

July 22, 2024

Anne Milgram
Administrator
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

RE: Docket No. DEA-1362, Schedules of Controlled Substances: Rescheduling of Marijuana.

Dear Administrator Milgram:

Thank you for inviting comments on the rescheduling of cannabis. The undersigned epilepsy organizations are writing to share our unique perspective on this critical issue, given that some people with epilepsy use cannabis or FDA approved CBD products to treat their seizures and related comorbidities. Our priorities are that people with epilepsy have access to safe, legal, reliable, and properly tested medical cannabis while also facilitating more research into the potential benefits and risks of cannabis for epilepsy and seizures. We believe that rescheduling cannabis from schedule I to schedule III of the Controlled Substances Act (CSA) will help to achieve these objectives.

Approximately 1 in 26 Americans will develop epilepsy at some point in their lifetimes. Epilepsy is a disease or disorder of the brain which causes reoccurring seizures. It is a spectrum disease comprised of many diagnoses including an ever-growing number of rare epilepsies. There are many different types of seizures and varying levels of seizure control. There is no one-size-fits-all treatment for epilepsy, and about 30% of people with epilepsy – over one million people – lack seizure control despite available treatments. Uncontrolled seizures greatly impede quality of life and can lead to disability, injury, and even early death. Each year, 1 out of 1,000 people with epilepsy die due to Sudden Unexpected Death in Epilepsy (SUDEP). This number dramatically increases to 1 in 150 for people whose seizures are not controlled.

Our groups are committed to supporting provider-directed and person-centered care, and to exploring and advocating for all potential treatment options for epilepsy, including further studies with cannabis. Medical cannabis should be used in close consultation with the person with epilepsy's medical provider, and they should not stop taking their other medications without direction from their provider. Both the person with epilepsy and their provider also need to know what is in the cannabis product and at what quantities.

We are grateful that there is one Food and Drug Administration (FDA) approved CBD product, Epidiolex[®], available to treat seizures associated with three rare forms of epilepsy. However, this product has a limited indication and some people with epilepsy cannot access it. Our organizations hope that there will be broadened access and additional FDA-approved CBD products in the future. As with any other medication or treatment option for epilepsy, people who suddenly stop taking

medical cannabis are at increased risk for breakthrough seizures and related complications, including accident, injury, and even early death.

Rescheduling of Cannabis

We support the DEA's proposal to reschedule cannabis to schedule III, which would be an acknowledgement by the federal government that some forms of cannabis have possible medical uses. Rescheduling would be in alignment with the experiences of people with epilepsy who use cannabis and have found some forms of the product effective for controlling their seizures.

Rescheduling would also facilitate more research on epilepsy and seizures and cannabis. Most of the high-quality research on epilepsy to date has been done through the studies on Epidiolex[®], which were rigorous, randomized, and double-blind, but focused on rare forms of epilepsy.^{1,2} Rescheduling would allow for more research on the medical uses of cannabis in all forms of epilepsy and different seizure types. A better understanding of how cannabis works in controlling seizures, as well as the possible benefits and risks of other symptoms often associated with epilepsy, would assist people with epilepsy and their health care providers in deciding when and how to use this treatment. Additionally, rescheduling would also allow for the study of cannabis for the comorbid conditions sometimes experienced by people with epilepsy. Additional quality research would help to address the issues found by the University of Florida and the FDA in their reviews of the medical research on cannabis and epilepsy that were cited in the proposed rule.

Limits of Rescheduling

We support rescheduling, but also wish to highlight the possible limits of rescheduling for people with epilepsy. Rescheduling will not legalize cannabis, and there will still be conflicts between state and federal law on this issue. Due to these legal restrictions, people with epilepsy who use cannabis as a medical treatment may face difficulties in areas such as workplace drug testing or traveling to other states with their medication. If people with epilepsy stop taking cannabis due to these restrictions, then they could once again face uncontrolled seizures and related dangerous complications. If rescheduled, cannabis would also still not be covered by insurance, and it could be costly for people with epilepsy.

Our organizations hope that more treatments are approved by the FDA for epilepsy and seizures but in the interim, strongly believe that CBD products manufactured with appropriate quality control must remain on the market for people with epilepsy who need them. Since rescheduling would not make cannabis regulated or labeled by the FDA like other medications, people with epilepsy and their health care providers would not always know what is in the product or the correct dose. They could face safety concerns and possible harmful interactions with other medications. Therefore, we will continue to advocate for a strong regulatory pathway for CBD products.

¹ Devinsky O, Cross JH, Laux L, et al. : Trial of Cannabidiol for Drug-Resistant Seizures in the Dravet Syndrome. *N Engl J Med.* 2017;376:2011–2020.

² Devinsky O, Patel AD, Cross JH, et al. : Effect of Cannabidiol on Drop Seizures in the Lennox-Gastaut Syndrome. *N Engl J Med.* 2018;378(20):1888–97.

Conclusion

Thank you again for the opportunity to weigh in on the proposal to reschedule cannabis from schedule I to schedule III. The undersigned organizations support this important proposal. If you have any questions, please do not hesitate to contact Roxanne Yaghoubi at ryaghoubi@efa.org or any of our community members.

Sincerely,

Autism Science Foundation
BDSRA Foundation
BPAN WARRIORS
Child Neurology Foundation
Coalition to Cure CHD2
CSNK2A1 Foundation
CSNK2B Foundation
CTNNB1 Connect & Cure
CURE Epilepsy
Cure GABA-A
CureSHANK
Danny Did Foundation
Decoding Developmental Epilepsies
Doose Syndrome Epilepsy Alliance
Dravet Syndrome Foundation
Empowering Epilepsy
Epilepsies Action Network
EPILEPSY ALLIANCE AMERICA
Epilepsy Alliance Louisiana
Epilepsy Foundation
Epilepsy Foundation Texas
Epilepsy Reach Foundation
Epilepsy Services of NJ
Epilepsy Wellness Advocates
FAM177A1 Research Fund
Glut1 Deficiency Foundation
GRIN2B Foundation
Hope for HIE
Hope for ULD
International SCN8A Alliance
Lennox-Gastaut Syndrome (LGS) Foundation
Living Well with Epilepsy
NORSE Institute
Phelan-McDermid Syndrome Foundation
Rare Epilepsy Network Coordinating Committee
Sofie's Journey/Epilepsy Awareness Day EXPO
South Carolina Advocates for Epilepsy
SynGAP Research Fund
The Charlie Foundation
The SPATA Foundation
TSC Alliance