dec;23(10):719-742. doi: 10.1080/15622975.2022.2038797.
[13] Baranger DA, Miller AP, Gorelik AJ, Paul SE, Hatoum AS, Johnson EC, Colbert SM, Smyser CD, Rogers CE, Bijsterbosch JD, Agrawal A, Bogdan R. Prenatal marijuana exposure is associated with localized brain differences that partially mediate associations with increased adolescent psychopathology. medRxiv [Preprint]. 2023 Oct 17:2023.09.19.23295792. doi: 10.1101/2023.09.19.23295792.
[14] Baranger DAA, Paul SE, Colbert SMC, Karcher NR, Johnson EC, Hatoum AS, Bogdan R. Association of Mental Health Burden With Prenatal Marijuana Exposure From Childhood to Early Adolescence: Longitudinal Findings From the Adolescent Brain Cognitive Development (ABCD) Study. JAMA Pediatr. 2022 Dec 1;176(12):1261-1265. doi: 10.1001/jamapediatrics.2022.3191.

higher potency products for psychosis,[15] high-frequency or problem use,[16] and cannabis use-disorder,[17] although data quality may preclude quantitative meta-analyses. These

[15] Di Forti M, Morgan C, Dazzan P, Pariante C, Mondelli V, Marques TR, Handley R, Luzi S, Russo M, Paparelli A, Butt A, Stilo SA, Wiffen B, Powell J, Murray RM. High-potency cannabis and the risk of psychosis. Br J Psychiatry. 2009;195:488-491.
Hines LA, Freeman TP, Gage SH, Zammit S, Hickman M, Cannon M, Munafo M, MacLeod J, Heron J. Association of high-potency cannabis use with mental health and substance use in adolescence. JAMA Psychiatry. 2020;77:1044-1051.
Di Forti M, Sallis H, Allegri F, Trotta A, Ferraro L, Stilo SA, Marconi A, La Cascia C, Reis Marques T, Pariante C, Dazzan P, Mondelli V, Paparelli A, Kolliakou A, Prata D, Gaughran F, David AS, Morgan C, Stahl D, Khondoker M, MacCabe JH, Murray RM. Daily use, especially of high-potency cannabis, drives the earlier onset of psychosis in cannabis users. Schizophr Bull. 2014;40:1509-1517.
Di Forti M, Marconi A, Carra E, Fraietta S, Trotta A, Bonomo M, Bianconi F, Gardner-Sood P, O'Connor J, Russo M, Stilo SA, Marques TR, Mondelli V, Dazzan P, Pariante C, David AS, Gaughran F, Atakan Z, Iyegbe C, Powell J, Morgan C, Lynskey M, Murray RM. Proportion of patients in south London with first-episode psychosis attributable to use of high potency cannabis: a case-control study. Lancet Psychiatry. 2015;2:233-238.
Di Forti M, Quattrone D, Freeman TP, Tripoli G, Gayer-Anderson C, Quigley H, Rodriguez V, Jongsma HE, Ferraro L, La Cascia C, La Barbera D, Tarricone I, Berardi D, Szoke A, Arango C, Tortelli A, Velthorst E, Bernardo M, Del-Ben CM, Menezes PR, Selten JP, Jones PB, Kirkbride JB, Rutten BP, deHaan L, Sham PC, van Os J, Lewis CM, Lynskey M, Morgan C, Murray RM, Group E-GW. 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;6:427-436.
Quattrone D, Ferraro L, Tripoli G, La Cascia C, Quigley H, Quattrone A, Jongsma HE, Del Peschio S, Gatto G, Gayer-Anderson C, Jones PB, Kirkbride JB, La Barbera D, Tarricone I, Berardi D, Tosato S, Lasalvia A, Szoke A, Arango C, Bernardo M, Bobes J, Del Ben CM, Menezes PR, Llorca PM, Santos JL, Sanjuan J, Tortelli A, Velthorst E, de Haan L, Rutten BPF, Lynskey MT, Freeman TP, Sham PC, Cardno AG, Vassos E, van Os J, Morgan C, Reininghaus U, Lewis CM, Murray RM, Di Forti M, grp E-G. Daily use of high-potency cannabis is associated with more positive symptoms in first-episode psychosis patients: the EU-GEI case-control study. Psychol Med. 2021;51:1329-1337.
Schoeler T, Petros N, Di Forti M, Klamerus E, Foglia E, Ajnakina O, Gayer-Anderson C, Colizzi M, Quattrone D, Behlke I, Shetty S, McGuire P, David AS, Murray R, Bhattacharyya S. Effects of continuation, frequency, and type of cannabis use on relapse in the first 2 years after onset of psychosis: an observational study. Lancet Psychiatry. 2016;3:947-953.
Schoeler T, Petros N, Di Forti M, Klamerus E, Foglia E, Murray R, Bhattacharyya S. Effect of continued cannabis use on medication adherence in the first two years following onset of psychosis. Psychiatry Res. 2017;255:35-41.
[16] Bidwell LC, York Williams SL, Mueller RL, Bryan AD, Hutchison KE. Exploring cannabis concentrates on the legal market: User profiles, product strength, and health-related outcomes. Addict Behav Rep. 2018;8:102-106.
Barrington-Trimis JL, Cho J, Ewusi-Boisvert E, Hasin D, Unger JB, Miech RA, Leventhal AM. Risk of persistence and progression of use of 5 cannabis products after experimentation among adolescents. JAMA Netw Open. 2020;3:e1919792.
Chan GCK, Hall W, Freeman TP, Ferris J, Kelly AB, Winstock A. User characteristics and effect profile of Butane Hash Oil: An extremely high-potency cannabis concentrate. Drug Alcohol Depend. 2017;178:32-38.
Craft S, Winstock A, Ferris J, Mackie C, Lynskey MT, Freeman TP. Characterising heterogeneity in the use of different cannabis products: latent class analysis with 55 000 people who use cannabis and associations with severity of cannabis dependence. Psychol Med. 2020;50:2364-2373.
Daniulaityte R, Lamy FR, Barratt M, Nahhas RW, Martins SS, Boyer EW, Sheth A, Carlson RG. Characterizing marijuana concentrate users: A web-based survey. Drug Alcohol Depend. 2017;178:399-407.
Hines LA, Freeman TP, Gage SH, Zammit S, Hickman M, Cannon M, Munafo M, MacLeod J, Heron J. Association of high-potency cannabis use with mental health and substance use in adolescence. JAMA Psychiatry. 2020;77:1044-1051.
Meier MH. Associations between butane hash oil use and cannabis-related problems. Drug Alcohol Depend. 2017;179:25-31.
Okey SA, Meier MH. A within-person comparison of the subjective effects of higher vs. lower-potency cannabis. Drug Alcohol Depend. 2020;216:108225.
Palamar JJ, Lee L, Weitzman M. Prevalence and correlates of hashish use in a national sample of high school seniors in the United States. Am J Drug Alcohol Abuse. 2015;41:197-205.
Sagar KA, Lambros AM, Dahlgren MK, Smith RT, Gruber SA. Made from concentrate? A national web survey assessing dab use in the United States. Drug Alcohol Depend. 2018;190:133-142.
[17] Loflin M, Earleywine M. A new method of cannabis ingestion: the dangers of dabs? Addict Behav. 2014;39:1430-1433.
Bidwell LC, York Williams SL, Mueller RL, Bryan AD, Hutchison KE. Exploring cannabis concentrates on the legal market: User profiles, product strength, and health-related outcomes. Addict Behav Rep. 2018;8:102-106.

increases in frequency and problem use in turn increase the risk of most adverse outcomes, including for mental health and for pregnancy.

Our key comment is the following: despite the broad statutory definitions of marijuana, including "derivatives," the current complexity of this market in relation to these eight points means that "marijuana" cannot and should not be treated as a single entity for purposes of scheduling.

Instead, the DEA should recognize that "marijuana" is an umbrella term that covers a broad array of chemical substances and mixtures. The risks of addiction and the existence of accepted medical use are not homogenous across this wide range of products. Codeine, for example, is spread across schedules based on the risk of the specific product type. That approach would appear more reasonable for marijuana than treating the entire market uniformly. To reschedule all marijuana products that the industry has been able to imagine and create, no matter how hazardous or bereft of medical uses, makes little sense.

Focusing the benefits of rescheduling on a somewhat safer subset of cannabis products, that hew more closely to the eligibility criteria, would have the salutary effect of encouraging markets to shift back to somewhat safer, lower potency products to obtain tax benefits and potentially help reverse the dangerous and inexorable trend to higher and higher potency we have seen over the past decades.

Craft S, Winstock A, Ferris J, Mackie C, Lynskey MT, Freeman TP. Characterising heterogeneity in the use of different cannabis products: latent class analysis with 55 000 people who use cannabis and associations with severity of cannabis dependence. Psychol Med. 2020;50:2364-2373.

Hines LA, Freeman TP, Gage SH, Zammit S, Hickman M, Cannon M, Munafo M, MacLeod J, Heron J. Association of high-potency cannabis use with mental health and substance use in adolescence. JAMA Psychiatry. 2020;77:1044-1051.

Matsumoto T, Kawabata T, Okita K, Tanibuchi Y, Funada D, Murakami M, Usami T, Yokoyama R, Naruse N, Aikawa Y, Furukawa A, Komatsuzaki C, Hashimoto N, Fujita O, Umemoto A, Kagaya A, Shimane T. Risk factors for the onset of dependence and chronic psychosis due to cannabis use: Survey of patients with cannabis-related psychiatric disorders. Neuropsychopharmacol Rep. 2020;40:332-341.

Meier MH. Associations between butane hash oil use and cannabis-related problems. Drug Alcohol Depend. 2017;179:25-31.

Okey SA, Waddell JT, Corbin WR. I smoke alone: Indirect effects of solitary cannabis use on negative consequences through coping motives. J Stud Alcohol Drugs. 2022;83:721-730.

Sagar KA, Lambros AM, Dahlgren MK, Smith RT, Gruber SA. Made from concentrate? A national web survey assessing dab use in the United States. Drug Alcohol Depend. 2018;190:133-142.

We recommend:

1) Rescheduling should vary based on the specific composition of products, including concentration and modes of administration. Assessment of the eight points should be specific to different product groups and substances. Specific examples follow:

    a. Rescheduling should be agnostic as to whether the plant from which a product is derived was legally hemp or marijuana.

    b. Synthetically derived intoxicating cannabinoids, other than those approved for use by the FDA as pharmaceuticals, should remain or be placed on Schedule I or II, until or unless new evidence of safety and medical use emerges. These recently marketed substances have no accepted medical uses, lack significant study of safety, and yet appear to have the potential to generate significant psychological or physical dependence, as well as adverse effects, although data is insufficient.[18] These include, but are not limited to
        - Delta-3-tetrahydrocannabinol
        - Synthesized Delta-8-Tetrahydrocannabinol
        - Delta-8-Carboxy-Tetrahydrocannabinol
        - Delta-8-tetrahydrocannabinol acetate ester
        - Delta-9-Carboxy-Tetrahydrocannabinol
        - Delta-9-tetrahydrocannabinol acetate ester
        - Synthesized Delta-10-tetrahydrocannabinol
        - Delta-11-tetrahydrocannabinol
        - Hexahydrocannabinol
        - Hexahydrocannabinol-O-acetate
        - Hexahydrocannabiphorol
        - Tetrahydrocannabinol-O-acetate
        - Tetrahydrocannabioctyl
        - Tetrahydrocannabihexol
        - Tetrahydrocannabutol

[18] Denton EE, Jung SS, Ventura CAI. Clinical Diagnosis and Management of Gradual Onset Cannabis-Induced Psychosis Following the Consumption of Delta-8-Tetrahydrocannabinol. Cureus. 2024 Mar 3;16(3):e55464. doi: 10.7759/cureus.55464.

- Tetrahydrocannabiphorol
- Tetrahydrocannabiphorol Acetate
- 11-Nor-9-Carboxy-Delta-9-Tetrahydrocannabinol

c. High-potency concentrates such as shatter, wax, "Rick Simpson oil," very high potency vapes, etc., which have no documented medical benefits, but appear to carry a greater risk of generating addiction and psychosis, amongst other harms, should remain on Schedule I or II. These products have a higher potential for abuse and are more likely to lead to significant psychological or physical dependence and harm. Products for dabbing, for example, which provide amongst the most elevated doses, have a high potential for harm and no acceptable medical use. They do not belong on Schedule III. Regulators have varied in allowable cutoff points, with some U.S. States prohibiting concentrates over 60% THC and Quebec prohibiting all marijuana products over 30% THC.

d. Consider limiting the rescheduling of flower to Schedule III to lower potency products. While risk appears to increase above 10% THC, a least for psychosis,[19] it is unclear what the optimal cutoff is. Below 15% or 20% THC may be more reasonable. Similarly, edible rescheduling could be limited to lower-dose products. In general, research on marijuana medical uses has focused on products with lower doses and concentrations,[20] and while higher potency products are being used, it is not clear that there is evidence that they have accepted medical use.

e. Consider rescheduling topical products to lower risk schedules.

2) Allow researchers to work more closely with marijuana products available in state-regulated markets. This recommendation is adapted from comments being

[19] Di Forti M, Quattrone D, Freeman TP, Tripoli G, Gayer-Anderson C, Quigley H, Rodriguez V, Jongsma HE, Ferraro L, La Cascia C, La Barbera D, Tarricone I, Berardi D, Szöke A, Arango C, Tortelli A, Velthorst E, Bernardo M, Del-Ben CM, Menezes PR, Selten JP, Jones PB, Kirkbride JB, Rutten BP, de Haan L, Sham PC, van Os J, Lewis CM, Lynskey M, Morgan C, Murray RM; EU-GEI WP2 Group. The contribution of marijuana use to variation in the incidence of psychotic disorder across Europe (EU-GEI): a multicentre case-control study. Lancet Psychiatry. 2019 May;6(5):427-436. doi: 10.1016/S2215-0366(19)30048-3. Epub 2019 Mar 19.
[20] Bero L, Lawrence R, Oberste JP, Li T, Leslie L, Rittiphairoj T, Piper C, Wang GS, Brooks-Russell A, Yim TW, Tung G, Samet JM. Health Effects of High-Concentration Marijuana Products: Scoping Review and Evidence Map. Am J Public Health. 2023 Dec;113(12):1332-1342. doi: 10.2105/AJPH.2023.307414.

submitted by the University of California, however, we extend the exception to all NIH-funded research.

We are concerned that the DEA's effort to reschedule marijuana, marijuana extracts, and naturally derived delta-9-THC from Schedule I to Schedule III would still not allow researchers to conduct studies with products available in states that have passed medical and adult use marijuana laws. This would continue to hinder scientific understanding of marijuana and how marijuana impacts users of these products and others. On several occasions, the DEA notes in the NPRM that "additional information arising from this rulemaking will further inform the findings regarding the appropriate schedule for marijuana." For example, for Factor 5, the DEA notes that "additional information regarding the scope, duration, and significance of marijuana abuse may be appropriate for consideration in assessing this factor." Researchers are eager to fill any knowledge gaps, however, there is not currently a way for them to study marijuana products that individuals can buy in their own states.

Moreover, legal marijuana products are available in an array of forms (plant, edibles, vaping liquid, topical) that are currently unavailable when obtained through DEA-approved bulk marijuana suppliers. The effects of these varying modes of delivery and potential interactions with additive substances are insufficiently understood, and that will continue without proper research. We ask that the DEA exclude marijuana and marijuana derivatives, including plant-based derivatives and synthetically derived materials, that are used for conducting vetted research from the Schedule III and Schedule I classifications, respectively, to allow researchers to conduct research on marijuana products procured from any source legally operating in compliance with state laws.

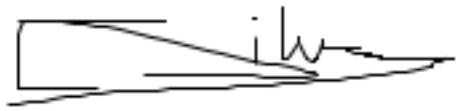
For example, DEA can include language in the proposed rule in § 1308.13(k) to specify that:

"An institution of higher education, as defined in Section 101 of the federal Higher Education Act of 1965 (20 U.S.C. Sec. 1001), or research institution engaged in National Institutes of Health funded research, may access and possess marijuana, marijuana extracts, and naturally derived delta-9-tetrahydrocannabinol available in

states that have enacted medical use and/or adult non-medical use marijuana laws, for the purposes of conducting academic research."

We appreciate the opportunity to contribute to this important regulatory discussion and are available to respond to any questions at lsilver@phi.org. We would also appreciate the ability to participate in any future hearings.

Sincerely,



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