UNITED STATES DEPARTMENT OF JUSTICE

Drug Enforcement Administration

In the Matter of **Schedules of Controlled Substances: Proposed Rescheduling of Marijuana**	**DEA Docket No. 1362** **Hearing Docket No. 24-44**

ORDER DENYING MOTION TO INTERVENE (MedPharm)

On May 21, 2024, the United States Department of Justice through the Drug Enforcement Administration (DEA or Agency) issued a notice of proposed rulemaking (NPRM) proposing to transfer marijuana from Schedule I of the Controlled Substances Act (CSA) to Schedule III. *Schedules of Controlled Substances: Rescheduling of Marijuana*, 89 Fed. Reg. 44597, 44597 (2024). Following the publication of the NPRM, the DEA Administrator determined that in-person hearing proceedings would be appropriate, and in an order dated August 29, 2024, fixed a December 2, 2024 commencement date. *Schedules of Controlled Substances: Rescheduling of Marijuana*, 89 Fed. Reg. 70148, 70148-49 (2024). Subsequently, the Administrator designated a subset of twenty-five (25) individuals and organizations (evidently culled from a larger group of requestors) to participate in the hearing (Designated Participants or DPs). The DPs were evidently each notified of their participation status by a separate email.

I was designated by the Administrator[1] to preside over the hearing proceedings, but was not involved in or apprised of the process utilized to select the DPs. In an order dated November 19, 2024 (the Standing Order), based on submissions by the DPs, I made determinations regarding standing and inclusion in these proceedings by applying the statutory and regulatory guideposts supplied by Congress and the CSA and its implementing regulations. In the Standing Order, the overwhelming majority of DPs maintained their status as participants, but standing assessments were reached regarding any future discretionary decisions as to the potential weight to be assigned in the recommended decision.

[1] 21 C.F.R. § 1316.52.

On November 12, 2024, MedPharm, a DEA registrant (by its own representation), filed a motion bearing the caption "Motion to Intervene" (Motion to Intervene or MTI) seeking an order from this tribunal authorizing its inclusion among the DPs, notwithstanding the fact that it has not been designated as a Designated Participant by the DEA Administrator. MTI at 1-3.

In its MTI, MedPharm expends considerable effort into outlining some positive attributes of its mission, outlining ways in which it would seek to establish standing under the Administrative Procedure Act (APA), and pointing out how any marijuana rescheduling hearing would greatly benefit from its participation. However, as explained in more detail in the Standing Order issued by this tribunal, potential, meaningful input, and even arguable APA standing is not the full extent of the inquiry. *City of San Antonio v. Civil Aeronautics Board*, 374 F.2d 326, 329 (D.C. Cir. 1967) ("No principle [of] administrative law is more firmly established than that of agency control of its own calendar."). The Agency is endowed with the right to place reasonable limits on the number of participants in a given APA hearing. *Id.* Which is, when reduced to its essence, precisely what the Administrator did in exercising her discretion in determining the number and nature of participants. To be sure, thousands upon thousands of individuals and entities across the country could add value to the issues to be decided here, but they cannot all be included.

Regarding the Administrator's decision not to extend a participation invitation to MedPharm, it is useful to view the current dynamic in the backdrop of the APA and the CSA's implementing regulations. The authority of a DEA Administrative Law Judge (ALJ) and the duration of that authority is circumscribed by the regulations. Per the regulations, an ALJ is designated to handle a case by the DEA Administrator.[2] 21 C.F.R. § 1316.52. The ALJ's "functions … commence upon his designation and terminate upon the certification of the record to the Administrator." *Id.* Thus, the time the DPs were selected by the Administrator preceded my authority to act on the case. Even more importantly, in the APA, Congress decreed that "[o]n appeal from or review of the [ALJ's recommended decision] the agency has all the powers which it would have in making the [recommended decision] … except as it may limit the issues on notice or by rule." 5 U.S.C. § 557(b). Appeals flow *from the ALJ to the Administrator,* not the other way around. I have not been designated to review the Administrator's prehearing actions

[2] Actually, in most cases, the case is forwarded to the DEA Office of Administrative Law Judges, and assigned by the DEA Chief Judge. Here, the Administrator made the designation herself.

on this matter or the manner in which her DP decisions were reached, issued, or not issued.[3] The Administrator exercised her discretion to fix the number of DPs to be included, and to expand that number would effectively overrule her decision and exceed the proper and logical role of the ALJ under the APA and the CSA.[4] Accordingly, no action can or will be taken on MedPharm's Motion to Intervene.

Dated: November 22, 2024

JOHN MULROONEY

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JOHN J. MULROONEY, II
Chief Administrative Law Judge

CERTIFICATE OF SERVICE

This is to certify that the undersigned, on November 22, 2024 caused a copy of the foregoing to be delivered to the following recipients: (1) James J. Schwartz, Esq., Counsel for the Government, via email at james.j.schwartz@dea.gov; Jarrett T. Lonich, Esq., Counsel for the Government, via email at jarrett.t.lonich@dea.gov; and S. Taylor Johnston, Esq., Counsel for the Government, via email at stephen.t.johnston@dea.gov; (2) the DEA Government Mailbox, via email at dea.registration.litigation@dea.gov; (3) Tristan Cavanaugh, Esq., Counsel for Village Farms International, via email at tcavanaugh@porterwright.com; (4) Nikolas S. Komyati, Esq., Counsel for National Cannabis Industry Association, via email at nkomyati@foxrothschild.com; William Bogot, Esq., Counsel for National Cannabis Industry Association, via email at wbogot@foxrothschild.com; and Khurshid Khoja, Esq., Counsel for National Cannabis Industry Association, via email at khurshid@greenbridgelaw.com; (5) John Jones and Dante Picazo for Cannabis Bioscience International Holdings, via email at ir@cbih.net; (6) Abdul Kallon, Esq., Counsel for Hemp for Victory, via email at AKallon@perkinscoie.com; (7) Shanetha Lewis for Veterans Initiative 22, via email at info@veteransinitiative22.com; (8) Kelly Fair, Esq., Counsel for The Commonwealth Project, via email at Kelly.Fair@dentons.com; (9) Rafe Petersen, Esq., Counsel for Ari Kirshenbaum, via email at Rafe.Petersen@hklaw.com; (10) David G. Evans, Esq., Counsel for Cannabis Industry Victims Educating Litigators, Community Anti-Drug Coalitions of America, Phillip Drum, Kenneth Finn, International Academy on the Science and

[3] *See SEC v. Chenery Corp.*, 318 U.S. 80, 87 (1943) ("The grounds upon which an administrative order must be judged are those upon which the record discloses that its action was based."). As I have discussed in other orders, while the decision to include or exclude a party arguably bears the hallmarks of a final agency action (5 U.S.C. § 702; 21 U.S.C. § 877), at least one Circuit Court is not altogether convinced that anything is really final and reviewable until the whole adjudication has run its course. *Miami-Luken, Inc. v. DEA*, 900 F.3d 738, 743 (6th Cir. 2018) (The court held that a subpoena decision is not rendered final merely because the agency's highest authority issued the decision prior to an ultimate disposition of the case.).

[4] Admittedly, had the standing determination been deferred to await the action of the ALJ, matters would have been procedurally different and the Administrator could have exercised her unquestioned authority to review my ruling on the matter. But that is not the way the matter progressed.

Impacts of Cannabis, and National Drug and Alcohol Screening Association, via email at thinkon908@aol.com; (11) Patrick Philbin, Esq., Counsel for Smart Approaches to Marijuana, via email at pphilbin@torridonlaw.com; and Chase Harrington, Esq., Counsel for Smart Approaches to Marijuana, via email at charrington@torridonlaw.com; (12) Stephanie E. Masker, Esq., Counsel for National Transportation Safety Board, via email at stephanie.masker@ntsb.gov; (13) Eric Hamilton, Esq., Counsel for the State of Nebraska, via email at eric.hamilton@nebraska.gov; and Zachary Viglianco, Esq., for the State of Nebraska, via email at zachary.viglianco@nebraska.gov; (14) Gene Voegtlin for International Association of Chiefs of Police, via email at voegtlin@theiacp.org; (15) Gregory J. Cherundolo for Drug Enforcement Association of Federal Narcotics Agents, via email at executive.director@afna.org; (16) Reed N. Smith, Esq., Counsel for the Tennessee Bureau of Investigation, via email at Reed.Smith@ag.tn.gov; and Jacob Durst, Esq., Counsel for Tennessee Bureau of Investigation, via email at Jacob.Durst@ag.tn.gov; and (17) Matthew Zorn, Esq., Counsel for Erin Gorman Kirk for the State of Connecticut and Counsel for Ellen Brown, via email at mzorn@yettercoleman.com; and (18) Andrew Kline, Esq., Counsel for MedPharm and Hemp for Victory, via email at akline@perkinscoie.com; and Shane Pennington, Esq., Counsel for MedPharm and Village Farms International, via email at spennington@porterwright.com.

QUINN FOX

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Quinn Fox
Staff Assistant to the Chief Judge
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UNITED STATES DEPARTMENT OF JUSTICE

Drug Enforcement Administration

In the Matter of **Schedules of Controlled Substances: Proposed Rescheduling of Marijuana**	**DEA Docket No. 1362** **Hearing Docket No. 24-44** **Administrative Law Judge** **John J. Mulrooney, II**

MOTION TO INTERVENE

I. Introduction

MedPharm, holder of certificate of registration from the Drug Enforcement Administration ("DEA") to research marijuana, qualifies to participate in the above-captioned rescheduling action as DEA considers (1) rescheduling that substance from schedule I to schedule III and (2) other "additional controls."

As MedPharm explained in its timely-filed petition to participate, MedPharm is an "interested person" within the Controlled Substances Act's (the "CSA") "zone of interests" because it is both regulated by marijuana scheduling and protected by the CSA as a DEA registrant.[1] And even if the stricter Article III standing analysis determines interested-person status, MedPharm has standing to participate. Because the Proposed Rule[2] and any other controls DEA places on marijuana would directly regulate MedPharm, it will remain a direct target of DEA's marijuana regulations going forward.[3]

The DEA Administrator excluded MedPharm from a list of "Designated Participants" for the ALJ hearing on marijuana rescheduling and other marijuana-specific controls currently scheduled for December 2, 2024. *See* 21 C.F.R. §§ 1308.44(b) and 1316.48. DEA provided no response to MedPharm's request to participate or explanation for MedPharm's exclusion. In fact, MedPharm only learned of its exclusion after this Tribunal released DEA Headquarters' list of Designated Participants. To MedPharm's knowledge, not one DEA-licensed marijuana researcher made the Administrator's list of "Designated Participants," leaving a significant gap in knowledge as DEA considers whether to reschedule marijuana.

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[1] Exhibit 1 (Sept. 30, 2024, Email to DEA enclosing ATACH petition); Exhibit 2 (Sept. 26, 2024, Email to DEA enclosing MedPharm petition).

[2] *Schedules of Controlled Substances: Rescheduling of Marijuana*, 89 Fed. Reg. 44,597 (May 21, 2024) (the "Proposed Rule").

[3] *See* Exhibit 2 at 2, 6–10. MedPharm was included in the revised/second ATACH petition after DOJ initially requested filing by U.S. Mail and later extended the deadline for filing petitions, allowing for electronic filing by email.

This Tribunal should therefore grant MedPharm's request to intervene and allow it to participate in the hearing.[4]

II. Background

A. MedPharm is a DEA-registered marijuana researcher.

Under the CSA's closed regulatory system, all persons or entities in the "legitimate distribution chain" of controlled substances must register with DEA under the criteria in 21 U.S.C. § 823. *See* H.R. Rep. 91-1444, 91st Cong., 2nd Sess. (1970) reprinted in 1970 U.S.C.C.A.N. 4566, 4589; 21 C.F.R. §§ 1301.11, 1301.18. MedPharm holds an active certificate of registration with DEA as a schedule I researcher approved to study marijuana.

MedPharm's research focuses on marijuana's potential medical utility for the treatment of neurodegenerative diseases such as Alzheimer's and Parkinson's. MedPharm also applied for DEA registration as a marijuana bulk manufacturer of marijuana in 2016. MedPharm's bulk-grower application remains unresolved and pending for decision before DEA. During its application and approval processes with DEA, MedPharm has incurred significant expenses, including application fees and the installation of several high-quality, certified safes and security monitoring systems. Further, MedPharm has been subject to several on-site inspections by DEA diversion agents. MedPharm has maintained constant, open, and transparent communications with its local DEA agency contacts and operates a research program in complete compliance with DEA requirements.

MedPharm has invested several years of time and significant monetary resources into establishing a first-of-its-kind research and production facility. It has implemented Current Good Manufacturing Practices, Good Agricultural and Collection Practices, and ISO 17025. It is also Hazardous Materials and Handling audited and accredited. In addition, MedPharm has spent years collaborating with the University of Iowa's Department of Neurology, School of Public Health, and the Institute for Clinical and Translational Science to organize and prepare to conduct a unique clinical trial involving marijuana. Its research team has several sources of research funding, including, for example, grant funding from the Institute of Cannabis Research at Colorado State University-Pueblo, where it collaborates with research teams from the University of Colorado's Anschutz and Boulder campuses to investigate the quality of products within Colorado's adult-use marijuana marketplace.

Currently, MedPharm is using neuronal and organoid 2D and 3D cellular cultures to investigate the effect of cannabinoids on the hallmarks of neuroinflammation. Dr. Duncan Mackie, MedPharm's Director of Pharmacology and Experimental Therapeutics, has over a decade of experience in drug discovery, cellular and molecular biology, and pharmacology. He previously worked at the University of North Carolina's School of Medicine identifying molecular mechanisms that control vascular development in mouse models. He has published in high-impact journals such as the Proceedings of the National Academy of Sciences and the Journal of Experimental Medicine. During the past 5 years with MedPharm, he has developed a rigorous,

[4] MedPharm was included in the revised/second request to participate by its trade association, the American Trade Association for Cannabis and Hemp ("ATACH"), after DOJ initially requested filing by U.S. Mail and later extended the deadline for filing petitions, allowing for electronic filing by email.

externally funded research program centered around the endocannabinoid system and its role in modulating the immune system during the onset of neurodegenerative diseases such as Alzheimer's and Parkinson's. Currently. Researchers have recognized that neuroinflammation plays a key role in the development and progression of these diseases, and Dr. Mackie's research program has identified important drug targets within the endocannabinoid system that could provide for routes of therapeutic intervention. To this end, Dr. Mackie utilizes the most advanced scientific techniques to model neuroinflammation in both cellular and organoid drug discovery paradigms, allowing for the identification of key signaling pathways and the monitoring of pro- and anti-inflammation markers expressed by the cells that make up with brain (i.e., neurons, astrocytes, and microglia). The drug screening platform allows Dr. Mackie's research team to measure the effects of cannabinoid isolates, cannabinoid combinations, and natural whole cannabinoid extracts on cytokine and chemokine production during inflammatory insult, which mimics what occurs during the development of these devastating neurogenerative diseases. This early drug discovery and pre-clinical work is the first step toward the development of a Food and Drug Administration ("FDA")-approved drug, which is the ultimate goal of MedPharm's research program. All results from this work will be included in potential Investigational New Drug Applications to the FDA.

Lastly, MedPharm has worked with Colorado State University on a recent National Institutes of Health application looking at intoxicated driving effects of co-administration of cannabis and alcohol in addition to work with Northwestern University examining the effects of cannabinoids on traumatic brain injuries. No other Designated Parties possess comparable knowledge or experience.

B. DOJ issues the Proposed Rule rescheduling marijuana, and DEA announces that it is considering "other controls" on marijuana.

On May 21, 2024, the United States Department of Justice ("DOJ") issued a Notice of Proposed Rulemaking ("NPRM" or "Proposed Rule") proposing to transfer marijuana from schedule I of the CSA to schedule III. *Schedules of Controlled Substances: Rescheduling of Marijuana*, 89 Fed. Reg. 44,597 (May 21, 2024). It also announced that DEA would consider "marijuana-specific controls that would be necessary to comply with relevant treaty obligations in the event that, after the hearing, a final order reschedules marijuana." Proposed Rule at 44,599; *Questions Related to the Potential Rescheduling of Marijuana,* 45 Op. O.L.C. ___ at 4 (Apr. 11, 2024) ("OLC Opinion").

The U.S. Attorney General had to take two historically unprecedented steps because DEA was so opposed to rescheduling marijuana and the related NPRM. First, he had to refer related interagency legal disputes over the appropriate standards to apply to the scheduling process to the Office of Legal Counsel ("OLC") for resolution. *See Schedules of Controlled Substances: Rescheduling of Marijuana*, 89 Fed. Reg. 44,597, 44,599 (May 21, 2024) ("The Attorney General then sought the legal advice of the [OLC] at DOJ on questions relevant to this rulemaking proceeding."). Second, he had to promulgate and sign the NPRM himself. *Id.* at 44,622 (reflecting the signature of the Attorney General instead of the DEA Administrator). When OLC made favorable decisions consistent with previous scientific findings of, and recommendations from, the Department of Health and Human Services ("HHS"), DEA apparently still refused to support rescheduling and

the NPRM. To MedPharm's knowledge, this is the first time in the history of drug scheduling under the CSA that either of these steps was "necessary."

DOJ emphasized in the NPRM itself that "DEA has not yet made a determination as to its views of the appropriate schedule for marijuana." *Id.* at 44,601. In the NPRM, DEA refused to support the proposal to move marijuana to schedule III and declared "its belie[f] that additional information arising from this rulemaking will further inform the findings regarding the appropriate schedule for marijuana." Proposed Rule at 44,601.

Under § 811(b) of the CSA, "the Attorney General shall, ***before*** initiating proceedings under subsection (a) to control a drug . . . and ***after*** gathering the necessary data, request from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be controlled. . . ." (emphases added). The NPRM however, went on to flag several categories of evidence DEA "anticipate[d]" it would receive during the remainder of the rulemaking process that, in its view, would bear on the scheduling decision, including:

- "additional data on seizures of marijuana by law enforcement, cannabis-related ED visits, as well as updated epidemiological survey data since 2022" (Proposed Rule at 44,602);
- "additional data on diversion from State programs and DEA-registered manufacturers" (*id.*);
- "additional data" showing that "[marijuana] has reinforcing effects characteristic of drugs of abuse," and "[d]ata on marijuana seizures [and] widespread availability and trafficking" (*id.* at 44,603);
- "additional data on marijuana's pharmacological effects" (*id.* at 44,605);
- "additional data on other marijuana constituents, routes of administration of marijuana, and the impact on Δ9-THC potency" (*id.* at 44,607);
- "additional data regarding marijuana's history and current pattern of abuse" (*id.*);
- "additional information regarding the scope, duration, and significance of marijuana abuse" (*id.* at 44,613);
- "additional data on public safety risks, risks from acute and chronic marijuana use via oral and inhaled administration routes, and the impact of Δ9-THC potency" (*id.* at 44,614); and
- "additional psychic or physiological dependence liability" (*id.* at 44,615).

Congress required DEA to gather the necessary data ***first*** for a reason—namely, so that HHS could consider it as part of its scientific and medical evaluation and scheduling recommendation. By flagging categories of "necessary data" that it believes undermine the Proposed Rule in the NPRM, instead of gathering them ahead of time for HHS review as the statute requires, DEA created a blueprint for prohibitionist organizations. Indeed, in a June 2024 webinar, Smart Approaches to Marijuana's ("SAM") second in command, Luke Niferatos, said that DEA was "giving a roadmap for how to rebut [its] own Proposed Rule."[5] SAM then implored its followers to do DEA's bidding by tracking down the missing information DEA had requested. SAM was joined on that webinar by Dr. Russel Kramer and Sue Thau, representatives of the International Academy on the Science and Impact of Cannabis ("IASIC") and the Community Anti-Drug Coalitions of America

[5] Smart Approaches to Marijuana, SAM Webinar: Rescheduling of Marijuana, YOUTUBE (June 17, 2024), https://www.youtube.com/watch?v=3NWSz5LXRa4, at 24:25.

("CADCA"), respectively. Perhaps unsurprisingly, DEA included all three organizations on its list of Designated Participants in these proceedings. *See infra*, Part 2.D.

The Proposed Rule also noted that DEA may hold a hearing to "receive factual evidence and expert opinion regarding whether marijuana should be transferred to schedule III of the list of controlled substances." Proposed Rule at 44,599 (cleaned up). The agency subsequently announced that it would hold such a hearing on December 2, 2024. *See Notice of Hearing on Proposed Rulemaking*, 89 Fed. Reg. 70,148 (Aug. 29, 2024).

C. MedPharm timely filed a robust and well-grounded request to participate in the hearing on the Proposed Rule.

MedPharm timely filed a request to participate with the DEA Administrator on September 26, 2024.[6] In that request, MedPharm explained that it is an "interested person" under any definition. First, it falls within the CSA's "zone of interests" because it is both regulated by the scheduling of marijuana and protected by the CSA as a DEA registrant.[7] Second, MedPharm meets Article III's injury-in-fact requirement because the Proposed Rule would directly regulate MedPharm.[8] MedPharm also submitted a robust revised request to participate through its trade association, ATACH, on September 30, 2024.[9] ATACH also filed timely and substantive public comment on behalf of MedPharm and its other members on July 22, 2024, in response to a government request for such information.[10]

D. The DEA Administrator excluded MedPharm from the list of Designated Participants without notice or explanation.

DEA did not respond to either the MedPharm or ATACH requests to participate. DEA regulations require such matters to be handled by a "presiding officer," which the regulations define to mean an administrative law judge. *See* 21 C.F.R. § 1316.42 (defining "presiding officer"); *see also id.* § 1316.52 (mandating that the "presiding officer, designated by the Administrator, shall preside over all hearings"). Instead, the DEA Administrator excluded MedPharm and ATACH from a list of Designated Participants and likewise failed to provide any notice or explanation for the presumed denial of those requests to participate.

Notwithstanding the exclusion of this highly qualified DEA-licensed researcher with standing, the DEA Administrator's Designated Participants list includes multiple prohibitionist organizations, conservative law enforcement agencies, and others who clearly oppose the Proposed Rule that DEA, as the putative proponent of the NPRM, is obligated to defend. The deck appears to be stacked against those in favor of promulgation of the NPRM that was proposed by DOJ and supported by HHS and OLC. The list was seemingly created by the DEA Administrator herself, without even so much as consultation with this Tribunal, and it includes only a handful of witnesses

[6] Exhibit 2.

[7] *Id.*, at 6–7.

[8] *Id.*, at 7–10. MedPharm was included in the revised/second ATACH petition after DOJ initially requested filing by U.S. Mail and later extended the deadline for filing petitions, allowing for electronic filing by email.

[9] Exhibit 1.

[10] ATACH's public comment is available at https://schedulingreform.org/coalition-comment.

who support the Proposed Rule. Alarmingly, it is anything but clear that any of the prohibitionists that the Administrator designated as participants have standing to participate. For instance, SAM, IASIC, CADCA, prohibitionist Dr. Kenneth Finn, the International Association of Chiefs of Police, the Drug Enforcement Association of Federal Narcotic Agents, the National Sheriffs' Association, the Tennessee Bureau of Investigation, and the Attorney General of Nebraska all clearly oppose the transfer of marijuana to schedule III. In addition to favoring prohibitionists who objectively lack standing, the list is also nearly devoid of DEA researchers, scientists, or doctors who could offer serious expertise on marijuana's relative abuse potential compared to other drugs in schedule I or II. This is particularly confounding, given that one of the most important issues facing this Tribunal is the determination of marijuana's relative abuse potential. Finally, the Administrator's list is also devoid of anyone with experience in the 38 states currently regulating medical marijuana, including states with longstanding regulated medical programs and experience with medical use in treatment in the United States, or others possessing evidence to support the findings of HHS or DOJ.

In short, the list of participants is not designed to offer the best evidence to support the findings of our leading health agencies. Instead, it is designed to thwart a legitimate process that DEA's parent agency has indicated is lawful and thus should be defended. By inserting itself into these proceedings to rig the list of Designated Parties before referring this matter to this Tribunal, DEA has undermined the legitimacy of these proceedings before they have even begun. Through its off-the-record pre-determination of who may and may not present evidence in these proceedings, DEA has impeded this Tribunal's ability to discharge its duty to develop a full administrative record and ensure the fairness and transparency that DEA regulations and the APA demand. No objective observer could attribute these actions to an agency with an open mind seeking to follow the law and the science where it leads on the question of whether marijuana belongs in schedule III.

III. This Tribunal should allow MedPharm to intervene.

A. The process for selecting Designated Participants violated the APA.

The Proposed Rule is a "scheduling action" under 21 U.S.C. § 811(a). *See* Proposed Rule at 44,598; *id*. at 44,621. Congress required that such an action "shall be made on the record after [an] opportunity for a hearing pursuant to the rulemaking procedures prescribed by the [APA]." 21 U.S.C. § 811(a). Under the APA, 5 U.S.C. § 555(b), "an interested person may appear before an agency or its responsible employees for the presentation, adjustment, or determination of an issue, request, or controversy in a proceeding," "[s]o far as the orderly conduct of public business permits."

DEA regulations permit an "interested person" to file a request to participate in a hearing. 21 C.F.R. § 1308.44(c). The APA provides that "[p]rompt notice shall be given of the denial in whole or in part of a written application, petition, or other request of an interested person made in connection with any agency proceeding. Except in affirming a prior denial or when the denial is self-explanatory, the notice shall be accompanied by a brief statement of the grounds for denial." 5 U.S.C. § 555(e).

In addition, "courts will not rubberstamp a challenged denial [of a request to participate in agency proceedings] based merely upon an assertion of justification." *Animal Legal Def. Fund, Inc. v.*

Vilsack, 237 F. Supp. 3d 15, 22–23 (D.D.C. 2017). "The agency must refrain from employing its discretion [about who participates] in an unreasonably overbroad or otherwise arbitrary manner." *Id*.

Here, DEA did not respond to either MedPharm's or ATACH's request to participate. Instead, the Administrator excluded both would-be parties without notice or explanation. Indeed, on October 31, 2024, this Tribunal observed that "it is not transparent in the present record" whether the Designated Participants are "eligible [to participate in the hearing] as an interested person" or whether they had "timely" applied to do so.[11] Alas, it is anything but clear how and why DEA Headquarters made the decisions to admit or reject certain participants. What is perfectly clear is that there was an alarming lack of transparency in the decision-making process: several prohibitionist organizations without standing were chosen after having submitted skeletal requests to participate; and numerous parties that have standing but were not chosen, including MedPharm and ATACH, should have been.[12]

MedPharm thus files this petition to intervene. To comply with the APA and allow it to "effectively preside over th[e] hearing," this Tribunal asked the Designated Participants to answer certain questions about their identity and interest in and position on the Proposed Rule. MedPharm answers those questions below.

B. MedPharm qualifies as an "interested person" entitled to participate in the hearing.

This Tribunal can and should allow MedPharm, a DEA-registered marijuana researcher, to participate in the December 2 hearing. As the Presiding Officer in these proceedings, this Tribunal has a "duty to conduct a fair hearing, to take all necessary action to avoid delay, and to maintain order." *See* 21 C.F.R. § 1316.52. For that reason, this Tribunal has "all powers necessary to th[o]se ends," *id.*, including to grant intervention.

DEA regulations define "interested person" as "any person adversely affected or aggrieved by any rule or proposed rule issuable pursuant to [21 U.S.C. § 811]." 21 C.F.R. § 1300.01(b).[13]

DEA has not formally defined "adversely affected or aggrieved." *See In the Matter of Scheduling 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT*, DEA Dkt. No. 22-15 (May 6, 2022) at 2 ("ALJ Order").[14] In May 2022, another Administrative Law Judge ("ALJ") of this Tribunal concluded that the test for whether a particular entity is "adversely affected or aggrieved" by a proposed scheduling action (and thus qualifies as an "interested person" under DEA's definition of that term) was satisfied when the person "ha[s] an interest in the[] proceedings" that is "arguably within the zone of interests" of § 811(a) of the CSA. ALJ Order at 5 (internal

[11] Exhibit 3 (Order, Hearing Docket No. 24-44 (Oct. 31, 2024)) ("Preliminary Order").

[12] The state of Colorado also submitted a timely petition to participate based on its ten years of experience regulating a state-legal medical marketplace. Colorado, like MedPharm, never received any response from DEA or explanation for why their petition was not granted.

[13] Pursuant to 21 C.F.R. § 1300.01(b), "person" includes "any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity."

[14] This ALJ Order is attached as Exhibit 3.

quotations omitted). Given Congress' intent to "make agency action presumptively reviewable," the "zone of interests" test is "not meant to be especially demanding." *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209, 225 (2012) (citation omitted).

A party falls "within the zone of interests," the ALJ explained, "if they are regulated by the particular agency action being challenged, or if they are considered to be protected by the statute in question." ALJ Order at 5 (quoting *MD Pharm., Inc. v. DEA*, 133 F.3d 8, 12 (D.C. Cir. 1998)). The statute in question—the CSA—was enacted with "the main objectives of combating drug abuse and controlling the legitimate and illegitimate traffic in controlled substances." *Gonzales v. Oregon,* 546 U.S. 243, 250 (2005).

MedPharm falls within the CSA's "zone of interests" for two reasons. First, MedPharm is regulated by the scheduling of marijuana. *Compare, e.g.*, ALJ Order at 7–9 (recognizing the "interested person" status of multiple entities based on nearly identical considerations). MedPharm is a DEA-registered marijuana researcher with ongoing marijuana research projects. MedPharm's registration is a property interest affected by the Proposed Rule. *See Lujan v. G & G Fire Sprinklers, Inc.*, 532 U.S. 189, 196 (2001); Odette L. Campbell, M.D., 80 Fed. Reg. 41,062, 41,067–68 (2015) (citing *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976); and then citing *Mullane v. Cent. Hanover Bank & Tr.*, 339 U.S. 306, 313 (1950)). If DEA were to reject the Proposed Rule in favor of either maintaining marijuana's schedule I classification or transferring it to schedule II—rules that remain "issuable" as a result of these proceedings, *see* 21 C.F.R. § 1300.01(b) (defining "interested person" to mean "any person adversely affected or aggrieved by any rule or proposed rule *issuable* pursuant to section 201 of the Act" (21 U.S.C. 811) (emphasis added))—MedPharm would have to comply with significantly stricter regulatory requirements than if marijuana were in schedule III, including, for example:

- Research with schedule I substances requires an FDA-approved protocol—an arduous and costly requirement that does not apply to research with substances in any other schedule. *See* 21 C.F.R. § 1301.18.
- The inventory requirements for substances in schedules I and II are significantly stricter than those applicable to substances in schedule III. *See id.* § 1304.11(e)(6).
- The export requirements that would apply to marijuana were it transferred to schedule III are significantly less strict than those currently applicable under schedule I. *See id.* § 1312.21.
- The restrictions on orders for schedule I and II substances are significantly stricter than those applicable to substances in schedule III. *See, e.g.*, *id.* §§ 1305.04 and 1305.21.
- The storage requirements applicable to schedule I substances are significantly more burdensome than those that apply to substances in schedule III. *See id.* § 1301.71.

Second, MedPharm, a DEA-registered marijuana researcher, is protected by the CSA as an entity with express permission from DEA to handle marijuana for legitimate research purposes. *See MD Pharm*, 33 F.3d at 12; *Gonzales*, 546 U.S. at 250.

In recent scheduling actions, DEA has argued that a person qualifies as an "interested person" only if they can demonstrate injury-in-fact under Article III standing doctrine sufficient to pursue litigation in federal court. *See* ALJ Order at 4. ALJs have correctly rejected that argument. *See id.* at 5–6. The Article III standing requirement comes from "case or controversy" language in the

U.S. Constitution applicable to *federal courts*. That "case or controversy" language does not appear in 5 U.S.C. § 555(b). *See generally CACI, Inc.-Fed. v. United States*, 67 F.4th 1145, 1151 (Fed. Cir. 2023) ("zone-of-interests" requirement separate from Article III standing). In any event, MedPharm qualifies as an interested person even under that stricter standard.

Courts routinely hold that costly regulatory burdens constitute "injury in fact" sufficient for Article III standing. *See Metro. Wash. Chapter, Associated Builders & Contrs., Inc. v. District of Columbia*, 62 F.4th 567, 573 (D.C. Cir. 2023) ("[Litigant] can bring this action in its own right based on its allegations that it incurs increased administrative costs to comply with the statute's hiring and reporting requirements. . . .") (citing cases). Increased compliance costs confer standing even on parties that are not directly regulated. *See, e.g.*, *Ass'n of Private Sector Colls. & Univs. v. Duncan*, 681 F.3d 427, 457–58 (D.C. Cir. 2012) (party not directly regulated by agency rule had standing based on increased compliance costs resulting from regulation of a different party). Indeed, "monetary harms" "readily qualify as concrete injuries under Article III." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 425 (2021).

MedPharm meets Article III's injury-in-fact requirement because DEA's potential rejection of the Proposed Rule *or* DEA's adoption of "additional controls" on marijuana would impose additional compliance costs, as described above. *See Metro. Wash. Chapter*, 62 F.4th at 573; *Ass'n of Private Sector Colls. & Univs.*, 681 F.3d at 457–58.

Finally, the "additional controls" DEA is contemplating to ensure that any potential rescheduling complies with international treaty obligations would also injure MedPharm.[15] While MedPharm does not know the details of the "additional controls" that DEA has in mind, any requirements beyond those applicable to schedule III substances generally would impede MedPharm's current and future research projects, including potentially life-saving treatments. These impediments would not only harm MedPharm's bottom line, but they would ultimately undermine public health and safety generally.

Thus, even under Article III standards, MedPharm qualifies as an "interested person" and is therefore entitled to participate in these proceedings.

C. MedPharm's participation would facilitate the orderly conduct of public business.

MedPharm's intervention is necessary for a fair hearing that includes all perspectives, especially as MedPharm's participation would facilitate the orderly conduct of public business. *See* 5 U.S.C. § 555(b) (allowing for the participation of "an interested person" before an agency "[s]o far as the orderly conduct of public business permits").

MedPharm is a licensed DEA marijuana researcher that supports the Proposed Rule, and as discussed above, the DEA Administrator's Designated Participants list—apparently created without consulting this Tribunal—includes far more entities that clearly oppose the Proposed Rule that DEA is obligated to defend. In addition, MedPharm provides a unique perspective as a DEA-registered marijuana researcher. *Nichols v. Bd. of Trustees of Asbestos Workers Loc. 24 Pension*

[15] NPRM at 44,620–21.

Plan, 835 F.2d 881, 897 (D.C. Cir. 1987); *Animal Legal Def. Fund*, 237 F. Supp. 3d at 22–23. While this Tribunal may have concerns about opening the door to multiple intervenors, it set a filing date for November 12, 2024, and could admit parties who demonstrated standing and timely filed a motion to intervene. MedPharm has done both here.

Moreover, DEA cannot shoulder the burden of proof in these proceedings because it did not propose the NPRM—DOJ did. As this Tribunal's Preliminary Order emphasized, "Under the APA, 'the proponent of a[n] . . . order has the burden of proof'" in an administrative hearing process like this one. Preliminary Order 2–3 (quoting 5 U.S.C. § 556(d)); *see also id. at* 3 ("'At any hearing, the proponent for the issuance, amendment, or repeal of any rule shall have the burden of proof.'" (quoting 21 C.F.R. § 1316.56)). But DEA is not the "proponent of" the Proposed Rule. DOJ proposed the NPRM precisely because DEA did not and does not support it. As such, DOJ is the proponent of the Proposed Rule, and DOJ must bear the burden of proof under the APA and DEA regulations. And because DEA took the unusual and very deliberate step of *refusing* to be the proponent of the Proposed Rule, permitting it to bear the burden of proof would turn the controlling APA provisions and DEA regulations on their heads.

IV. Conclusion

MedPharm is an interested person with standing to participate in the upcoming hearing on the Proposed Rule. It requests intervention and participation in these proceedings.

In its Preliminary Order dated October 21, 2024, this Tribunal requested certain information from the Designated Parties. To facilitate this Tribunal's consideration of this Motion, MedPharm provides the same requested information below:

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

Name: MedPharm

Address: 3855 Quentin St, Denver, CO 80239

Phone Number: 720-697-7554

Principal Mission: MedPharm is a DEA-licensed cannabis researcher.

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

Notices of appearance for MedPharm's counsel, Andrew Kline, Perkins Coie LLP, and Shane Pennington, Porter Wright Morris & Arthur LLP, are attached hereto as Exhibits 4 and 5, respectively.

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

MedPharm, a DEA-registered marijuana researcher, timely filed with the DEA Administrator a request to participate on September 26, 2024. The email correspondence with DEA is attached hereto as Exhibit 2. ATACH later electronically filed an updated and timely petition on September 30, 2024; the transmittal email is attached as Exhibit 1.

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

MedPharm incorporates the above submission as its response to this question.

(5) Whether the Designated Participant supports or opposes the scheduling action the DEA seeks in its NPRM.

MedPharm supports schedule III but does not currently have enough information to know whether it supports or opposes new DEA controls being contemplated by DEA as part of this rulemaking.[16]

MedPharm is prepared to offer testimony on whether the Proposed Rule sets forth substantial evidence that marijuana's potential for abuse is comparable to substances in schedule III. Neither the Proposed Rule nor the supporting materials present *substantial* evidence that marijuana's abuse potential is higher than that of substances in schedule IV or V. A drug in schedule V has a low potential for abuse and limited physical dependence or psychological dependence relative to the drugs in schedule IV. Compared to benzodiazepines in schedule IV, marijuana has a low potential for abuse and lower psychological dependence. Marijuana use may produce some level of dependence, and cessation of use may produce withdrawal symptoms.[17] But dependence associated with marijuana use and marijuana withdrawal is far less significant than benzodiazepine dependence and benzodiazepine withdrawal.[18]

MedPharm's own experience and research, along with other emerging research that has come to light since the comment period on the Proposed Rule closed, confirms and

[16] In the interest of completeness, MedPharm also provides what the "General Notice of Hearing" asked persons seeking to participate in the rescheduling hearing to provide: (1) Stating with particularity with interest of the person in the proceeding; (2) Stating with particularity the objections or issues concerning which the person desires to be heard; and (3) Stating briefly the position of the person regarding the objections or issues. MedPharm's answer to #1 is above. MedPharm's answers to #2 and #3 are incorporated into its response above the line.

[17] *See, e.g.*, Jason P. Connor, et al., *Cannabis use and cannabis use disorder*, 7 NATURE REVIEWS DISEASE PRIMERS 16 (Feb. 25, 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8655458/.

[18] *Compare* Jason P. Connor et al., *Clinical management of cannabis withdrawal*, 117 ADDICTION 2075–95 (Jan. 2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9110555/, *with* Lone Baandrup, et al., *Pharmacological interventions for benzodiazepine discontinuation in chronic benzodiazepine users*, 3 COCHRANE DATABASE OF SYSTEMATIC REVIEWS 3 (Mar. 15, 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6513394/.

strengthens this conclusion. MedPharm is prepared to present evidence and expert testimony on this issue.

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

MedPharm and its attorneys of record have no known conflicts of interest in this proceeding themselves. There are, however, compelling grounds for believing that DEA opposes the NPRM, leading MedPharm to conclude that permitting DEA to act as the proponent of the NPRM in these proceedings would create a conflict of interest.

Respectfully yours,

Andrew J. Kline
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SPennington@porterwright.com

Attorneys for Proposed Intervenor MedPharm

Enclosures:

Exhibit 1: Sept. 30, 2024 Email to DEA enclosing ATACH petition

Exhibit 2: Sept. 26, 2024, Email to DEA enclosing MedPharm petition

Exhibit 3: *In the Matter of Scheduling 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT*, DEA Dkt. No. 22-15 (May 6, 2022)

Exhibit 4: Notice of Appearance of Andrew J. Kline

Exhibit 5: Notice of Appearance of Shane Pennington

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) 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 and Andrew J. Kline at akline@perkinscoie.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 Sheriffs' Association, via email at sheriffskinner@collincountytx.gov and ykaraman@sheriffs.org.

Andrew J. Kline

Exhibit 1

From:	Kline, Andrew (DEN)
To:	nprm@dea.gov
Cc:	Mullin, Hanna (WDC); Tobin, Thomas (SEA); Kallon, Abdul (SEA); spennington@porterwright.com; Shah, Sopen (MSN)
Subject:	Docket No. DEA-1362
Date:	Monday, September 30, 2024 3:04:30 PM
Attachments:	2024-09-30 ATACH Request to Participate in Hearing (final).pdf

Docket No. DEA-1362

Dear Administrator Milgram,

Attached is the American Trade Association of Cannabis and Hemp's (ATACH) request to participate in the December 2, 2024 hearing regarding the Rescheduling of Marijuana, 89 Fed. Reg. 44,597, Docket DEA-1362. This updated petition replaces ATACH's petition filed on June 17, 2024.

We respectfully request acknowledgement of receipt of this petition please.

Best,

Andrew
Andrew Kline
FIRMWIDE CO-CHAIR, CANNABIS INDUSTRY GROUP
Perkins Coie
1900 Sixteenth Street Suite 1400
Denver, CO 80202-5255
+1.303.291.2307
AKline@perkinscoie.com
perkinscoie.com

Exhibit 2

From:	Kline, Andrew (DEN)
To:	nprm@dea.gov
Cc:	Mullin, Hanna (WDC); Tobin, Thomas (SEA); Kallon, Abdul (SEA); spennington@porterwright.com
Subject:	Docket No. DEA-1362
Date:	Thursday, September 26, 2024 4:07:16 PM
Attachments:	2024-09-26 Final - Petition for MedPharm to Appear at Hearing (Docket No. DEA-1362).pdf

Docket No. DEA-1362

Dear Administrator Milgram,

Attached is MedPharm's request to participate in the December 2, 2024 hearing regarding the Rescheduling of Marijuana, 89 Fed. Reg. 44,597, Docket DEA-1362.

We respectfully ask that the DEA grant this request.

Thank you for your attention to matter. We look forward to your response.

Respectfully submitted,

Andrew Kline
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Exhibit 3

UNITED STATES DEPARTMENT OF JUSTICE

Drug Enforcement Administration

In the Matter of **Scheduling 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT**	**Docket No. 22-15**

ORDER GRANTING IN PART GOVERNMENT'S MOTION TO DISMISS IN PART

On January 14, 2022, the Drug Enforcement Administration (DEA) published a Notice of Proposed Rulemaking (NPRM), with the docket number DEA-623, titled "Schedules of Controlled Substances: Placement of 4-hydroxy-*N*,*N*-diisopropyltryptamine (4-OH-DiPT), 5-methoxy-*alpha*-methyltryptamine (5-MeO-AMT), 5-methoxy-*N*-methyl-*N*-isopropyltryptamine (5-MeO-MiPT), 5-methoxy-*N*,*N*-diethyltryptamine (5-MeO-DET), and *N*,*N*-diisopropyltryptamine (DiPT) in Schedule I." 87 Fed. Reg. 2376 (2022). The NPRM proposes to place the five tryptamine hallucinogens (4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT) in schedule I of the Controlled Substances Act (CSA). *Id.* On January 31, 2022, Panacea Plant Sciences (Panacea) filed a Request for Hearing (RFH). On February 14, 2022, Jason Wallach and Hamilton Morris, Kykeon Biotechnologies Inc. (Mindstate) and Tactogen Inc. (Tactogen), and Amy Rising filed RFHs.

On April 18, 2022, the Government filed its Motion to Dismiss in Part (Government's Motion) alleging that not all parties requesting a hearing have standing and asking this tribunal to dismiss "any party that cannot establish interested person status for at least one of the substances[.]"[1] Gov't Mot. at 1. Additionally, the Government requests that this tribunal "limit

[1] The Government concedes that Jason Wallach and Hamilton Morris, who are proceeding jointly, established standing in their RFH with respect to DiPT. Gov't Mot. at 9. In the April 26, 2022 status conference, counsel for Dr. Wallach and Mr. Morris indicated that they only intended to request a hearing with respect to the proposed scheduling of DiPT and do not wish to challenge the proposed scheduling of the other four tryptamines. Accordingly, Dr. Wallach and Mr. Morris' standing to challenge the proposed scheduling of DiPT is not challenged herein.

the hearing on this proposed rulemaking to those substances for which an interested person has requested a hearing." *Id.* at 1-2.

ADMINISTRATIVE STANDING

"The starting point in determining administrative standing should be the language of the statutes and regulations that provide for an administrative hearing, appeal or intervention." *Koniag, Inc., Uyak v. Andrus*, 580 F.2d 601, 614 (D.C. Cir. 1978) (Bazelon, J., concurring); *see Koniag*, 580 F.2d at 606. The standing analysis is thus an individualized one, within the context of the regulations and the statutory scheme as a whole. *Nichols v. Bd. of Trs.*, 835 F.2d 881, 896 n.108 (D.C. Cir. 1987).

This is a scheduling proceeding under § 811 of the CSA. The regulations governing scheduling proceedings provide that an "interested person" may request a hearing on the proposed scheduling of a substance. *See* 21 C.F.R. § 1308.44. The regulations define "interested person" as "any person adversely affected or aggrieved by any rule or proposed rule issuable pursuant" to 21 U.S.C. § 811. *Id.* § 1300.01. A person requesting a hearing must state "with particularity" his interest in the proceeding. *Id.* § 1316.47(a).

The Agency has not interpreted either "interested person" or "any person adversely affected or aggrieved," although there are two Agency rulemaking proceedings in which the Agency found a party requesting a hearing did not meet the definition of "interested person." *See Schedules of Controlled Substances: Placement of Lorcaserin into Schedule IV*, 78 Fed. Reg. 26701, 26703 (2013) (denying a request for hearing because a concern that the substance had a large potential for abuse was insufficient to show that the party requesting a hearing was an "interested person"); *Schedules of Controlled Substances: Placement of Lacosamide into Schedule V*, 74 Fed. Reg. 23789, 23789 (2009) (denying a request for hearing because the party's statement that "lack of information and inappropriate comparisons to other drugs precluded the scheduling" did not sufficiently establish standing as an "interested person").

In the absence of an official Agency interpretation, this tribunal looks to general principles on standing. Standing to sue in federal court stems from the Article III case or controversy requirement and thus requires injury-in-fact. *See, e.g., Spokeo, Inc. v. Robbins*, 578 U.S. 330, 338-39 (2016). Moreover, federal courts have put on a "judicial gloss" of prudential standing called the "zone of interests" test limiting who may challenge an agency action. *See Animal Legal Def. Fund v. Espy*, 23 F.3d 496, 502 (D.C. Cir. 1994). But standing before an administrative agency is

more permissive than before an Article III court. *See Gettman v. DEA*, 290 F.3d 430, 434 (D.C. Cir. 2002) ("Because agencies are not constrained by Article III, they may permit persons to intervene in the agency proceedings who would not have standing to seek judicial review of the agency action."); *Envirocare, Inc. v. NRC*, 194 F.3d 72, 74 (D.C. Cir. 1999) ("Agencies, of course, are not constrained by Article III of the Constitution; nor are they governed by judicially-created standing doctrines restricting access to the federal courts. The criteria for establishing 'administrative standing' therefore may permissibly be less demanding than the criteria for 'judicial standing.'"); *Nichols*, 835 F.2d at 896 n.108 ("We emphasize that parties may validly participate in agency proceedings even absent standing to obtain judicial review."); *Koniag*, 580 F.2d at 606 (a party need not be "excluded from participation before the agency if it does not have a sufficient interest to meet Article III requirements for judicial review.").

Applying the "'interested person' concept to parties not entitled to judicial review resists precise legislative or judicial delineation, and requires close scrutiny, in the context of the statutory and regulatory schemes governing the proceedings in which intervention is sought, of the private interest asserted." *Nichols*, 835 F.2d at 896 n.108 (internal citations omitted). Thus, standing before an agency is not synonymous with standing before a federal court and requires a close examination of the applicable regulations. *Id.*; *see also Koniag*, 580 F.2d at 614. More precisely, the question here is what "adversely affected or aggrieved" requires within the context of the CSA and the limited Agency caselaw for standing in these proceedings.

The Agency has taken the position, in the context of mootness, that it is not bound by Article III. *See, e.g.*, *The Pharmacy Place*, 86 Fed. Reg. 21008, 21008 (2021); *Jeffrey D. Olsen, M.D.*, 84 Fed. Reg. 68474, 68476 (2019).

> The subject matter of agencies' jurisdiction naturally is not confined to cases or controversies inasmuch as agencies are creatures of [A]rticle I. Though agencies must act without arbitrariness, . . . still agencies are generally free to act in advisory or legislative capacities…[which] is obvious in the case of rulemaking[.]

Olsen, 84 Fed. Reg. at 68478 (quoting *Tennessee Gas Pipeline v. Fed. Power Comm'n*, 606 F.2d 1373, 1379 (D.C. Cir. 1979)). While not directly on point, the Agency's position is instructive given that courts have routinely stated that (with some caveats): "the doctrine of mootness can be described as the doctrine of standing set in a time frame: The requisite personal interest that must exist at the commencement of the litigation (standing) must continue throughout its existence (mootness)." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs.*, 528 U.S. 167, 189-90 (2000)

(internal quotations omitted) (noting exceptions to this rule). Given that the Administrator has rejected the application of Article III in the context of mootness in Agency proceedings, the logical extrapolation of those decisions is that § 1300.01 does not incorporate the requirements of Article III standing.

The Government, however, argues that "adversely affected or aggrieved" applies no differently here than how it has historically been interpreted in federal courts. Gov't Mot. at 4-5. "The phrase 'person adversely affected or aggrieved' is a term of art used in many statutes to designate those who have ***standing to challenge*** or appeal an agency decision, ***within the agency*** or before the courts." *Id*. at 4 n.1 (emphasis in original) (quoting *Dir., Off. of Workers' Comp. Programs, Dept. of Lab. v. Newport News Shipbuilding and Dry Dock Co. (Newport News)*, 514 U.S. 122, 126 (1995)). The phrase appears in the judicial review provision of the Administrative Procedure Act (APA) and similarly appears in the CSA's judicial review provision. *See* 5 U.S.C. § 702 ("A person…adversely affected or aggrieved by agency action within the meaning of the relevant statute[] is entitled to judicial review thereof."); 21 U.S.C. § 877 ("any person aggrieved by a final decision of the Attorney General may obtain review of the decision"). Courts have interpreted the APA's judicial review provision as requiring a party to show that he is both "injured in fact by agency action and that the interest he seeks to vindicate is arguably within the 'zone of interests to be protected or regulated by the statute' in question." *Newport News*, 514 U.S. at 127 (quoting *Ass'n of Data Processing Serv. Orgs., Inc. v. Camp*, 397 U.S. 150, 153 (1970)). Additionally, courts interpreting the CSA's judicial review provision have similarly found that it "merely requires that the litigant have Article III standing and prudential standing—i.e., arguably be within the 'zone of interests.'" *Bonds v. Tandy*, 457 F.3d 409, 413 (D.C. Cir. 2006); *see PDK Lab'ys Inc. v. DEA*, 362 F.3d 786, 793 (D.C. Cir. 2004).

The Government's interpretation of *Newport News*, however, is too broad. That decision—which involved federal judicial review—stands merely for the proposition that a party challenging an agency decision *in federal court* lacks standing unless the party can establish it had injury-in-fact and fell within the statute's zone of interests from the very beginning of the case, including before the Agency. *Newport News*, 514 U.S. at 126. But it does not support the proposition that a party must be excluded from *an agency proceeding* if it fails to make that showing. *See Gettman*, 290 F.3d at 434; *Koniag*, 580 F.2d at 606. Similarly unpersuasive are the other cases cited by the Government. While courts have interpreted "adversely affected or aggrieved" as requiring Article

III and prudential standing, those courts were examining statutory provisions establishing standing to seek judicial review before a federal court, not standing before an agency. *See Newport News*, 514 U.S. at 127; *Bonds*, 457 F.3d at 413; *PDK Lab'ys*, 362 F.3d at 793. As discussed above, courts have repeatedly rejected the presumption that Article III applies to agency proceedings, as has this Agency, in the context of mootness. Moreover, the Government's argument runs counter to the established principle that administrative standing is more permissive than Article III standing. *See Gettman*, 290 F.3d at 434. Accordingly, the Government's argument is unpersuasive.[2]

The parties find common ground on applying the zone of interests test, which provides that a party requesting a hearing must have an interest in these proceedings and that interest must be "arguably within the zone of interests…" *PDK Lab'ys*, 362 F.3d at 791 (quoting *Ass'n of Data Processing*, 397 U.S. at 153). The parties requesting a hearing have the burden of proving that they have standing to participate in these proceedings.[3] The test is "not meant to be especially demanding[;]" however, where the party is not the subject of the agency action, the party's interests must not be "so marginally related to or inconsistent with the purposes implicit in the statute." *Clarke v. Secs. Indus. Ass'n.*, 479 U.S. 388, 399 (1987). A party falls "within the zone of interests if they are regulated by the particular agency action being challenged, or if they are considered to be protected by the statute in question." *MD Pharm., Inc. v. DEA*, 133 F.3d 8, 12 (D.C. Cir. 1998) (citing *First Nat'l Bank & Tr. Co. v. Nat'l Credit Union Admin.*, 988 F.2d 1272, 1275 (D.C. Cir. 1993)). To be clear, "[j]udicially-devised prudential standing requirements, of which the 'zone of interests' test is one, are also inapplicable to an administrative agency…The doctrine of prudential standing, like that derived from the Constitution, rests on considerations 'about the proper—and properly limited—role of the courts in a democratic society.'" *Envirocare*, 194 F.3d at 75 (quoting *Warth v. Seldin*, 422 U.S. 490, 498 (1975)). But, while prudential standing is not necessarily required for administrative standing, absent additional guidance from the Agency, the zone of interests standard provides an instructive framework to interpret the meaning of "adversely affected or aggrieved."

[2] Even if the regulations require injury-in-fact, that would not change the outcome of this case. *See infra* note 4.

[3] While 21 C.F.R. § 1316.56 provides that the moving party has the burden of proof, the regulations require that the party requesting a hearing demonstrate their interest in these proceedings at the outset. *See* 21 C.F.R. § 1316.47(a).

For these proceedings, the CSA and, specifically, § 811 establish the zone of interests. The overall purpose of the CSA is "to protect the public from the deleterious effects of the illegitimate use and distribution of controlled substances." *Bonds*, 457 F.3d at 415; *see Gonzales v. Oregon*, 546 U.S. 243, 250 (2005) (the CSA was enacted with "the main objectives of combating drug abuse and controlling the legitimate and illegitimate traffic in controlled substances"). To accomplish its purpose, "the CSA creates a comprehensive, closed regulatory regime criminalizing the unauthorized manufacture, distribution, dispensing, and possession of substances classified in any of the [CSA's] five schedules." *Gonzales*, 546 U.S. at 250. Section 811 regulates how substances may be added, removed, or transferred between the five schedules. 21 U.S.C. § 811. The consequence of such action is that a party may be required to obtain a registration to handle a scheduled substance. 21 U.S.C. § 823; *see MD Pharm.*, 133 F.3d at 13 (the CSA "is a quintessential entry-restricting statute."). As the Government notes, "[r]esearch of controlled substances is within the class of activity regulated by the CSA." Gov't Mot. at 8. Therefore, the zone of interests encompassed by § 811 and the CSA as whole includes researchers who would be regulated by the scheduling of a particular substance.

ANALYSIS

For the following reasons, I find that Panacea, Mindstate, and Tactogen have met the regulatory definition of "interested person" and, thus, have standing to participate in these proceedings.[4] Ms. Rising, however, does not have standing as an "interested person." I also reject the Government's general proposition that an "interested person" may only address a tryptamine if it has established standing for that specific tryptamine.

[4] While not required, the parties requesting a hearing at issue, with the exception of Ms. Rising, can also show injury-in-fact. In its Partial Withdrawal of its Motion to Dismiss in Part (Government's Partial Withdrawal), the Government concedes that Tactogen can show injury-in-fact. Gov't Partial Withdrawal at 1-2. Further, as researchers, Panacea, Mindstate, and Tactogen would suffer economic harm if the tryptamines are scheduled because they would have to obtain a registration to continue their respective projects. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992).

1. Panacea Plant Sciences

In its RFH and Opposition to the Government's Motion, Panacea, as required by 21 C.F.R. § 1316.47(a), stated "with particularity" its interests in these proceedings.[5] *See* Panacea RFH at 3; Panacea Opp'n to Gov't Mot. at 2-3. Specifically, Panacea is a biotech company and has been studying, in collaboration with a Canadian company, the five tryptamines and "other similar compounds in order to treat conditions like depression, anxiety, post-traumatic stress disorder (PTSD) and traumatic brain injury (TBI)." Panacea RFH at 1, 3. Panacea started a project with a doctor at the University of Massachusetts to develop medical therapies utilizing the five tryptamines and other compounds, but Panacea discontinued the project due to the "the potential of conflict and future scheduling." Panacea Opp'n to Gov't Mot. at 2. Additionally, Panacea has patent filings that cover the five tryptamines. *Id.* at 3. Panacea is also collaborating and contracting with other companies and universities to study the five tryptamines and develop therapies, so scheduling the tryptamines will require Panacea to apply for both a manufacturing and research DEA registration. *Id.* at 2-3. Obtaining a registration will be costly for Panacea and cause delays in its research and projects. *Id.*

Panacea meets the regulatory definition of "interested person" under the CSA, as scheduling any or all of the five tryptamines will adversely affect its interests and Panacea's interests fall within the CSA's zone of interests. Panacea falls within the zone of interests because it would be regulated by the scheduling of the five tryptamines; Panacea has ongoing research and projects involving the five tryptamines, and Panacea will be required to obtain a registration to continue its work if the tryptamines are scheduled. *See MD Pharm.*, 133 F.3d at 12-13; *First Nat'l Bank & Tr. Co.*, 988 F.2d at 1275. The potential added cost of obtaining a registration has already forced Panacea to discontinue one project and may require Panacea to discontinue other projects

[5] The Government argues that Panacea failed to state its interests in its RFH "with particularity," so, if this tribunal does not dismiss Panacea from these proceedings, the tribunal should require Panacea to provide a more detailed statement of its interests. Gov't Mot. at 11. Panacea's RFH provided substantially more detailed information regarding its interests than the two scheduling cases relied on by the Government where the Administrator found that the statements of interest lacked particularity. *Id.* (citing *Placement of Lorcaserin into Schedule IV*, 78 Fed. Reg. at 26703; *Placement of Lacosamide into Schedule V*, 74 Fed. Reg. at 23789). Panacea's Opposition to the Government's Motion further supplemented its statement of interests and provided this tribunal with sufficient information to determine whether Panacea is an "interested person." *See* Panacea Opp'n to Gov't Mot. at 2-3.

or increase the costs of those projects. Since the purpose of § 811 is to determine whether a substance should be scheduled, thereby bringing the substance under the purview of the CSA and restricting access to it, Panacea's interest in continuing to use the five tryptamines directly relates to the purpose of § 811. Therefore, Panacea has standing in these proceedings.

2. Mindstate and Tactogen

In their joint RFH and Opposition to the Government's Motion, Mindstate and Tactogen, as required by 21 C.F.R. § 1316.47(a), stated "with particularity" their interests in these proceedings.[6] *See* Mindstate & Tactogen RFH at 2; Mindstate & Tactogen Opp'n to Gov't Mot. at 3-4, Ex. A. Specifically, Mindstate is a research company that "develops psychedelic drug therapies for intractable mental health conditions" and is "currently investigating one or more of the Five Tryptamines in preclinical research." Mindstate & Tactogen RFH at 2. Mindstate is building a database of phenomenological and biochemical data on psychedelic compounds. Mindstate & Tactogen Opp'n to Gov't Mot. at 3. Mindstate must work with tryptamines to complete this project and other projects to develop and bring compounds to market. *Id.* at 4. Tactogen is a public benefit corporation "developing safer, more effective prescription medicines for mental wellness" and is "currently investigating one or more of the Five Tryptamines as part of a program to develop new medicines." Mindstate & Tactogen RFH at 2. Tactogen has had one published patent application under the Patent Cooperation Treaty on the use of tryptamines for mental disorders. Mindstate & Tactogen Opp'n to Gov't Mot. at 4.

Mindstate and Tactogen each qualify as an "interested person" under the CSA because scheduling any or all of the five tryptamines will adversely affect each of their interests and such interests fall within the zone of interests.[7] Mindstate and Tactogen fall within the CSA's zone of interests because they would be regulated by the scheduling of the five tryptamines. *See MD Pharm.*, 133 F.3d at 12-13; *First Nat'l Bank & Tr. Co.*, 988 F.2d at 1275. Both companies would

[6] The Government makes the same argument, as it did with respect to Panacea's RFH, that Mindstate and Tactogen's RFH lacked particularity. *See supra* note 5; Gov't Mot. at 12-13. Mindstate and Tactogen's RFH provided enough detail, and their Opposition to the Government's Motion further supplemented their statement of interests to determine if they are an "interested person." *See* Mindstate & Tactogen RFH at 2; Mindstate & Tactogen Opp'n to Gov't Mot. at 3-4, Ex. A.

[7] The Government concedes that Tactogen has established standing with respect to 5-MeO-MiPT. Gov't Partial Withdrawal at 1-2. The Government maintains that Tactogen has still not established standing with respect to the other four tryptamines. *Id.*

be required to obtain registrations to continue their respective projects; Mindstate's development of compounds for mental health conditions and Tactogen's development of therapies for mental wellness would be regulated by the CSA if the five tryptamines are scheduled. Like Panacea, Mindstate and Tactogen's interests in using the tryptamines directly relate to the purpose of § 811. Therefore, Mindstate and Tactogen have standing in these proceedings.

3. Amy Rising

In her RFH, Ms. Rising stated that the proposed scheduling of the five tryptamines "would result in barriers to research and the denial [of] life-saving healthcare to US patients" and that they should be placed in schedule V, not schedule I. Rising RFH at 1-2. In her Opposition to the Government's Motion, Ms. Rising stated that she met with the "senate DEA liaison and senate judiciary counsel at their request to discuss the upcoming renewal of the Fentanyl Analogues" several times between August and December 2019. Rising Opp'n to Gov't Mot. at 1-2. Additionally, the Food and Drug Administration "declared psilocybin a 'breakthrough therapy' for treatment-resistant depression." *Id.* at 1. Ms. Rising further indicated that the "National Institute on Drug Abuse Director" stated that obtaining a schedule I DEA registration is administratively challenging and time consuming, so scientists may be deterred from researching schedule I substances. *Id.* at 2. Ms. Rising concluded that she has interests in the scheduling status of the five tryptamines and placing them in schedule I will "impose greater burdens on research, create barriers to access and impose undue difficulty on policy makers…" *Id.*

Ms. Rising has failed to establish her interest in these proceedings. She has provided no information as to what her specific interest is, such as her career or credentials; rather, she simply asserts that she is interested. *See id.* at 2 ("Amy Rising has provided the example of her work and interests in the scheduling status of" the five tryptamines). The only example she has provided of her work is meetings with government officials regarding psilocybin and the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, Pub. L. No. 116-114 S. 3201, 116th Cong. (2020), but she does not explain how the meetings related to the five tryptamines, let alone her role and purpose in those meetings. *See id.* She argues that scheduling the five tryptamines in schedule I will create barriers to research but offers no information as to how or why she is affected by potential barriers for research. *See id.* 2-3.

Ms. Rising's general assertion of interest does not meet the regulatory requirements that she both have an interest in these proceedings and that she state that interest "with particularity."

21 C.F.R §§ 1300.01(b), 1316.47(a); *see Placement of Lorcaserin into Schedule IV*, 78 Fed. Reg. at 26703 (denying a request for hearing because a person's generalized concern was insufficient to demonstrate an interest in the proceeding); *Placement of Lacosamide into Schedule V*, 74 Fed. Reg. at 23789 (same). Therefore, given Ms. Rising's failure to show her interest in these proceedings, she does not have standing to appear in these proceedings.

4. Standing as to Individual Tryptamines

The Government argues that this tribunal should further limit standing in two respects: (1) it should only allow a hearing on those tryptamines for which parties have standing; and (2) an "interested person" should only be allowed to contest a tryptamine for which it has established standing. Gov't Mot. at 6-7. The Government argues that, while the tryptamines are similar and consolidated into one NPRM, there will be five distinct rules. *Id.* The Government cites no support for the proposition that one NPRM and one rulemaking process results in distinct rules.[8] Additionally, 21 C.F.R. § 1300.01 defines "interested person" as "any person adversely affected or aggrieved *by any rule or proposed rule*…" (emphasis added). There is one proposed rule,[9] not five, so any person adversely affected or aggrieved by the scheduling of one of the tryptamines has standing to challenge the proposed rule in its entirety.

Moreover, the Administrator opted to combine the five tryptamines into one rulemaking process and did so, in part, because of the similarity of those substances to each other and to already-controlled substances. NPRM, 87 Fed. Reg. at 2378. Additionally, the NPRM (as well as the Department of Health and Human Services evaluations and recommendations) includes scientific references that deal generally with tryptamines and compare the substances to each other and already-controlled substances. *Id*. at 2378-81. On this basis, a wholesale limitation of the parties is unjustified and would prove impractical at the merits hearing; it would be incongruous to parse the rulemaking process when the Agency has chosen to proceed under one proposed rule.

[8] The Government does cite 21 U.S.C. § 811(a)(1); however, § 811(a)(1) provides only that the Attorney General may schedule a substance if he makes findings as to such substance. *See* Gov't Mot. at 6. Section 811(a)(1) is silent as to standing for an "interested person" to challenge those findings and whether one rulemaking process for multiple substances results in distinct rules or one rule encompassing multiple substances.

[9] The NPRM also repeatedly states that it is one "proposed action," not five. *See* NPRM, 76 Fed. Reg. at 2376-78, 2381-82.

Further, even if I were to accept the Government's proposition that each "interested person" must have standing with respect to each tryptamine to fully participate in these proceedings, Panacea, Mindstate, and Tactogen have established standing for all five of the tryptamines. Panacea expressly stated that it is researching the five tryptamines, so scheduling any or all of the tryptamines will adversely affect Panacea. Panacea Opp'n to Gov't Mot. at 2-3. The Government concedes that Tactogen is an "interested person" with respect to 5-MeO-MiPT (Gov't Partial Withdrawal at 1-2), and Mindstate is currently utilizing 5-MeO-MiPT and 4-OH-DiPT (Mindstate & Tactogen Opp'n to Gov't Mot., Ex. A at 2). Both companies are arguably within the zone of interests for the other tryptamines because their research and projects will be limited, as the other tryptamines are analogues or related to hallucinogenic substances that the companies are currently studying. Mindstate & Tactogen Opp'n to Gov't Mot. at 14. In sum, the zone of interests test is not meant to be demanding nor are Mindstate and Tactogen's interests inconsistent with the purpose of § 811. *See Clarke*, 479 U.S. at 399; *MD Pharm.*, 133 F.3d at 12-13. Therefore, I reject the Government's argument to partition the hearing by tryptamine and "interested person."

CONCLUSION

Accordingly, the Government's Motion is **GRANTED IN PART** and **DENIED IN PART**. The Government's Motion is **GRANTED** with respect to Amy Rising and **DENIED** with respect to Panacea, Mindstate, and Tactogen.

Dated: May 6, 2022

TERESA A. WALLBAUM
Administrative Law Judge

CERTIFICATE OF SERVICE

This is to certify that the undersigned, on May 6, 2022, caused a copy of the foregoing to be delivered to the following recipients:

(1) John E. Beerbower, Esq., Counsel for the Government, via email at John.E.Beerbower@dea.gov and to the DEA Government Mailbox at dea.registration.litigation@dea.gov;
(2) David Heldreth, CEO of Panacea Plant Sciences, via email at davidh@panaceaplantsciences.net;
(3) John T. Hunter, Esq., Counsel for Jason Wallach and Hamilton Morris, via email at john@hljdefense.com;
(4) Matt Baggott, Tactogen Inc., via email at matt@tactogen.com;
(5) Dillian DiNardo, Kykeon Biotechnologies Inc., via email at dillan@mindstate.design;
(6) Graham Pechenik, Esq., Counsel for Tactogen Inc. and Kykeon Biotechnologies Inc., via email at graham@calyxlaw.com;
(7) Matthew C. Zorn, Esq., Counsel for Tactogen Inc. and Kykeon Biotechnologies Inc., via email at mzorn@yettercoleman.com; and
(8) Amy Rising, via email at amynicholerising@gmail.com.

Aniayah S. Beckford
Staff Assistant to Judge Wallbaum

Exhibit 4

UNITED STATES DEPARTMENT OF JUSTICE

Drug Enforcement Administration

In the Matter of **Schedules of Controlled Substances: Proposed Rescheduling of Marijuana**	**DEA Docket No. 1362** **Hearing Docket No. 24-44** **Administrative Law Judge** **John J. Mulrooney, II**

Dated: November 12, 2024
Drug Enforcement Administration, Attn: Hearing Clerk/OALJ
8701 Morrissette Drive, Springfield, VA 22152

NOTICE OF APPEARANCE

Please take notice that undersigned counsel will appear in the above-referenced matter on behalf of MedPharm. MedPharm intends to introduce evidence in support of its position described in its September 26, 2024 request for participation and November 12, 2024 response to this Tribunal's October 31, 2024 Preliminary Order.

All notices to be sent pursuant to this appearance should be addressed to:

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Pursuant to 21 C.F.R. § 1316.50, undersigned counsel attests that he is a licensed attorney in good standing and that no disciplinary proceedings are pending against him in any jurisdiction where he is licensed to practice law.

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Attorney for Proposed Intervenor MedPharm

Exhibit 5

UNITED STATES DEPARTMENT OF JUSTICE

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Pursuant to 21 C.F.R. § 1316.50, undersigned counsel attests that he is a licensed attorney in good standing and that no disciplinary proceedings are pending against him in any jurisdiction where he is licensed to practice law.

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