November 12, 2024

Hon. John J. Mulrooney, II
Chief Administrative Law Judge
Drug Enforcement Administration
U.S. Department of Justice
8701 Morrissette Drive
Springfield, VA 22152

Re: U.S. Drug Enforcement Administration Preliminary Order with Respect to the Proposed Rescheduling of Marijuana; Docket No. 1362, Hearing Docket No. 24-44 (October 31, 2024)

Dear Judge Mulrooney:

The Commonwealth Project presents this notice to the Drug Enforcement Administration ("DEA") in response to its October 31 Preliminary Order regarding the DEA's planned hearing on a proposed rule to reclassify marijuana from Schedule I to Schedule III of the Controlled Substances Act ("CSA"). First and foremost, The Commonwealth Project is appreciative of the opportunity to be designated as one of 25 organizations to participate in the rescheduling hearing and present its comments on this historic action.

Please find below the Commonwealth Project's response to the DEA's October 31 Preliminary Order to establish that we have made timely application and are eligible as an "interested person" to participate in the hearing:

(1) The name, address, phone number, and general nature/principal mission of the DP's practice, profession, or business.

Name: The Commonwealth Project
Address: 340 Royal Poinciana Way,
Suite 317-434,
Palm Beach, FL 33480
Phone: 617-450-4000

Principal Mission: The Commonwealth Project – founded by Howard Kessler – is committed to advocating on behalf of and prioritizing the 65+ population and integrating medical cannabis into mainstream health care for seniors. The Commonwealth Project is laying the groundwork for a robust, patient-centered research and care demonstration model for medicinal cannabis. The model aims to broaden seniors' access to cannabis-

based therapies by creating a medical experience that includes insurance coverage, including Medicare reimbursement, and ongoing clinical guidance and monitoring by healthcare professionals.

Our efforts are driven by a compassionate desire to assist millions of older adults managing increasingly complex health issues as they age by pioneering a new, innovative and complementary approach to revolutionize the senior healthcare landscape — rooted in the belief that medical cannabis could be harnessed to not only provide older Americans with an alternative to traditional prescription medications, including opioids, but to reduce soaring health care costs saddling millions of seniors.

Our founder, Howard Kessler has helped to establish pilot programs at senior living facilities, where medical cannabis-based products were administered to residents by healthcare professionals. These pilot programs enabled experts to conduct first-of-its-kind, comprehensive studies into the use of medical cannabis in senior care. One of the studies found that more than 80 percent of participants were positively impacted by cannabis and nearly three-quarters said cannabis was more cost-effective than their prescription drugs.

The Commonwealth Project offers unparalleled medical expertise to this process regarding the medical impacts of cannabis on senior populations. Our organization was the first to study the use of medical cannabis in senior care, inspiring partnerships with medical experts like Dr. Peter Grinspoon of Massachusetts General Hospital and Harvard Medical School and advocacy giants like LeadingAge, which represents 5,000 aging focused organizations to develop evidence-based programs for the treatment of ailments in the over-65 patient population.

(2) A notice of appearance for the counsel(s) of record that will be representing the DP at the hearing.

Kelly Fair
Dentons US LLP
Address: 1999 Harrison Street
Suite 1210
Oakland, CA 94612
United States
Phone: 415-882-0117
Email: Kelly.Fair@dentons.com

(3) The date that a request for hearing and/or participation was properly filed by the DP with the DEA.

On September 27, 2024, the Commonwealth Project filed a Notice of Desired Participation in Drug Enforcement Administration Hearing with Respect to the Proposed Rescheduling of Marijuana; Docket No. DEA-1362 (August 28, 2024). Attached as **Exhibit A**. The September 27th filing was timely, as within 30 days after the date of publication of the notice of hearing in the Federal Register pursuant to 21 CFR 1308.44(B).

(4) Why/how the DP would be sufficiently "adversely affected or aggrieved" by the proposed scheduling action to qualify as an "interested person" under the regulations.

The Commonwealth Project would be adversely affected and aggrieved if (a) the DEA does not expeditiously reschedule marijuana from Schedule I to III, which is uncertain from the NPRM; and alternatively (b) marijuana were rescheduled from Schedule I to III without regulations to adequately consider the effect of rescheduling cannabis from Schedule I to Schedule III for individuals who are 65 and older.

First, our organization would be adversely affected and aggrieved if rescheduling is rejected or unduly delayed because our mission is to integrate cannabis healthcare into broader healthcare practices. Because the DEA has made clear that it has "not yet made a determination as to its views of the appropriate schedule for marijuana,"[1] it is both fitting and necessary that proponents of such rescheduling be heard on how an outcome other than schedule III (i.e. schedule I or II) would adversely affect our ability to carry out our mission. Our organization intends to provide factual evidence and expert opinion in support of rescheduling that the DEA has expressly requested to issue a final rule. The longer the DEA prolongs finalizing this rule and remains uncertain issuing regulations that would reschedule cannabis from Schedule I to Schedule III, the more American seniors will miss out on the benefits made possible by medicinal cannabis.

Second, the Commonwealth Project will be adversely affected and aggrieved if a final rule does not include direction and/or regulation providing explicit rules, guidance, and safe harbor for those incorporating marijuana into healthcare programs, which is missing from the DEA's current proposed rule. The lack of this clarity disparately impacts American Seniors, one of our most vulnerable populations. Seniors are the fastest growing demographic of medical cannabis users in the country – increasingly turning to medical cannabis as a cost-effective alternative to traditional painkillers for age-related health conditions like chronic pain, anxiety, insomnia, nausea from cancer treatment, and even neurodegenerative disorders like dementia and Alzheimer's disease. In fact, 30% of people over the age of 65 take five or more pharmaceuticals every day. In states where marijuana is legal, doctors prescribed an average of 1,826 fewer daily doses of painkillers

[1] *Schedules of Controlled Substances: Rescheduling of Marijuana*, 89 Fed. Reg. 44597, 44601 (2024) (hereinafter, the "NPRM").

per year to patients enrolled in Medicare Part D – which would result in a cost savings of up to $500 million per year just for pain treatment if medical marijuana access was legal nationwide.

By swiftly rescheduling cannabis from Schedule I to Schedule III, there will be greater, but not complete, certainty for seniors, researchers, and physicians to engage in research or pilot healthcare projects that examine the benefits and distribution of medical cannabis. Therefore, the Commonwealth Project respectfully asks that the final rule mandating rescheduling should include, at a minimum, an explicit assurance that participants, researchers, and individuals and/or organizations that engage or participate in health care projects will suffer no adverse consequences from any federal agency. Absent that, the Commonwealth Project may be unable to continue its mission.

(5) Whether the DP supports or opposes the rescheduling action the DEA seeks in its NPRM.

The Commonwealth Project strongly supports the Department of Health and Human Services' strong recommendation to reschedule cannabis from Schedule I to Schedule III under the CSA, and the Department of Justice's ("DOJ") and the DEA's NPRM that proposes doing so. Absent rescheduling, even in those states where cannabis has been legalized, America's seniors will continue to be relegated to the existing state marketplace with little to no clinical guidance, medical oversight or reimbursement mechanism.

In its July 22 comments submitted to the DEA in response to its NPRM and Request for Comments regarding the reclassification of cannabis from Schedule I to Schedule III of the CSA, the Commonwealth Project encouraged the DEA and the White House to move as expeditiously as possible on rescheduling. Attached as **Exhibit B**. If a final rule is not published in an expedited fashion, it is the Commonwealth Project's view that we and the rest of the scientific community will remain limited in its capacity to move forward with research and demonstration trials that have the potential to bring the much needed and undisputed benefits of these therapies to as many seniors as possible.

(6) Any known conflicts of interest with DEA or DOJ leadership or personnel that may require disclosure.

The Commonwealth Project has no conflicts of interest with DEA or DOJ leadership or personnel that may require disclosure.

CERTIFICATE OF SERVICE

This is to certify that the undersigned, on November 12, 2024, caused a copy of the foregoing to be delivered to the following recipients: (1) James Schwartz, Esq., Counsel for the Government, via email at james.j.schwartz@dea.gov; (2) the DEA Government Mailbox, via email at dea.registration.litigation@dea.gov; (3) Shane Pennington for Village Farms International, via email at spennington@porterwright.com; (4) Aaron Smith for National Cannabis Industry Association, via email at aaron@thecannabisindustry.org and michelle@thecannabisindustry.org; (5) Chad Kollas for American Academy of Hospice and Palliative Medicine, via email at wchill@aahpm.org; (6) John Jones for Cannabis Bioscience International Holdings, via email at ir@cbih.net; (7) Robert Head for Hemp for Victory, via email at robert@bluecordfarms.com; (8) Erin Gorman Kirk for the State of Connecticut, via email at erin.kirk@ct.gov; (9) Ellen Brown for Massachusetts Cannabis Advisory Board, via email at ellen@greenpathtraining.com; (10) Shanetha Lewis for Veterans Initiative 22, via email at info@veteransinitiative22.com; (11) Jason Castro for The Doc App. Dba, My Florida Green, via email at jasoncastro@myfloridagreen.com; (12) Katy Green for The Commonwealth Project, via email at kag@platinumadvisors.com; (13) Ari Kirshenbaum for Saint Michael's College, via email at mslade@cannabispublicpolicyconsulting.com; (14) Jo McGuire for National Drug and Alcohol Screening Association, via email at jomcguire@ndasa.com; (15) Patrick Philbin for Smart Approaches to Marijuana, via email at pphilbin@torridonlaw.com; (16) Roneet Lev for International Academy on the Science and Impact of Cannabis, via email at roneetlev@gmail.com; (17) David Evans for Cannabis Industry Victims Educating Litigators, via email at thinkon908@aol.com; (18) Kenneth Finn, via email at kfinn@springsrehab.net; (19) Jennifer Homendy for National Transportation Safety Board, via email at executivesecretariat@ntsb.gov and correspondence@ntsb.gov; (20) Phillip Drum, via email at phillipdrum@comcast.net; (21) Attorney General Mike Hilgers for the State of Nebraska, via email at zachary.viglianco@nebraska.gov; (22) International Association of Chiefs of Police, via email at voegtlin@theiacp.org; (23) Drug Enforcement Association of Federal Narcotics Agents, via email at marshallfisher@rocketmail.com; (24) Natalie P. Hartenbaum for American College of Occupational and Environmental Medicine, via email at occumedix@comcast.net and craig@acoem.org; (25) Sue Thau for Community Anti-Drug Coalitions of America, via email at cdoarn@cadca.org; (26) Tennessee Bureau of Investigation, via email at kim.litman@tbi.tn.gov; and (27) National Sheriff's Association, via email at sheriffskinner@collincountytx.gov and ykaraman@sheriffs.org.

Kathleen A G

Katy Green

Exhibit A

September 27, 2024

Hon. Anne Milgram
Administrator
Drug Enforcement Administration
U.S. Department of Justice
8701 Morrissette Drive
Springfield, VA 22152

Re: Notice of Desired Participation in Drug Enforcement Administration Hearing with Respect to the Proposed Rescheduling of Marijuana; Docket No. DEA-1362 (August 28, 2024)

Dear Administrator Milgram:

The Commonwealth Project presents these comments to the Drug Enforcement Administration ("DEA") in response to its August 28 Notice of Hearing on Proposed Rulemaking regarding the reclassification of marijuana from Schedule I to Schedule III of the Controlled Substances Act. First and foremost, The Commonwealth Project applauds the historic action taken by the Department of Justice ("DOJ") and the DEA to initiate rescheduling of marijuana from Schedule I to Schedule III under the Controlled Substances Act ("CSA").

The Commonwealth Project is a humanitarian effort working to legitimize and integrate medical cannabis within the existing US health care system. Specifically, it's the goal of the Commonwealth Project to improve the health experience of individuals 65+ by allowing medical cannabis to be part of their overall health care. The Commonwealth Project is laying the groundwork for a robust and patient-centric research and care demonstration model for medicinal cannabis that takes into consideration the unique healthcare delivery challenges faced by America's seniors.

In its July 22 comments submitted to the DEA in response to its Notice of Proposed Rulemaking and Request for Comments regarding the reclassification of marijuana from Schedule I to Schedule III of the Controlled Substances Act, the Commonwealth Project encouraged the DEA and the White House to move as expeditiously as possible on rescheduling. If a final rule is not published before the end of the year, the scientific community will remain limited in its capacity to move forward with research and demonstration trials that will bring the much needed and undisputed benefits of these therapies to as many seniors as possible.

Federal lawmakers in opposition to the DEA's proposed rescheduling of cannabis from Schedule I to Schedule III have formally written to agency officials expressing their view that the rule "fails to provide adequate science and data to support moving marijuana to schedule III and should not have been signed or published."[1] While recent changes to federal law under the Medical Marijuana and Cannabidiol Research Expansion Act (MMCREA) aim to expand

[1] https://mjbizdaily.com/wp-content/uploads/2024/07/Lawmaker-rescheduling-letter.pdf

research of medical marijuana, there remains a deficiency in available research on the long-term health impacts of marijuana use or potential medical use.

However, further delaying the rescheduling of cannabis will only further exacerbate the challenges that potential participants in scientific studies and pilot programs currently face, including uncertainty about whether there will be repercussions if they take part in such research activities. There is an entire industry waiting to address the health needs of traditionally underserved portions of the 65+ population by providing critical research that could increase access to life-altering medical therapies.

By swiftly rescheduling cannabis from Schedule I to Schedule III, there will be greater, but not complete, certainty for seniors, researchers, and physicians to engage in research or pilot healthcare projects that examine the benefits and distribution of medical cannabis. Therefore, the Commonwealth Project holds that the final rule mandating rescheduling should include, at a minimum, an explicit assurance that participants, researchers, and individuals and/or organizations that engage or participate in health care projects will suffer no adverse consequences from any Federal agency.

Exhibit B

July 22, 2024

Hon. Anne Milgram
Administrator
Drug Enforcement Administration
U.S. Department of Justice
8701 Morrissette Drive
Springfield, VA 22152

Re: Proposed Rule, Drug Enforcement Administration; Schedules of Controlled Substances: Rescheduling of Marijuana; Docket No. DEA-1362 (May 21, 2024)

Dear Administrator Milgram:

The Commonwealth Project presents these comments to the Drug Enforcement Administration ("DEA") in response to its Notice of Proposed Rulemaking and Request for Comments regarding the reclassification of marijuana from Schedule I to Schedule III of the Controlled Substances Act. First and foremost, The Commonwealth Project applauds the historic action taken by the Department of Justice ("DOJ") and the DEA to initiate rescheduling of marijuana from Schedule I to Schedule III under the Controlled Substances Act ("CSA").

The Commonwealth Project is a humanitarian effort working to legitimize and integrate medical cannabis within the existing US health care system. In particular, the Commonwealth Project prioritizes the health needs of individuals 65 and over. Our efforts are driven by a compassionate desire to assist millions of seniors facing increasingly complex health issues as they age by offering medical cannabis as part of their overall health care.

Current Challenges

There are roughly 56 million adults ages 65 and older in the United States today, or 17 percent of the population — an unprecedented number driven by aging Baby Boomers.[1] By the end of this decade, the U.S. Census Bureau projects the total to grow by another 17 million older adults. Individuals 65 and older are the fastest growing segment of the population using or interested in using medical cannabis as a component of their health care regimen.

[1] https://www.census.gov/content/dam/Census/library/publications/2020/demo/p25-1144.pdf

With this explosive growth in older adults will come significant Medicare spending, testing an already deeply stressed system. One big driver: powerful prescription drugs, including opioids, which sometimes do not work as intended, can have unwanted side effects, and can be expensive and highly addictive.

Today, thirty-eight states, the District of Columbia, and four territories have state-level laws that allow the use of medical marijuana. The Commonwealth Project is seeking to speed the availability of medically administered Cannabis Based Therapies (CBT) to a range of demographics, most notably seniors over the age of 65. Scientific research has demonstrated that CBD therapies are particularly helpful and impactful for seniors struggling with pain management, insomnia, and psychiatric conditions such as anxiety and depression.

Doctors in states where medical cannabis has been authorized are currently prevented from "prescribing" a specific dosage of medical cannabis for their patients because of its status as a Schedule I drug, despite numerous studies showing that many U.S. physicians believe it can be therapeutic. Moreover, seniors currently don't have access to either a medically based cannabis healthcare experience or reimbursement through Medicare. Accordingly, the current status quo restricts seniors from having a comprehensive health experience that directly involves ongoing medical supervision with their physicians, guarantees access to new and safe products, monitors dosage and effectiveness, improves data collection, and promotes health equity, all of which limits uptake of CBT by seniors and its attendant benefits. The current situation creates an equity challenge; forcing seniors to pay out of pocket for medical marijuana restricts access and disproportionately affects historically underserved seniors.

In the meantime, cannabis companies in states that have legalized marijuana sales and use are filling that void — offering tips to seniors about formulations and doses, as well as creating and marketing products with no meaningful research into the effects on older consumers and without any clinical guidance. This and the proliferation of dubious online information means seniors have no trusted place to turn for credible clinical guidance — leaving them to the advice of friends, neighbors or an untrained salesperson working at a local dispensary.

Comments

Considering the challenges that all Americans, and particularly seniors face in accessing medical cannabis within their health care system, the Commonwealth Project urges the DOJ and the DEA to act swiftly and publish a Final Rule cementing this historic reform. A delay in promulgating rules would only serve to further perpetuate a status quo that is detrimental to the needs of today's seniors, who do not have the luxury of time.

At this time, researchers and suppliers of cannabis for medical research, as well as physicians, are offered certain protections under the Marijuana and Cannabidiol Research Expansion Act

(MMCREA) that allow them to legally distribute or discuss the harms and benefits of medical cannabis, respectively. However, federal lawmakers and stakeholders continue to voice concerns that MMCREA has not been implemented in line with Congressional intent and that researchers continue to face barriers from both the FDA and DEA.[2]

By rescheduling cannabis from Schedule I to Schedule III, there will be greater, but not complete, certainty for seniors, researchers, and physicians to engage in research or pilot health care projects that examine the benefits and distribution of medical cannabis. The final rule mandating rescheduling should include, at a minimum, an explicit assurance that participants, researchers, and individuals and/or organizations that engage or participate in health care projects will suffer no adverse consequences from any Federal agency.

Specifically, the Commonwealth Project also recommends that the DOJ issue a public memorandum that not only establishes greater assurance to these stakeholders, but that allows payer-providers to engage in research activities and pilot projects without facing any negative consequences or penalties from the Federal government. There is precedent by the DOJ to issue such a 'non-enforcement' memorandum. On August 29, 2013, former U.S. Deputy Attorney General published a memorandum, "Guidance Regarding Marijuana Enforcement," stating that the DOJ would not enforce federal marijuana prohibition in states that had, at the time, enacted laws legalizing marijuana in some form.

If the DOJ promulgates a final rule that reschedules marijuana from Schedule I to Schedule III under the CSA, physicians would be significantly less restricted in prescribing medical cannabis. As such, insurance plans would ultimately have to determine whether they will cover medical marijuana. It would also be up to the Centers for Medicare Services ("CMS") to determine whether Medicare Part D would cover medical marijuana for seniors. Currently, several prescription opioid pain medications – which are categorized as Schedule II substances – are covered under Part D, including hydrocodone (Vicodin®), oxycodone (OxyContin®), morphine, codeine, and fentanyl. However, a drug plan could decide that a patients' use of prescription opioids may not be safe and limit a patients' coverage of such drugs under its drug management program.

Under Medicare Part D, Medicare makes partially capitated payments to Part D sponsors for delivering prescription drug benefits to Medicare beneficiaries. If cannabis is rescheduled, medical marijuana manufacturers would have to negotiate with Part D sponsors on payment arrangements for the delivery of cannabis. These payment adjustments are then reported to CMS as Direct or Indirect Remuneration (DIR), which are reflected in drug rebates.

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[2] https://blumenauer.house.gov/sites/evo-subsites/blumenauer.house.gov/files/evo-media-document/2024-03-12%20Letter%20on%20MMCREA%20Implementation%20(3).pdf

If the DEA accepts HHS's recommendation to reschedule cannabis from Schedule I to Schedule III of the controlled substances act, cannabis will fall under an existing set of prescription requirements before use in a medical setting.

It is the goal of the Commonwealth Project to improve the health experience of individuals 65+ by allowing medical cannabis to be part of their overall health care. The Commonwealth Project is laying the groundwork for a robust and patient-centric research and care demonstration model for medicinal cannabis that takes into consideration the unique healthcare delivery challenges faced by America's seniors.

Specifically, the Commonwealth Project has been working with a range of partners (from payer-providers, research universities, retirement organizations and other stakeholders) to conduct a value-based medical cannabis demonstration model in a regulated state that breaks out the over 65 demographic. The pilot project would provide research needed to inform healthcare guidance for seniors' health care practitioners and safely shape the medical marijuana marketplace (i.e. safe, consistently-doses, accurately labeled products). Working directly with payer providers enables this project to gather real world data, validate the health outcomes, and calculate savings that an improved medicinal distribution model. The Commonwealth Project would share the findings of this project with the US government, toward the goal of establishing a more efficient, effective, and equitable distribution and oversight model for cannabis based therapies.

In states where marijuana is legal, doctors prescribed an average of 1,826 fewer daily doses of painkillers per year to patients enrolled in Medicare Part D — which would result in a cost savings of up to $500 million per year if medical marijuana access was legal nationwide.[3] Incorporating medical cannabis within health care will not only improve the health experience of individuals 65 and older but yield significant savings for the American taxpayer.

For these reasons, the Commonwealth Project encourages the DEA and the White House to move as expeditiously as possible on rescheduling, so that we can utilize rescheduling as a pivot point to move forward with research and demonstration trials that will bring the much needed and undisputed benefits of these therapies to as many seniors as possible.

The Commonwealth Project thanks the DOJ and the DEA for this important and historic rulemaking proposal and for the opportunity to comment.

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[3] Ashley Bradford, et al., "Medical Marijuana Laws Reduce Prescription Medication Use In Medicare Part D," *Health Affairs*, July 2016.

Sincerely,

Howard Kessler
Founder
The Commonwealth Project