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July 22, 2024

The Honorable Anne Milgram  
Administrator  
Drug Enforcement Administration

*Comments Submitted Electronically via Regulations.gov*

**Re: Docket No. DEA-1362 relating to the rescheduling of marijuana under the Controlled Substances Act**

Dear Administrator Milgram,

On behalf of the Schizophrenia & Psychosis Action Network (“SPAN”), thank you for the opportunity to provide comment on this proposed rule that seeks to reschedule marijuana from a schedule I to a schedule III controlled substance under the Controlled Substances Act (“CSA”).

SPAN is a 501(c)(4) advocacy organization that works to advance policies that shatter barriers to care for people living with schizophrenia and psychosis. Schizophrenia and psychosis disorders represent a unique subset of the broader mental health community; these conditions warrant special consideration as severe brain diseases.

It is estimated that there are 2.65 million people in the U.S. living with schizophrenia.<sup>1</sup> Schizophrenia is thought to be a progressive neurodevelopmental disorder that often first appears during adolescence as the brain is developing.<sup>2</sup> While genetic risk factors for schizophrenia have been identified, it is generally believed that a complex interplay between genetics and environment is responsible.<sup>3</sup> Disruptions in neurodevelopmental processes and other environmental factors, such as cannabis use, may result in the worsening of symptoms for those with schizophrenia.

It is from this perspective that SPAN urges the Department of Justice (“DOJ”) to carefully consider this proposed rule and its effect on all communities, particularly those with severe brain disease, and retain marijuana’s current classification as a schedule I controlled substance. As recently as 2016, the Drug Enforcement Administration (“DEA”) declined to accept a petition to reschedule marijuana, and SPAN believes this continues to be the best course of action.

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<sup>1</sup> Schizophrenia & Psychosis Action Alliance. (2021). *Societal Costs of Schizophrenia & Related Disorders* [Infographic]. [sczaction.org](https://www.sczaction.org). Retrieved from <https://www.sczaction.org>.

<sup>2</sup> Than, K.-S., Birch, K., Ching, K., Shafrin, J., Chou, J., & Baumgardner, J. (2021). *Societal Costs of Schizophrenia & Related Disorders* (p. 6). Schizophrenia & Psychosis Action Alliance. Retrieved from <https://www.sczaction.org>.

<sup>3</sup> *Id.*

We respectfully submit our comments structured largely around the eight-factor analysis required to support reclassification of a controlled substance under the CSA, focused on the factors for which SPAN has unique expertise and insight to offer.

***Failure to address or consider the impacts of marijuana on those with schizophrenia and psychosis undermines the eight-factor analysis conducted by the U.S. Department of Health and Human Services (“HHS”), and challenges the recommendation to reschedule marijuana to a class III controlled substance***

As detailed in the proposed rule, HHS conducted the eight-factor analysis required under the CSA for rescheduling drugs and, as a result, recommended to the DEA in August 2023 that marijuana be reclassified from a schedule I to a schedule III controlled substance. In further compliance with the CSA, the DOJ, through the DEA, has conducted its own eight-factor analysis (with deference to HHS), and states that “factual evidence (including scientific data) and expert opinions, including additional data regarding different forms, formulations, and delivery methods for marijuana, as well as evidence regarding the effects of marijuana at various dosages or concentrations, may be relevant”<sup>4</sup> to its evaluation of the current proposed rule.

In review of the rule and the eight-factor analysis initially produced by HHS and under current evaluation by the DEA, SPAN has recognized a glaring absence of attention paid to the impact on those suffering with schizophrenia and psychosis, as well as those at risk of these severe brain diseases. The analysis fails to provide evidence or reasoning to quell our concerns regarding the adverse effects marijuana will have on this particularly vulnerable population. The failure to address the anticipated impact on these communities speaks to a flaw in the eight-factor analysis conducted by HHS, undermining aspects of the reasoning upon which HHS issued its August 2023 recommendation, and which DEA should carefully consider in its current review of this proposed rule.

We believe that the analysis does not support moving marijuana from a schedule I to a schedule III controlled substance when evaluated through the lens of those suffering with schizophrenia and psychosis or at risk of such severe brain diseases for the reasons outlined below.

***Factor 1: Marijuana’s actual or relative potential for abuse appears to be on the rise given the increasing potency of the active ingredients in the drug***

In this proposed rule, the DEA acknowledges “that additional data in this area may be appropriate for consideration”<sup>5</sup> in the assessment of marijuana’s potential for abuse. We agree, particularly regarding the need for additional data regarding cannabis impacts those with schizophrenia and psychosis, or those who are at risk for such diseases.

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<sup>4</sup> Schedules of Controlled Substances: Rescheduling of Marijuana, Vol. 89, No. 99, Fed Reg. at 44601, May 21, 2024

<sup>5</sup> *Id.*

We know that the increasing potency of tetrahydrocannabinol (THC), the compound responsible for most of marijuana’s psychological effects, raises the drug’s risk and potential for abuse.<sup>6</sup> From 1995 to 2021, the average concentration of THC in marijuana has risen almost 400 percent.<sup>7</sup> Over the past two decades, the risk of potential marijuana abuse has heightened dramatically alongside the increasing THC concentration, raising serious questions about whether it should be rescheduled. Though HHS concluded that marijuana has a lower potential for abuse when compared to other controlled substances, the meteoric rise in potency since 1995 may undermine this conclusion.

Moreover, in Section VII “Determination of Appropriate Schedule for Marijuana” of this proposed rule, the DOJ lays out “[o]verall, these data demonstrate that \*\*\* marijuana is associated with a high prevalence of abuse,” but continues on to reason that the outcomes related to abuse warrant rescheduling marijuana to a schedule III controlled substance.<sup>8</sup> From SPAN’s perspective, we agree that marijuana has a high prevalence of abuse, but disagree that the “serious outcomes” related to this abuse are understood well enough to justify rescheduling marijuana. Without appropriate study and consideration of the outcomes on those living with schizophrenia and psychosis, and others suffering from severe brain diseases, any conclusions about the outcomes of marijuana abuse are premature. At the very least, further study of the actual or relative potential for abuse of marijuana in varying forms, formulas, and delivery methods, as well as varying levels of potency, is needed before rescheduling marijuana to a schedule III controlled substance.

***Factor 3: The wide variability of cannabinoid concentrations and chemical constituency among marijuana samples, as well as the significant impact the route of drug administration has on the pharmacokinetic profile of marijuana, warrants greater scientific understanding and more scientific knowledge before marijuana is rescheduled***

In the analysis of this factor, both HHS and DEA recognize the great variation in the pharmacokinetic profile of marijuana depending on the route of drug administration, as well as considerable variability in the cannabinoid concentrations and chemical constituency across marijuana samples, ultimately arriving at the conclusion that additional data may be appropriate for consideration. SPAN agrees that additional data and further research are justified given the likelihood that different formulations of marijuana are likely to have different impacts on users.

Specifically concerning the community SPAN represents, studies have shown that the use of high-potency cannabis can significantly increase the risk of developing a psychotic disorder such

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<sup>6</sup> Petrilli K, Ofori S, Hines L, Taylor G, Adams S, Freeman TP. Association of cannabis potency with mental ill health and addiction: a systematic review. *Lancet Psychiatry*. 2022;9(9):736- 750. doi:10.1016/S2215-0366(22)00161-4

<sup>7</sup> National Institute on Drug Abuse. Cannabis Potency Data.; 2022. <https://nida.nih.gov/research/research-data-measures-resources/cannabis-potency-data>

<sup>8</sup> Schedules of Controlled Substances: Rescheduling of Marijuana, Vol. 89, No. 99, Fed Reg. at 44616, May 21, 2024

as schizophrenia.<sup>9</sup> The increasing availability of high-potency cannabis will only continue if marijuana is rescheduled, likely increasing the instances of marijuana-induced psychosis.

Daily cannabis usage is associated with an increased risk of developing a psychotic disorder compared to never-users, while daily usage of highly potent cannabis increases the odds of a psychotic disorder developing by nearly five times.<sup>3</sup> It is imperative that the DOJ reviews this data when making their decision to reschedule marijuana. It is vital that the effects of high potency be studied thoroughly before marijuana is reschedule so the risks of psychosis onset are fully understood.

***Factor 6: Marijuana’s impact on public health is greater than recognized, particularly considering the link between marijuana and schizophrenia and psychosis***

In the DOJ’s proposal to reschedule marijuana, the subjective responses to marijuana in humans are described as “known and characterized since antiquity,”<sup>10</sup> though there is no mention of its high-risk potential to affect those with psychotic disorders. This assumption poses a direct danger to the health of those with schizophrenia, disregarding their importance as a subset within the larger public.

Though marijuana and CBD have been shown to have positive effects on certain mental disorders, like anxiety, it is still necessary to review the negative side effects it will have on those with rarer disorders. The risks marijuana poses to those with psychotic disorders like schizophrenia, detailed in above paragraphs, have not yet been reviewed or considered by the DEA or HHS in the analysis of this rescheduling effort thus far. The DOJ must carefully weigh the benefits and risks of marijuana, accounting for all populations and mental disorders. The perspective we represent, emphasizing the unique risks faced by these vulnerable populations, is crucial and cannot be ignored in this rescheduling effort. Maintaining the health and safety of these populations is essential to protect public health and uphold the integrity of mental health care.

Furthermore, it is estimated that 8%-32% of psychotic disorders might be prevented if heavy cannabis use were stopped.<sup>11</sup> The availability of high-potency cannabis (which is already at an all-time-high) will only continue to increase if marijuana is rescheduled. Those susceptible to the onset of psychotic disorders associated with heavy cannabis use, like adolescents, will have a higher likelihood of developing those disorders if nothing is done to protect them.

The risk to public health, therefore, is not limited to those who have disorders such as schizophrenia, but those vulnerable to developing them. In the interest of these individuals and broader public health, we must protect these populations, and reschedule marijuana only when the research is clear in how it impacts all potential users.

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<sup>9</sup> Di Forti M, 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 May;6(5):427-436. doi: 10.1016/S2215-0366(19)30048-3. Epub 2019 Mar 19. PMID: 30902669; PMCID: PMC7646282.

<sup>10</sup> Schedules of Controlled Substances: Rescheduling of Marijuana, Vol. 89, No. 99, Fed Reg. at 44604, May 21, 2024

<sup>11</sup> Murray RM, Di Forti M. Cannabis and psychosis: What degree of proof do we require? *Biol Psychiatry*. 2016;79(7):514-515. doi:10.1016/j.biopsych.2016.02.005

### ***Factor 7: Cannabis Use Disorder (“CUD”) must be better understood to accurately assess marijuana’s psychic or physiological dependence liability***

In the analysis of this factor, DEA states that concerns have been raised from medical professionals that cannabis use disorder is underdiagnosed, undertreated, and needs to be better understood and characterized to better inform users and treatment.<sup>12</sup> SPAN agrees with these medical professionals, and notes that the analysis of psychic and physiological dependence liability may differ when applied to those with schizophrenia or psychosis.

Cannabis use has been shown to make those with schizophrenia less likely to take their antipsychotic medications and cause a higher rate of relapse, more severe symptoms, an increase in violent behaviors and suicidal tendencies, and more frequent and longer hospital stays.<sup>13, 14, 15</sup>

SPAN also urges the DOJ to recognize the risk marijuana poses to adolescents. Cannabis is much more likely to provoke psychotic syndromes in adolescence, and more likely to lead to schizophrenia than other substances. Approximately 35% of those who develop cannabis-induced psychosis develop schizophrenia, more than 3x the percent of those who experience alcohol-induced psychosis.<sup>16, 17, 18, 19</sup>

Data and statistics like the above, as well as the exploration of the unique implications of marijuana on subsets of the population such as adolescents, should be taken into consideration when evaluating the psychic or physiological dependence liability of marijuana.

### **Conclusion**

We appreciate the opportunity to comment on this proposal to reschedule marijuana from a schedule I to a schedule III controlled substance. As an advocacy organization dedicated to advancing policies that remove barriers to care for individuals living with schizophrenia and prevent unnecessary development of similar psychotic disorders, we believe we bring a unique and valuable perspective on behalf of a vulnerable population.

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<sup>12</sup> Schedules of Controlled Substances: Rescheduling of Marijuana, Vol. 89, No. 99, Fed Reg. at 44615, May 21, 2024

<sup>13</sup> Arseneault L. Cannabis use in adolescence and risk for adult psychosis: longitudinal prospective study. *BMJ*. 2002;325(7374):1212-1213. doi:10.1136/bmj.325.7374.1212

<sup>14</sup> Hasan A, Von Keller R, Friemel CM, et al. Cannabis use and psychosis: a review of reviews. *Eur Arch Psychiatry Clin Neurosci*. 2020;270(4):403-412. doi:10.1007/s00406-019-01068-z

<sup>15</sup> Beaudoin M, Potvin S, Giguère CE, Discepola SL, Dumais A. Persistent cannabis use as an independent risk factor for violent behaviors in patients with schizophrenia. *Npj Schizophr*. 2020;6(1):14. doi:10.1038/s41537-020-0104-x

<sup>16</sup> Di Forti M, Sallis H, Allegrì F, et al. Daily use, especially of high-potency cannabis, drives the earlier onset of psychosis in cannabis users. *Schizophr Bull*. 2014;40(6):1509-1517. doi:10.1093/schbul/sbt181

<sup>17</sup> Godin S, Shehata S. Adolescent cannabis use and later development of schizophrenia: An updated systematic review of longitudinal studies. *J Clin Psychol*. 2022;78(7):1331-1340. doi:10.1002/jclp.23312

<sup>18</sup> Schubart CD, Van Gastel WA, Breetvelt EJ, et al. Cannabis use at a young age is associated with psychotic experiences. *Psychol Med*. 2011;41(6):1301-1310. doi:10.1017/S003329171000187X

<sup>19</sup> Khokhar JY, Dwiel LL, Henricks AM, Doucette WT, Green AI. The link between schizophrenia and substance use disorder: A unifying hypothesis. *Schizophr Res*. 2018;194:78- 85. doi:10.1016/j.schres.2017.04.016

We strongly urge the Department of Justice to consider the unique risks posed by rescheduling marijuana to individuals with schizophrenia and psychosis before moving forward with rescheduling marijuana. The absence of consideration of the schizophrenia and psychosis community in this proposed rule fails the estimated 2.65 million people living with schizophrenia in the United States, as well as their caregivers; heightens the risk for those who may develop these severe brain diseases; and could exacerbate the enormous cost and negative outcomes associated with schizophrenia and psychosis, as well as undertreated and underdiagnosed CUD more broadly.

Thank you for your consideration of our community, and for taking our unique views into perspective as you continue to evaluate this proposed rule.

Sincerely,

A handwritten signature in black ink that reads "Gordon Lavigne". The signature is written in a cursive, flowing style.

Gordon Lavigne  
Chief Executive Officer  
Schizophrenia & Psychosis Action Network