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 REGARDING STANDING, SCOPE, AND PREHEARING PROCEDURES

On Standing

The United States Department of Justice (DOJ) through the Drug Enforcement Administration (DEA or Agency) has initiated rulemaking proceedings to reschedule 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). In another order (General Notice of Hearing or GNoH) published in the Federal Register, the DEA Administrator (the Administrator) subsequently determined that hearing procedures are appropriate and fixed a December 2, 2024 hearing commencement date. *Schedules of Controlled Substances: Rescheduling of Marijuana*, 89 Fed. Reg. 70148, 70148-49. Subsequent correspondence by the Administrator listed twenty-five (25) designated participants (Designated Participants or DPs).[1] Concluding that more information about the DPs was a necessary prerequisite to competently conducting a fair hearing,[2] I tasked the Government and the DPs with furnishing additional information by November 12, 2024 in an order dated October 31, 2024 (Preliminary Order or Prelim. Ord.). Prelim. Ord. at 3. Most of the DPs timely complied with this directive,[3] including the instruction to supply information related to their respective

[1] The American Academy of Hospice and Palliative Medicine withdrew its request to participate in a document filed on November 8, 2024, as did the American College of Occupational and Environmental Medicine on November 12, 2024. Similarly, the National Sheriffs' Association has signaled its intent to submit a hearing waiver. These DPs are no longer parties to this proceeding and no standing recommendations have been made regarding them.

[2] 5 U.S.C. § 556(c)(5); 21 C.F.R. § 1316.52(c), (g), (h).

[3] The International Academy on the Science and Impact of Cannabis (IASIC) and Saint Michael's College (SMC) did not respond to the Preliminary Order. However, Ari Kirshenbaum, PhD is affiliated with SMC, and Kenneth Finn, M.D. is affiliated with IASIC. Neither of these DPs sought to either speak on behalf of these institutions or made any assertions relative to associational standing based on their respective affiliations. IASIC and SMC are no longer parties to this proceeding and this order contains no standing recommendations with respect to them.

arguments for standing under the Administrative Procedure Act (APA) and CSA and its implementing regulations.

The non-legislative transfer of controlled substances from one schedule to another by the DEA[4] is authorized only "after opportunity for a hearing pursuant to the rulemaking procedures" set forth in the Administrative Procedure Act. 21 U.S.C. § 811(a). Both the Agency's NPRM and the GNoH expressly invited "interested persons" seeking participation in this potential scheduling action to file applicable requests within specified deadlines. 89 Fed. Reg. at 44598; 89 Fed. Reg. at 70148-79; 21 U.S.C. § 811(a); 21 C.F.R. § 1308.44(a), (b).

The APA provides that "[s]o far as the orderly conduct of public business permits, an interested person may appear before an agency or [one of its ALJs][5] for the presentation, adjustment, or determination of an issue, request, or controversy in a proceeding. . . in connection with an agency function."[6] 5 U.S.C. § 555(b). When agencies are "charged with administering congressional statutes[, b]oth their power to act and how they are to act is authoritatively prescribed by Congress[.]" *City of Arlington, Tex. v. FCC*, 569 U.S. 290, 297 (2013); *see American Trucking Associations, Inc. v. United States*, 627 F.2d 1313, 1320 (D.C. Cir. 1980) ("When an agency exercises authority expressly delegated to it by Congress it is at the zenith of its powers."). However, even when operating "at the zenith of its powers,"[7] the agency is constrained to act within the parameters of the APA, the CSA, and any related regulations, and must refrain from actions which are arbitrary, capricious, and demonstrate an abuse of its Congressionally-authorized discretion. *American Trucking*, 627 F.2d at 1316, 1320-21.

Prior to the commencement of a hearing on the rescheduling of a controlled substance, a threshold determination must be made regarding the proper cadre of hearing participants. Standing to appear in an APA agency proceeding can differ markedly from the rigid standing

[4] The Attorney General's CSA authority has been delegated to the DEA Administrator by regulation. 28 C.F.R. § 0.100.

[5] 5 U.S.C. § 556(b)(3). The APA prescribes only three types of officials that may preside over an agency's evidentiary hearing: the agency head; one or more members of a body that comprises the agency; or an ALJ appointed in accordance with 5 U.S.C. § 3105. *Id.* at § 556(b). In the Department of Justice, the DEA is organizationally structured to exclusively utilize the third option. The same is true of the Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF) and the Bureau of Prisons (BOP). Neither the Attorney General nor the DEA Administrator preside over hearings, and neither agency has been equipped by Congress with a body such as the National Labor Relations Board, the Securities and Exchange Commission, or the National Transportation Safety Board to adjudicate factually contested cases.

[6] It is beyond argument that the scheduling, rescheduling, and descheduling of controlled substances is an agency function assigned to the DEA and specifically authorized by Congress. 21 U.S.C. § 811(a).

[7] *American Trucking*, 627 F.2d at 1320.

requirements incumbent on those seeking relief in the federal courts. *Fund Democracy, LLC v. SEC*, 278 F.3d 21, 27 (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."). To ensure proper separation of powers from the political branches, Article III, section 2 of the Constitution cabins the jurisdiction of the federal courts to cases and controversies. As such, those appearing before the courts must possess the requisite elements of Article III standing, *to wit*, a demonstration of a particularized injury that is: (1) actual or imminent; (2) caused by, or fairly traceable to an act that the litigant challenges in the litigation; and (3) redressable by the court. *FDA v. Alliance for Hippocratic Medicine*¸ 602 U.S. 367, 380-81 (2024); *Gettman v. DEA*, 290 F.3d 430, 432-33 (D.C. Cir. 2002). While this Article III standing threshold is present for a party seeking to challenge an action in the courts (even a person challenging an agency action under the APA),[8] it is not perforce coextensive with the relaxed level of standing required to appear in an agency administrative proceeding. *Gettman*, 290 F.3d at 433-34. The constraints of Article III standing rest "on considerations about the proper—and properly limited—role of the courts in a democratic society," *Envirocare of Utah, Inc. v. NRC*, 194 F.3d 72, 75 (D.C. Cir. 1999) (quoting *Warth v. Seldin*, 422 U.S. 490, 498 (1975)), whereas federal administrative agencies are not likewise restricted. *See, e.g.*, *New World Radio, Inc. v. FCC*¸ 294 F.3d 164, 172 (D.C. Cir. 2002); *Envirocare*¸ 194 F.3d at 74.

A lower standing threshold is often sensible in view of the potential public policy implications of many agency actions, and the application of this less rigorous procedural bar has been recognized, reviewed, and affirmed by the courts. *See, e.g., Gettman*, 290 F.3d at 433-34; *Animal Legal Defense Fund, Inc. v. Vilsack*, 237 F.Supp.3d 15, 21-22 (D.D.C. 2017). Further, as discussed, *supra*, because agencies are not limited in this way by Article III, they may, in their discretion, permit persons to intervene in their proceedings who would not otherwise have standing to seek judicial review of the agency action ultimately taken. *See, e.g., Fund Democracy*, 278 F.3d at 27. However, this is not to say that everyone must be inexorably welcomed to appear before every agency on every issue that touches widely on society or tugs at the heartstrings. The APA limits the ability to appear before an agency to "interested persons," which Congress further qualified by the phrase "[s]o far as the orderly conduct of public business permits . . . ." 5 U.S.C. § 555(b). Regrettably, the legislative histories of the APA and the CSA

[8] 5 U.S.C. § 702.

are of negligible assistance when narrowing the definition of who properly rests within the parameters of an "interested person" as it pertains to an administrative scheduling hearing before the DEA.

To be sure, agency adjudications (including DEA adjudications) can and do have their own standing requirements that are baked into the process by the APA, their enabling statutes, and their implementing regulations. It follows then, that leave to appear before an agency in its APA adjudications, that is, discernment of who is an "interested person" takes on a different form based on the fixed navigation points, including (and especially) the agency's regulations.

"[T]he starting point for an APA standing determination for a litigant before an administrative agency is not Article III, but is the statute that confers standing before that agency." *Ritchie v. Simpson*, 170 F.3d 1092, 1095 (Fed. Cir. 1999). The courts will generally examine an agency's enabling statute and implementing regulations to discern the intended, reasonable breadth of those with APA standing. *See, e.g., Ritchie*, 170 F.3d at 1095 (The court interpreted the standing language in the Lanham Act more broadly than did the agency.); *Koniag, Inc. v. Andrus*, 580 F.2d 601, 607-88 (D.C. Cir. 1978) (The court held that Alaska Statehood Act's attendant regulations indicated a broader class of interested parties than had been interpreted by the Secretary of the Interior.). Thus, the proper inquiry is centered around an interpretation of the statute(s) the agency administers. This analysis involves an examination of existing agency precedent, the legislative history of the statute(s), and/or subsequent regulations which the agencies have sought to carve out the proper scope of the relevant statute(s). *Ritchie*, 170 F.3d at 1095.

Turing to the present case, the Supreme Court has characterized the primary objectives of the CSA as aiming "to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances" by protecting against the diversion of drugs from legitimate channels. *Gonzales v. Raich*, 545 U.S. 1, 12-13 (2005). Further, the ultimate goal of protecting the public is served by the CSA's creation of "a comprehensive, closed regulatory regime criminalizing the unauthorized manufacture, distribution, dispensing, and possession of substances in any of the Act's five schedules." *Gonzales v. Oregon*, 546 U.S. 243, 250 (2006). In promulgating controls against diversion through the passage of the CSA, Congress manifested its intent to protect the public from the siphoning of dangerous and fungible controlled substances from the "closed regulatory" system. *Id.*

In delimiting the correct scope of public participation in agency proceedings, the courts have acknowledged that agencies possess broad discretion to limit the participation of interested individuals and organizations. *Nichols v. Board of Trustees of the Asbestos Workers Local 24 Pension Plan*, 835 F.2d 881, 897-99 (D.C. Cir. 1987); *Vilsack*, 237 F.Supp.3d at 21-22. Those who qualify as "interested persons" are entitled to participate in the hearing process[9] so long as their involvement does not compromise the "orderly conduct of public business." 21 C.F.R. § 1316.52; 5 U.S.C. § 555(b). This right to participate in the hearing process is not "blindly absolute" and considerations regarding the logistics of the hearing must be factored into the conferral of standing.[10] *Easton Utilities,* 424 F.2d at 852. However, in an agency's exercise of that discretion to limit participation, the courts will not countenance participation denial policies that are unreasonably overbroad or otherwise arbitrary, or merely based on assertions that interventions are generally burdensome or dilatory.[11] *Nichols*, 835 F.2d at 897.

Regrettably, the CSA, its legislative history, and its attendant regulations offer little in terms of guidance on the issue of who is an "interested party" in the context of controlled substance scheduling proceedings. The CSA regulations define the term "interested person" as "mean[ing] any person adversely affected or aggrieved by any rule or proposed rule issuable pursuant to [the scheduling provisions set forth in] 21 U.S.C. § 811." 21 C.F.R. § 1300.01(b); *see, e.g., Schedules of Controlled Substances: Placement of Lorcaserin into Schedule IV*, 78 Fed. Reg. 26701, 26703 (2013). It is noteworthy that, "[t]he 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." *Dir., Office of Workers' Comp. Programs, Dep't of Labor v. Newport News Shipbuilding & Dry Dock*

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[9] The APA intervention right as set forth in 5 U.S.C. § 555(b) "is universally understood to establish" participation rights for interested persons in "on-going agency proceeding[s]." *Block v. SEC*, 50 F.3d 1078, 1085 (D.C. Cir. 1995).

[10] Specifically, the "time of appearance, the status of the proceedings, [and] the administrative avenues established by other statutes and agency rules for participation" should be afforded consideration when fashioning rules of procedure and participation standards in agency proceedings. *Easton Utilities Commission v. Atomic Energy Commission,* 424 F.2d 847, 852 (D.C. Cir. 1970). Further, if the parties participating in an agency proceeding adequately represent the public interest and the interests of the petitioners, limiting the number of parties otherwise entitled to participate may be appropriate to avoid duplicative presentations. *See, e.g., City of San Antonio v. Civil Aeronautics Board*, 374 F.2d 326, 332-333 (D.C. Cir. 1967).

[11] A reviewing court's confidence in an agency's decision to limit public participation may be further bolstered by an agency's efforts to adhere to its own rules and procedures as set forth in their governing statutes and implementing regulations. *See, e.g., Easton Utilities*, 424 F.2d at 851 ("We find nothing whatsoever in the record which in any way challenges the reasonableness, the necessity for, or the propriety of this Commission rule. We are confronted only with the Commission's utilization of this rule under the factual situation of this case.").

Company, 514 U.S. 122, 126 (1995) ("person adversely affected or aggrieved" interpreted as sufficient to fulfill Article III standing requirements under the APA). By cabining its own scope of the term "interested persons" to include only "person[s] adversely affected or aggrieved by any rule or proposed rule" it is reasonable to conclude that the Agency regulation drafters intended a narrow, somewhat heightened interpretation of those permitted to appear in scheduling actions. 21 C.F.R. § 1300.01(b). There can be little doubt that the stewards of the Agency, at the time the regulation was promulgated, elected to seek input from a potential rules detractors/critics/opponents; in short, those who could demonstrate that they would be "adversely affected or aggrieved"[12] should the proposed rule become law. Stated differently, the Agency was not keen on producing an echo chamber of supportive comments to reinforce its intended result, but focused on hearing from those who feared the consequences of the proposed rule. A restricted standing interpretation is further buttressed by the highly technical nature of the facts to be adduced and analysis employed at a scheduling hearing. 21 U.S.C. § 811(b)-(f). Further, the NPRM, citing 21 C.F.R. § 1308.42, dictates that "the purpose of a hearing would be to receive factual evidence and expert opinion regarding whether marijuana should be transferred to schedule III of the list of controlled substances." 89 Fed. Reg. at 44599 (cleaned up).

Beyond the stark definition of "interested party"[13] employed in its regulations, the DEA has not promulgated additional regulations regarding the parameters that could assist in delineating the boundaries of who may appear at its internal proceedings. It is axiomatic that an ALJ may not entertain a challenge to its agency's regulations,[14] and the DEA has certainly not been bashful about reminding its judges that "[o]nce the [A]gency has ruled on a given matter … it is not open to reargument by the [ALJ]." *Clair L. Pettinger, M.D.*, 78 Fed. Reg. 61592, 61600 n.13 (2013). Among its published precedential decisions, the Agency has insisted that those seeking APA standing as an "interested person" must, in the hearing request, sufficiently articulate a persuasive basis for their standing. *See, e.g., Schedules of Controlled Substances: Placement of Lorcaserin into Schedule IV*, 78 Fed. Reg. at 26703 (The Agency denied a hearing request filed by a commenter "[b]ecause the commenter failed to provide sufficient information

[12] 21 C.F.R. § 1300.01(b).
[13] *Id.*
[14] *CropLife America v. EPA*, 329 F.3d 876, 882 (D.C. Cir. 2003); *Iran Air v. Kugelman*, 996 F.2d 1253, 1260 (D.C. Cir. 1993) ("It is commonly recognized that ALJs are entirely subject to the agency on matters of law.") (internal quotation marks omitted); *Oestereich v. Selective Service System Local Bd. No. 11*, 393 U.S. 233, 242 (1968) (Harlan, J., concurring).

to demonstrate that he meets the definition of "interested person" as set forth in the regulations ….").

Relaxed is not synonymous with nonexistent, and an *interesting* person (someone the ALJ—or the Administrator—may subjectively believe possesses the potential for objectively meaningful and insightful input) is likewise not synonymous with an "interested person" (a person entitled to request and participate in an APA hearing before DEA involving the scheduling of controlled substances). The potentially relaxed requirements of APA standing notwithstanding, the Agency has a right to exercise some level of control over those who appear in its proceedings,[15] and a concomitant right to expect its ALJs to adhere to its regulations and its precedents.[16] Contrariwise, that the regulations authorize a narrow segment of the population to *request* and participate in a scheduling hearing (in the case of the CSA regulations, a very narrow segment) does not perforce preclude the Agency (or this tribunal) from hearing and considering viewpoints from those unable to shoulder the burden of establishing standing. Stated differently, the Agency may be at liberty to conclude that its proposed action could benefit somewhat by listening to at least some of those who might support is proposed rule (*i.e.*, the echo chamber). Logically, however, the applicable CSA regulations were clearly drafted in a manner that the views of those participants who demonstrate APA standing (within the bounds of reasonable discretion) should be afforded a stronger voice or more weight in the ultimate decision. A contrary conclusion would arguably eviscerate the purpose for the regulation's standing standards.

With those parameters in mind, a review of available precedent, in the courts and inside the Agency, reveals some considerations that can inform an equitable determination here on the issue of APA standing in scheduling matters before the DEA.[17] Several of the Agency's

[15] *City of San Antonio*, 374 F.2d at 329 ("No principle [of] administrative law is more firmly established than that of agency control of its own calendar.").
[16] *Pettinger*, 78 Fed. Reg. at 61600 n.13.
[17] Agencies, including the DEA, are empowered to issue "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice" without engaging in the formal notice and comment or hearing procedures set elsewhere in the APA. 5 U.S.C. § 553. It is worth noting, that when presented with the opportunity to adjust its stance on the definition of "interested persons," the Agency has declined to do so and has demonstrated some level of consistency (albeit sparse in analysis) in fashioning its own view of who is "adversely affected or aggrieved." *See Consolidation, Elimination, and Clarification of Various Regulations*¸ 62 Fed. Reg. 13938, 13942 (1997); *Consolidation, Elimination, and Clarification of Various Regulations*, 61 Fed. Reg. 8503, 8508 (1996). In its response to a commenter who sought to amend the definition of "interested person" in proceedings involving the importation of controlled substances, DEA concluded that the definition of "interested person" was "sufficiently

previous scheduling endeavors pursuant to 21 U.S.C. § 811 failed to garner hearing requests,[18] however, there are some analytical navigation points, including measures some other federal agencies have taken (with varying levels of success on review in the courts) to assist in shaping the appropriate contours of APA standing in scheduling actions at DEA. To that end, the issue of whether the DPs have alleged sufficient APA standing to participate in this rescheduling hearing should be assessed by balancing the following four considerations (the Standing Considerations or SCs): (1) whether the requestor possesses a substantial interest in the proceedings (*to wit*, would be adversely affected or aggrieved if the proposed rule were promulgated) and/or otherwise satisfies the requirements of Article III standing; (2) whether the request complies with clear, reasonable procedural agency directives; (3) whether the request exceeds the scope of the NPRM; and (4) whether, in the discretion of the Agency, the participation of a particular requestor would meaningfully assist the decisionmaking and/or whether the interests of multiple requestors are amenable to consolidation or exclusion to accommodate orderly proceedings.

> ***APA Standing Consideration One****: Whether the DP/Requestor Possesses a Substantial Interest in the Outcome of the Proceedings (to wit, would be adversely affected or aggrieved if the proposed rule were promulgated) and/or Otherwise Satisfies the Requirements of Article III Standing*. Beyond a doubt, by the plain language of the CSA and its implementing regulations, this is the most powerful and issue-dispositive factor. *Ritchie*, 170 F.3d at 1095; *Koniag*, 580 F.2d at 608 Where a requestor demonstrates a substantial interest in the outcome of an administrative proceeding (*to wit*, aggrievement or adverse affect from promulgation of the NPRM), that requestor should ordinarily have a right to participate. *See BPI v. Atomic Energy Commission*, 502 F.2d 424, 427 (D.C. Cir. 1974). Likewise, a demonstration that a requestor would be entitled, when the adjudication is final, to judicial review of an agency action (*i.e.*, the requestor has proffered enough to satisfy the requirements of Article III standing) will ordinarily

precise to fulfill [its] intended purpose." *Consolidation, Elimination, and Clarification of Various Regulations*, 62 Fed. Reg. at 13938.

[18] *See, e.g., Schedules of Controlled Substances: Removal of Naloxegal from Control*¸ 80 Fed. Reg. 3468, 3469 (2015); *Schedules of Controlled Substances: Placement of Brivaracetam into Schedule V*, 82 Fed. Reg. 13067, 13067 (2017); *Schedules of Controlled Substances: Placement of Solriamfetol in Schedule IV*, 85 Fed. Reg. 643, 643 (2020).

qualify that person as an "interested person" who normally should be permitted to be heard in an administrative proceeding. *Nichols*, 835 F.2d at 896; *Vilsack*, 237 F.Supp.3d at 21; *but see Envirocare*, 194 F.3d at 75.[19] *Envirocare* notwithstanding, granting APA standing to a requestor who, in its request and attendant filings, has averred sufficient facts to demonstrate that it would have Article III standing to challenge a DEA scheduling action on appeal in federal court is the analytically superior option. Further, the legislative history of the Controlled Substances Act illuminates that requestors that possess sufficient interest in engaging with the dual goals of the Act (to protect the public's health and ensure the closed regulatory system of controlled substances) will likely have a strong case for establishing their participation rights.[20] In view of the DEA's narrow definition of "interested person" under its regulations,[21] this aspect of Standing Consideration One, must generally be afforded controlling weight. That is to say, the Agency's insistence that some demonstration that the person seeking a ticket to appear in its proceedings articulate a demonstration that the interested person will be "adversely affected or aggrieved by any … proposed rule," constitutes a condition precedent for APA standing is not unreasonable. Others who are interested, but do not qualify as "interested persons" under the regulations, may not necessarily be foreclosed from a voice in the process, and had the opportunity to file written comments. 5 U.S.C. § 553(c); 21 C.F.R. § 1308.44(g); 89 Fed. Reg. at 44598. That said, a rational, supported application of the APA qualifier language that interested persons may appear "[s]o far as the orderly conduct of public business permits" can trump standing in APA proceedings. 5 U.S.C. § 555(b); *Vilsack*, 237 F.Supp.3d at 22.

***APA Standing Consideration Two**: Whether the Request Complies with Clear, Reasonable Procedural Agency Directives*. While the Consideration One requirements

[19] The *Envirocare* court relied liberally on *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 84-42 (1984), which has been subsequently reversed by *Loper Bright Enterprises v. Raimondo*, 144 S.Ct. 2244, 2273 (2024).

[20] The text and legislative history of the CSA appears bereft of any indication that it was promulgated to protect the employment interests of a registrant. *See, e.g., Bonds v. Tandy*, 457 F.3d 409, 415-16 (5th Cir. 2006) ("a pharmacist's interest in employment is not arguably within the zone of interests protected by the statute. Accordingly, [the pharmacist] is not a 'person aggrieved' under [the CSA]"). *See also, Alliance for Hippocratic Medicine*, 602 U.S. at 385-87 (finding that doctors lacked Article III standing when attempting to challenge the regulation of a drug they did not prescribe or use themselves).

[21] 21 C.F.R. § 1300.01(b).

are of paramount importance, there are also factors that can potentially further narrow participation, and satisfaction of Consideration One is by no means a *carte blanche* to entry into the proceedings. The courts have upheld an agency's requestor denials based on the failure of the requestor to abide the agency's reasonable procedural requirements. *BPI*, 502 F.2d at 427-29 (Participation denial upheld where requestor failed to fulfill agency requirement to specify the basis for the requested participation.); *Easton Utilities*, 424 F.2d at 850 (Participation denial upheld where requestor submitted petition beyond regulatory deadlines and after hearings had been conducted.). In *Easton Utilities* the court held:

> We do not believe that the affirmative grant of a right to appear is blindly absolute, without regard to time of appearance, the status of the proceedings, the administrative avenues established by other statutes and agency rules for participation, or most importantly, as 'the orderly conduct of public business permits.'

424 F.2d at 852. As discussed, *supra*, the DEA currently has no regulations specifically directed towards hearing requestor requirements beyond the bare "interested person" limitation and definition in the CSA and its implementing regulations. Accordingly, resort must be had to the relatively sparse collection of (analytically barren) final orders addressing participation requests, the APA and its interpretive precedent, and the terms of the NPRM. Hearing requests have been rejected by DEA in the face of an individual's failure to comply with procedural directives. *See Placement of Controlled Substances: Placement of Cathinone and 2,5-Dimethoxy-4-ethylamphetamine Into Schedule I*, 58 Fed. Reg. 4316, 4316 (1993) (denying a request for hearing because it was not filed in accordance with the directives as established by the regulation); *Schedules of Controlled Substances: Placement of ()cis-4-methylaminorex into Schedule I*¸ 54 Fed. Reg. 14799, 14799 (1989) (same). The Agency has held that a requestor must supply some specific information regarding his/her/its theory of standing under the "interested person" standard. *See Schedules of Controlled Substances: Placement of Lacosamide into Schedule V*, 74 Fed. Reg. 23789, 23789 (2009). Similarly, the Agency has interpreted its regulations as requiring that "any person requesting a hearing *must state with particularity* his interest in the proceeding." *Id.* (internal quotations omitted) (emphasis supplied). Inasmuch as the Agency has historically demanded a narrow, individualized,

statement of a requestor's adverse outcome or aggrievance to merit participation in the scheduling hearing process, the failure to provide one militates against participation.

The NPRM in this case has similarly required that hearing requests in this rescheduling action must: "(1) state with particularity the interest of the person in the proceeding; (2) state with particularity the objections or issues concerning which the person desires to be heard; and (3) state briefly the position of the person regarding the objections or issues." 89 Fed. Reg. at 44598. In this regard, it is not the place of the ALJ to conduct extra-record research or engage in broad conjecture about the potential benefits of each requestor. These hearing request requirements are not optional, and the evaluation can only be made on the four corners of the Designated Participants' responses to the Preliminary Order (Preliminary Order Responses or PORs).

***APA Standing Consideration Three**: Whether the Request Exceeds the Scope of the NPRM*. Consideration Three presents an additional limitation. As discussed, *supra*, the Agency is authorized to act within the parameters set forth by Congress. In *Olsen v. DEA*, 776 F.2d 267, 267 (11th Cir. 1985), the court upheld a participation denial by members of the Ethiopian Zion Coptic Church (the Church) in pursuit the Church's efforts to acquire a religious exemption for its members to use marijuana. The Church petitioned for rescheduling under 21 U.S.C. § 811, and the court held that an effort to seek a religious exemption fell outside the (scheduling) scope of § 811. *Id.* Thus, a requestor who seeks participation to acquire relief that is outside the scope of rescheduling (*e.g.*, descheduling, decriminalization, etc.) can properly be denied on that basis alone.

***APA Standing Consideration Four**: Whether, in the Discretion of the Agency, the Participation of a Particular Requestor Would Meaningfully Assist the Decisionmaking and/or Whether the Interests of Multiple Requestors are Amenable to Consolidation or Exclusion to Accommodate Orderly Proceedings*. The DEA Administrator has been charged by Congress in exercising discretion in assigning schedule placement for a plethora of potentially dangerous, addictive medications. 28 C.F.R. § 0.100; 21 U.S.C. § 811. It is imperative that she and her Agency possess the latitude to regulate participation

to include requestors who can render meaningful assistance to her determination, and to exclude those who are not objectively in a position to do so. *Cf.*, *Nichols*, 835 F.2d at 897 (agencies should have discretion to exclude requestors who would fail to assist the agency's decisionmaking); *Cities of Statesville v. Atomic Energy Commission*, 441 F.2d 962, 977 (D.C. Cir. 1969) (agencies should have broad discretion to determine the sources reasonably required to supply the assistance it needs in vindicating the public interest). Thus, if there is a requestor who possesses information that the DEA Administrator deems keenly important to rendering a scheduling determination that is legally correct and consistent with public interest within the meaning of the CSA, she must be afforded a healthy level of discretion to grant participation. This Consideration by no means creates APA standing, but on a pragmatic level, the Administrator, through her Government counsel, are permitted to call witnesses at a contested hearing, and her inclination to hear from a wider spectrum of society is entitled to a level of deference.

Reasonable, pragmatic considerations on the part of the agency are also valid. Even parties with a solid, substantial interest in the proceedings (Consideration One) are not immune from logistical concerns. In upholding the authority of an agency to limit and consolidate an unwieldy number of requestors, the D.C. Circuit rendered the following holding:

> Practical problems of calendar administration confront an agency whenever related applications are pending at the same time. Consolidation, scope of the inquiry, and similar questions are housekeeping details addressed to the discretion of the agency and, due process or statutory considerations aside, are no concern of the courts.

City of San Antonio, 374 F.2d at 329. An agency may take reasonable steps to avoid obstructing or overburdening the proceedings, or to avoid unduly broadening the issues considered. *Nichols*, 835 F.2d at 897. Thus, the DEA is not required to accommodate a cast of thousands in conducting its scheduling hearings, and may, where appropriate, prescribe reasonable limits based on size and common interests of the requestors.[22] As

[22] The court went on to explain in *City of San Antonio* that while true "that a party with a substantial interest in the proceeding has a right to intervene . . . But a finding of substantial interest must be related to a particular proceeding. And a proceeding must be manageable if it is going to be conducted in such a manner as will be conducive to the proper dispatch of business and to the ends of justice." *Id.* at 332 (internal citation and punctuation omitted); *see also*, *Cities of Statesville*, 441 F.2d at 977 (*en banc*) (Even in the face of a substantial interest on the part of a requestor "an agency should be accorded broad discretion in establishing and applying rules for public participation,

discussed, *supra*, the APA qualifies the appearance rights of participants with the language "[s]o far as the orderly conduct of business permits,"[23] so long as the discretion is exercised rationally. *Vilsack*, 237 F.Supp.3d at 24. As a result, the consolidation of parties may be a necessary function of the administrative hearing process. When resolving procedural issues, such as consolidation, that are not specifically addressed by the relevant authorities (the APA, the CSA, and their implementing regulations), the Federal Rules of Civil Procedure provide useful guidance.[24] Rule 42(a) of the Federal Rules of Civil Procedure authorizes the consolidation of actions that "involve a common question of law or fact" by permitting the judge to "join for hearing . . . any or all matters at issue in the actions;" "consolidate the actions; or" "issue any other orders to avoid unnecessary cost or delay." The trial judge[25] is afforded "large discretion in the matter [of consolidation] which will not be interfered with except in a clear case of abuse …." *Davis v. Yellow Cab Co.*, 220 F.2d 790, 791 (5th Cir. 1955). There is no magic quantum of common facts (or law) and likewise no disparity as to which party's evidence should weigh in (or be omitted from) the analysis. Under the like considerations that support case consolidation, when requestors present overlapping or duplicative interests and proposed testimony, this may pose a powerful and persuasive reason to "avoid unnecessary cost or delay" through either limitation of viewpoints, or even consolidation of parties. Fed. R. Civ. P. 42(a). "Participation in agency [APA rulemaking] proceedings does not necessarily entail full-fledged party intervention. Rather, agencies have ample authority to shape the manner in which intervenors will participate." *Vilsack*, 237 F.Supp.3d at 24 (quotation marks and internal citation omitted).

As discussed, *supra*, this tribunal has not been furnished with copies of the responses filed by the DPs with the Administrator. Accordingly, the APA standing determinations set forth

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including how many are reasonably required to give the agency the assistance it needs in vindicating the public interest") (internal punctuation and quotation marks omitted).

[23] 5 U.S.C. § 555(b).

[24] *But see, Roy E. Berkowitz, M.D.*, 74 Fed. Reg. 36758, 36759 (2009) (noting that DEA administrative hearings are not bound by the Federal Rules of Civil Procedure); *Kamir Garces-Mejias, M.D.*, 72 Fed. Reg. 54931, 54932 (2007) (same).

[25] The Supreme Court, in reviewing the boundaries of immunity relative to an agency ALJ, has held that "[t]here can be little doubt that the role of the modern federal . . . administrative law judge within [the framework of the APA] is 'functionally comparable' to that of a [U.S. District Court] judge." *Butz v. Economou*, 438 U.S. 478, 513 (1978). While the scope of this functional equivalence is not without limitations, it is correctly applied to the issuance of procedural rulings within the context of an APA administrative hearing.

herein are rendered based exclusively on an evaluation of the Preliminary Order Responses provided by the Designated Participants. The respective determinations have been made light of the Four APA Standing Considerations (SCs One-Four) discussed above, and (in no particular order) will be herein evaluated *in seriatim*.

Cannabis Bioscience International Holdings (CBIH)

In its POR, CBIH describes itself as "a corporation devoted to research and development in healthcare, particularly in cannabinoid-based formulations aimed at advancing medical treatment options for serious diseases." CBIH POR at 1. This requestor elaborates that its "mission centers on leveraging the therapeutic potential of cannabis-derived compounds to enhance patient care and broaden the scientific understanding of cannabis in medical applications." *Id.*

As its basis for APA standing, CBIH represents that it anticipates that the placement of marijuana in Schedule III will "facilitate significant advancements in medical research, patient care, and regulatory clarity, directly impacting [CBIH's] ability to conduct cannabinoid-based research" and that the proposed rescheduling would be "integral to CBIH's mission to provide safe, accessible, and evidence-based cannabis-derived treatments, which would be otherwise constrained under the existing Schedule I classification." *Id.* at 2. Further, CBIH represents that rescheduling would advance its intellectual property goals, and specifically catalogues a list of recently-filed patent applications. *Id.*

The POR regarding this requestor does not specify how it would be "adversely affected or aggrieved" by the *promulgation* of the proposed rescheduling rule, but rather, explains that its research and pecuniary interests would be advanced by rescheduling. This is a requestor who aspires to pursue the purported benefits of marijuana for commercial use. Thus, this requestor has not demonstrated that it would be adversely affected or aggrieved by promulgation of the NPRM, and instead avers that it will not accrue the benefits it aspires to in the event marijuana is not rescheduled into Schedule III. Rescheduling presents a potential benefit to this requestor, but declining to do so will not adversely affect its interests beyond the status quo. Accordingly, consideration of SC One (aggrievement, adverse impact or Article III standing) does not inure to this requestor's benefit.

Under SC Two (compliance with procedural directives), the RFH was apparently timely, and the POR is clear in its support of the proposed rescheduling, discusses the issues upon which it desires to be heard, and adequately outlines its position. On the whole, this requestor has complied with the relevant Preliminary Order and the procedural directives of the Agency in the NPRM. Thus, SC Two does not disfavor APA standing.

Similarly, inasmuch as the POR is laser focused on the rescheduling depicted in the NPRM and its potential impact on CBIH, SC Three (within the scope of the NPRM) militates in favor a grant of APA standing for this requestor.

Regarding SC Four (Meaningful Assistance/Consolidation Potential), a company dedicated to developing new, medically significant formulations of marijuana products with shared scientific and commercial objectives could potentially have expertise and access to relevant information that could potentially be helpful to the Agency in deciding whether to proceed with its proposed rescheduling rule. Beyond that, the Administrator has identified this requestor as a DP, which is entitled to significant deference. Inasmuch as CBIH shares a pecuniary/commercial concern with other requestors, it may by prudent to consider a consolidation of presentations with other DPs who also favor the proposed rescheduling.

Upon a thoughtful balance of the four SC Factors, CBIH has certainly not demonstrated that promulgation of the NPRM will adversely affect or aggrieve its interests within the unambiguous, directive terms of the regulations. Upon consideration of the powerful Factor One, this requestor has **NOT DEMONSTRATED STANDING BUT MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. Analyzing the other SC Factors (in particular, SC Four, as evidenced by the Administrator's designation) militate in favor of CBIH's participation in these proceedings, but the issue of standing may properly be factored into the weight accorded to its presentation in this recommended decision.

<u>International Association of Chiefs of Police (IACP)</u>

In its POR, the IACP describes itself as "the world's largest and most influential professional association for police leaders … committed to advancing safer communities through thoughtful, progressive police leadership." IACP POR at 1. This requestor claims to "speak[] out on behalf of law enforcement." *Id.*

IACP's POR opposes the NPRM because, in its view, the proposed rescheduling change would present "a significant shift in federal drug policy with significant implications for public safety, public health and the ability of police agencies to protect the public," presumably all of which would negatively impact on, *inter alia*: policing, firearms regulations, public and workplace safety, impaired driving, impairment standards, and firearms regulation. *Id.* at 2.

In this regard, IACP's assertion of standing under SC One (aggrievement, adverse impact or Article III standing) depends entirely upon its ability to demonstrate associational standing.

> An association only has standing to bring suit on behalf of its members when its members would otherwise have standing to sue in their own right, the interests [the association] seeks to protect are germane to the organization's purpose, and neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.

Fund Democracy, 278 F.3d at 25 (citing *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000)). Here, the interests cited by IACP, at least as articulated as adverse (that is, the potentially adverse impact rescheduling could have on the law enforcement efforts to enforce driving and other impairment-related and fit-for-duty laws regularly enforced by many of its members), could conceivably be adversely impacted by promulgation of the NPRM. Accordingly, SC One favors standing in this case.

With respect to SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR is responsive, and consistent with the Preliminary Order and the procedural directives of the Agency. Likewise, the subject matter of the POR is entirely within the proper scope of the NPRM (SC Three). On the issue of SC Four (Meaningful Assistance/Consolidation Potential), the POR posits a wide reservoir of access to members with the potential to speak authoritatively on the listed issues of concern, a law enforcement perspective is quite valuable, and even beyond all that, that the Administrator approved IACP's status as a DP is entitled to significant deference. The law enforcement focus expressed by this requestor may well be best served by consideration of consolidation with other like-minded requestors.

Accordingly, inasmuch as all four of the SCs favor standing, this DP has **ESTABLISHED STANDING AND MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. This requestor may wish to give serious consideration to presentation consolidation with other enforcement-motivated requestors who are unsupportive of the proposed rescheduling.

Veterans Initiative 22 (VI-22)

In its POR, VI-22 defines itself as "a non-profit organization whose mission is veteran suicide prevention" and that its focus is helping veterans, their families and first responders "by providing resources, employment opportunities, and … advocating for safe access to affordable cannabis …." VI-22 POR at 2. The POR does not reference any specific or estimated number of veteran members or beneficiaries or how its services are designed to assist those veterans, but it does posit that the NPRM would facilitate cannabis research, improve veterans' access to marijuana as an alternative treatment option, and reduce legal barriers to veterans who seek to use marijuana as medicine. *Id.* at 5.

It is not necessary to reach the issue of associational standing. Irrespective of the size of its membership or the scope of its beneficiaries, VI-22's POR does not specify how it or its beneficiaries would be "adversely affected or aggrieved" by the *promulgation* of the proposed rescheduling rule. It is VI-22's stated position that those it helps would markedly benefit by DEA's embracement of the NPRM and rescheduling of marijuana to Schedule III. Specifically, the POR argues that promulgation of the NPRM will encourage research into the substance's benefits, make it more accessible to veterans, and diminish some legal barriers that affect the organization's beneficiaries. Thus, this requestor has not demonstrated that it or those it assists would be adversely affected or aggrieved by promulgation of the NPRM. Rescheduling presents a potential benefit to this requestor and its veterans, and will not adversely affect any of its espoused causes related to marijuana. Accordingly, consideration of SC One (aggrievement, adverse impact or Article III standing) does not inure to this requestor's benefit.

With respect to SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR is responsive, and consistent with the Preliminary Order and the procedural directives of the Agency. Likewise, the subject matter of the POR is entirely within the proper scope of the NPRM (SC Three). The POR's demonstration under SC Four (Meaningful Assistance/Consolidation Potential) is stronger on its commitment to its positions than it is on access to a wide range of relevant experts, but that the Administrator approved VI-22's status as a DP is entitled to significant deference.

Upon a thoughtful balance of the four SC Factors, VI-22 has not demonstrated that promulgation of the NPRM will adversely affect or aggrieve its own interests or the interests of those on whose behalf it advocates. Placing appropriate regulatory emphasis on the powerful

Factor One, this requestor has **NOT DEMONSTRATED STANDING BUT MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. Consideration of the other SC Factors (in particular, SC Four, as evidenced by the Administrator's designation) lend some support to allowing this requestor's participation in these proceedings, but the issue of standing may properly be factored into the weight accorded to its presentation in this recommended decision. The veteran-focused concerns of this requestor may lend itself well to consolidating its presentation with other veteran-focused DPs who also favor promulgation of the NPRM.

Kenneth Finn, M.D.

Dr. Finn's POR lists his extensive medical qualifications and his considerable experience writing, lecturing, and testifying on the issue of marijuana use. Finn POR at 1. Although affiliated with numerous organizations, including the International Academy on the Science and Impact of Cannabis,[26] the POR identifies his interest in the NPRM exclusively as a physician, and not on behalf of IASIC or any other organization, thereby precluding consideration of associational standing. According to the POR, this requestor has multiple relevant board certifications and practices pain medicine. *Id.* Dr. Finn alleges that as a physician, the promulgation of the NPRM would adversely affect him because the lack of satisfactory research into cannabis and the absence of any dosing guidelines or care standards from the Food and Drug Administration (FDA) would render him unable to competently prescribe or administer the substance as a drug for his patients. *Id.* at 1-3.

In *FDA v. Alliance for Hippocratic Medicine*, the Supreme Court held that a group of physicians challenging FDA regulations lacked standing to do so based on anticipated hurdles in patient treatment. 602 U.S. at 380-81. The Court specifically declined to create a "doctor standing" doctrine,[27] but was equally unambiguous in holding that the plaintiff-doctors "may present their concerns and objections to the President and FDA in the regulatory process …." *Id.* at 397. Which segues nicely to the subject of APA standing. As discussed, *supra*, the requirements of APA standing are not coextensive with standing under Article III, and are principally driven by the applicable agency regulations. *Ritchie*, 170 F.3d at 1095. Here, Dr.

[26] *Supra* note 3.
[27] *Id.* at 391-92.

Finn has raised issues related to his pain management practice where he claims that he will be adversely affected by the promulgation of the NPRM. Without reaching the issue as to whether any of his anticipated difficulties have merit, this type of allegation clearly sounds within the reach of the APA and CSA's standing requirements under the regulations, and militate in favor of standing under SC One (aggrievement, adverse impact or Article III standing).

With respect to SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR is responsive, and consistent with the Preliminary Order and the procedural directives of the Agency. Likewise, the subject matter of the POR is entirely within the proper scope of the NPRM (SC Three). On the issue of SC Four (Meaningful Assistance/Consolidation Potential), the POR essentially offers the potential testimony of Dr. Finn, whose credentials arguably represent a considerable array of subject matter experience and knowledge on subjects relevant to the NPRM determination. Furthermore, the Administrator approval of Dr. Finn's status as a DP is entitled to significant deference.

Accordingly, inasmuch as all four of the SCs favor standing, this DP has **ESTABLISHED STANDING AND MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. The medical practitioner-focused interests of this requestor may render it sensible for him to consider presentation consolidation with other, medical practitioner DPs who also disfavor the proposed rescheduling action.

Phillip Drum, PharmD

Dr. Drum's POR lists his extensive qualifications as a pharmacist and his considerable experience writing, lecturing, and testifying on the issue of marijuana use and impairment. Drum POR at 1-2. Dr. Drum alleges that as a pharmacist, the promulgation of the NPRM would adversely affect him because, at least in his view, the FDA did not perform the functions that pharmacists depend upon for the safe, effective, and professional exercise of pharmacy. *Id.* Specifically, the lack of the package inserts required to accompany all medications will, at least in his view, result in an inability to comply with the standards of his profession. *Id.* According to Dr. Drum's POR:

> As a [Schedule III] product, marijuana products need an approved package insert listing medical indication for use, scientific evidence of the benefits exceeding the risks, use in the approved indication, the appropriate dosage for various patient populations (age, pregnancy status, metabolic and clearance status, etc.), potential

> adverse effects along with the incidence of occurrence, standard concentrations of active ingredients (there are over 100+ cannabinoids in marijuana), storage requirements and clinically relevant drug interactions. Dispensing these products without such information pose[s] a safety risk and inability of a pharmacist to provide required patient education about the safe use of their medicine. None of this information for marijuana has been performed [sic] by the FDA, unlike the package insert currently available for the single [sic] cannabinoid products – dronabinol and cannabidiol.

Id. at 1-2. Thus, by Dr. Drum's reckoning, without research and action by FDA, he cannot do his job and serve his pharmacy patients within the standards of his profession.

As discussed, *supra*, inasmuch as in *Alliance for Hippocratic Medicine*, the Supreme Court declined to create standing for physicians, it is beyond doubt that a similar logic precludes Article III standing for Dr. Drum based exclusively on his status as a pharmacist. 602 U.S. at 396. As has been discussed extensively, elsewhere in this order, the requirements of APA standing are not coextensive with standing under Article III, and are principally driven by the applicable agency regulations. *Ritchie*, 170 F.3d at 1095. Here, Dr. Drum has raised issues related to pharmacy practice, and claims that he and his patients stand to be adversely affected by the promulgation of the NPRM. Without reaching the issue as to whether any of his anticipated difficulties have merit, this type of allegation clearly sounds within the reach of APA/CSA standing under the regulations, and militate in favor of standing under SC One (aggrievement, adverse impact or Article III standing).

With respect to SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR is responsive and consistent with the Preliminary Order and the procedural directives of the Agency. Likewise, the subject matter of the POR is entirely within the proper scope of the NPRM (SC Three). On the issue of SC Four (Meaningful Assistance/Consolidation Potential), Dr. Drum's POR exclusively offers his own potential testimony, which arguably appears to reflect a considerable breadth of subject matter experience and knowledge on subjects relevant to the NPRM determination. Furthermore, the Administrator approval of Dr. Drum's status as DP's is entitled to significant deference.

Accordingly, inasmuch as all four of the SCs favor standing, this DP has **ESTABLISHED STANDING AND MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. The medical practitioner-focused interests of this requestor may render it

sensible to consider presentation consolidation with other, medical-practitioner DPs who also disfavor the NPRM.

Community Anti-Drug Coalitions of America (CADCA)

CADCA's POR states that it represents "over 7,000 substance use prevention coalitions that involve multiple sectors of a community including schools, law enforcement, youth, parents, healthcare, media, tribal communities and others who are involved in comprehensively addressing locally identified substance use issues, including marijuana." CADCA POR at 2. According to this DP, the mission of its members "is to keep communities safe, healthy and drug free by stopping, delaying and mitigating initiation into substance use …." *Id.* CADCA asserts that promulgation of NPRM would greatly increase funding sources of pro-marijuana entities, and thereby render it more difficult to achieve mission goals within its budget, thereby greatly reducing the support it will be able to render to its coalition members. *Id.* at 6.

SC One (aggrievement, adverse impact or Article III standing) consideration is dependent upon a determination that CADCA has associational standing. That is, that CADCA's "members would otherwise have standing to sue in their own right, the interests [the association] seeks to protect are germane to the organization's purpose, and neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Fund Democracy*, 278 F.3d at 25 (citing *Friends of the Earth*, 528 U.S. at 181). Assuming (as proffered) that its substance abuse coalitions are uniformly dedicated to the local and national reduction of marijuana use, each one would be adversely affected by a regulatory action that would potentially disproportionately fund pro-marijuana advertising and advocacy efforts. Accordingly, CADCA has demonstrated sufficient associational standing to have that factor militate in favor of standing under SC One.

With respect to SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR is responsive, and consistent with the Preliminary Order and the procedural directives of the Agency. Likewise, the subject matter of the POR is entirely within the proper scope of the NPRM (SC Three). On the issue of SC Four, as described in the POR, CADCA's seven-thousand-member-coalition breadth would apparently make a potentially large number of experts with knowledge available to contribute to potentially add meaningful

input to the Agency's NPRM determination. Furthermore, that the Administrator approved CADCA's status as a DP is entitled to significant deference.

Accordingly, inasmuch as all four of the SCs favor standing, CADCA has **ESTABLISHED STANDING AND MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. The substance-abuse-prevention focus of this requestor may be best served by considering consolidation of its presentation with other abuse-prevention-motivated DPs who also are unsupportive of the proposed rescheduling.

Cannabis Industry Victims Educating Litigators (CIVEL)

In its POR, CIVEL describes itself as "a marijuana industry victims' advocacy organization" and alleges that its "victims of the marijuana industry … have been, are being, or will actually be harmed by [promulgation of the NPRM because it] will increase the use of marijuana, reduce the perception of its dangerousness and lower medical standards for deciding what is a medicine …."[28] CIVEL POR at 4. While not altogether clear from the POR, CIVEL is apparently engaged in the active representation of individuals who claim/have claimed harmful effects from marijuana, and equips trial attorneys and the public with legal citations and tactical approaches for engaging in anti-marijuana litigation. *Id.* at 3-4.

Reviewing its POR under SC One (aggrievement, adverse impact or Article III standing) CIVEL's APA standing is dependent on whether it has made a persuasive case for associational standing. That is, that CIVEL's "victims" "would otherwise have standing to sue in their own right, the interests [the association] seeks to protect are germane to the organization's purpose, and neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Fund Democracy*, 278 F.3d at 25 (citing *Friends of the Earth*, 528 U.S. at 181). Assuming (as proffered) that the "victims" it advocates and litigates for allege they have each been harmed by marijuana and an NPRM that could potentially increase its societal prevalence exponentially, each of the "victims" could allege sufficient harm to justify

[28] The POR purports to contain citations for two cases where state courts have granted associational standing for CIVEL under state law. CIVEL POR at 4. While a limited, excerpted portion of an unreported New York trial court decision that was supplied by CIVEL appears to find associational standing by placing reliance on an affidavit executed by one of the plaintiffs (*Cannabis Impact Prevention Coalition and Cannabis Industry Victims Seeking Justice, et al v. Hochul, et al*, Albany County, NY, Index No. 905386-23), the other case (*Botteon and CIVEL, et. al., MID-L-001241-24*) is arguably less helpful in this regard.

associational standing for this DP. Accordingly, CIVEL has demonstrated sufficient associational standing to have that factor militate in favor of standing under SC One.

Regarding SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR is responsive, and consistent with the Preliminary Order and the procedural directives of the Agency. Likewise, the subject matter of the POR is entirely within the proper scope of the NPRM (SC Three). On the issue of SC Four, as described in the POR, CIVIL's active litigation and litigation support missions provide a sufficient basis to conclude that it would possess knowledge that could be instrumental in an accurate disposition of this NPRM determination. Furthermore, that the Administrator approved CIVEL's status as a DP is entitled to significant deference.

Accordingly, inasmuch as all four of the SCs favor standing, CIVEL has **ESTABLISHED STANDING AND MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. The substance-abuse-prevention/victim focus of this requestor may be best served by considering consolidation of its presentation with other, abuse/prevention requestors who also oppose the NPRM.

Hemp for Victory (HFV)

In its POR, HFV defines itself as "a non-profit organization dedicated to educating the public about why veterans are using medical cannabis over prescription pharmaceuticals, including dangerous and addictive opioids and other controlled substances." HFV POR at 1. The POR explains the organization's mission as "educat[ing] and bring[ing] awareness to the natural solution of cannabis as a way for veterans to manage the mental and physical challenges that often result from military service and to ensure that veterans face neither discrimination nor penalty for their use of medical marijuana." *Id.* The POR does not reference any specific or estimated number of veteran members or beneficiaries, but outlines its education and advocacy mission, and asserts that:

> Because of marijuana's [S]chedule I status under federal law, [HFV's] veteran [b]oard members and the veterans for whom they advocate currently face both discrimination and liability if they use medical marijuana. As a result, they cannot obtain access to medicine that they need from the Department of Veterans Affairs and are, in many cases, forced to rely instead on the harmful pharmaceutical drugs that are driving much of our veteran suicide epidemic.

Id. at 4.

It is not necessary to reach the issue of associational standing here. Irrespective of the size of its membership or the sincerity of the organization's commitment, HFV's POR does not specify how it or its beneficiaries would be "adversely affected or aggrieved" by the *promulgation* of the proposed rescheduling rule. HFV's POR is not shy about stating that its goal is the descheduling of marijuana altogether (not part of this NPRM in any way). However, it is HFV's stated position that the placement of cannabis into Schedule III would present "an incremental step toward its ultimate goal" of removing marijuana from the list of scheduled drugs entirely. *Id.* at 5. Thus, this requestor has not demonstrated that it or those it advocates on behalf of would be adversely affected or aggrieved by promulgation of the NPRM. Actually, as conceded by its POR, rescheduling presents a potential benefit to this requestor and its veterans, and will not adversely affect any of its espoused educational and advocacy causes related to marijuana. Accordingly, consideration of SC One (aggrievement, adverse impact or Article III standing) does not inure to this requestor's benefit.[29]

With respect to SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR is responsive, and consistent with the Preliminary Order and the procedural directives of the Agency. Likewise, the subject matter of the POR is generally within the proper scope of the NPRM (SC Three). The POR's demonstration under SC Four (Meaningful Assistance/Consolidation Potential) names a single witness, but that witness certainly presents as a potential source of authoritative information that could prove helpful in the decision the Agency must make. Additionally, the Administrator's approval of HFV as a DP warrants significant deference.

Upon a thoughtful balance of the four SC Factors, HFV has not demonstrated that promulgation of the NPRM will adversely affect or aggrieve its own interests or the interests of those on whose behalf it advocates. Placing appropriate weight on Factor One, this requestor has **NOT DEMONSTRATED STANDING BUT MAY CONTINUE TO PARTICIPATE IN**

[29] The balance of this requestor's arguments in favor of standing are wholly unpersuasive. To argue, at this procedural juncture, that the DEA is an improper advocate or sponsor of its own NPRM adds nothing to the standing equation and (at least on the present record) presents little more than an *ad hominem* distraction from the important advocacy and adjudicative work to be accomplished in these proceedings. A separate motion has been filed on this issue and it will be addressed in a separate order. Further, that HFV has been accorded associational standing in unrelated proceedings where a member had the ability to demonstrate Article III standing does not advance its argument in these proceedings regarding its APA standing.

THESE PROCEEDINGS. Consideration of the other SC Factors (in particular, SC Four, as evidenced by the Administrator's designation) lend some support to allowing this requestor's participation in these proceedings, but the issue of standing may properly be factored into the weight accorded to its presentation in this recommended decision. This requestor remains a DP, and may be well served by considering a consolidation of presentation with other veteran-access-focused participants who also favor the proposed rescheduling action.

National Drug & Alcohol Screening Association (NDASA)

In its POR, NDASA identifies itself as "a non-profit professional association representing more than 5,000 private and public sector employers and service agents, domestically and internationally, who administer and manage workplace drug and alcohol testing programs." NDASA POR at 1. Drug testing by NDASA members is carried on in the private and public sectors and regulated by various government standards. In addition to a high level of private-sector testing, the government testing includes the Nuclear Regulatory Commission (NRC) and the U.S. Department of Transportation (DOT). *Id.* at 1-2. The DOT testing is carried out in accordance with mandatory statutory and regulatory requirements. Because, according to NDASA, the authority of the U.S. Department of Health and Human Services (HHS) to test only extends to controlled substances in Schedules I and II (not III), promulgation of the NPRM would cause a cessation of marijuana drug testing in key transportation safety positions, to include the following: "airline pilots, air traffic controllers, school bus drivers, subway and train operators, ferry operators, pipeline operators, and truck drivers." *Id.* at 3. At least in the view of the requestor, this feature of the NPRM would cause its membership to suffer profound and detrimental financial and professional consequences. For these reasons, and reasons of public safety, NDASA opposes the NPRM.

As its POR is structured, standing under SC One (aggrievement, adverse impact or Article III standing) is dependent upon a determination that NDASA has associational standing. That is, that NDASA's "members would otherwise have standing to sue in their own right, the interests [the association] seeks to protect are germane to the organization's purpose, and neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Fund Democracy*, 278 F.3d at 25 (citing *Friends of the Earth*, 528 U.S. at 181). Assuming (as proffered) that rescheduling marijuana to Schedule III would inflict financial and

professional harm on its members, NDASA has demonstrated sufficient associational standing to have this critical factor militate in favor of standing under SC One.

With respect to SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR is responsive, and consistent with the Preliminary Order and the procedural directives of the Agency. Likewise, the subject matter of the POR is entirely within the proper scope of the NPRM (SC Three). On the issue of SC Four (Meaningful Assistance/Consolidation Potential) NDASA's POR references the organization's executive director, but in view of the size and specialization of this requestor, it would seem that it would have no shortage of qualified witnesses among its five-thousand-strong membership that could prove helpful in the decision the Agency must make. Additionally, the Administrator's approval of NDASA as a DP warrants significant deference.

Accordingly, inasmuch as all four of the SCs favor standing, NDASA has **ESTABLISHED STANDING AND MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. This requestor could potentially benefit by considering consolidation with another requestor whose focus is founded in concerns over the potential limitations the NPRM may inflict upon testing for public safety.

The Commonwealth Project (TCP)

In its POR, TCP defines itself as an entity "committed to advocating on behalf of and prioritizing the 65+ population and integrating medical cannabis into mainstream health care for seniors." TCP POR at 1. This requestor appears to be an advocacy group focused on senior citizens and claims to be "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." *Id.* at 2.

On the issue of SC One (aggrievement, adverse impact or Article III standing), the POR's description of TCP renders it unnecessary to reach the issue of associational standing. The POR does not specify how it or its senior-beneficiaries would be "adversely affected or aggrieved" by the *promulgation* of the proposed rescheduling rule. In fact, according to its POR, the only potential aggrievement to this requestor and those seniors it advocates for would be "if rescheduling is rejected or unduly delayed." *Id.* at 3. Not only would the proposed rescheduling not adversely affect or aggrieve this organization, but it has posited that it cannot happen fast

enough for its liking. Accordingly, consideration of SC One does not inure to this requestor's benefit.

With respect to SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR (while perhaps not altogether clear as to how the requestor executes its objectives) is generally responsive, and consistent with the Preliminary Order and the procedural directives of the Agency. Likewise, the subject matter of the POR is within the scope of the NPRM (SC Three). The POR's demonstration under SC Four (Meaningful Assistance/Consolidation Potential) does not identify a particular witness or source of expertise that would be particularly knowledgeable, but a source of the perspective of senior citizens added to the decisional equation would be important and potentially helpful to a resolution of the NPRM. Additionally, the Administrator's approval of TCP as a DP warrants significant deference.

Upon a thoughtful balance of the four SC Factors, TCP has not demonstrated that promulgation of the NPRM will adversely affect or aggrieve its own interests or the interests of those on whose behalf it advocates (just the opposite in fact). Placing appropriate weight on Factor One, this requestor has **NOT DEMONSTRATED STANDING BUT MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. Consideration of the other SC Factors (in particular, SC Four, as evidenced by the Administrator's designation) lend some support to allowing this requestor's participation in these proceedings, but the issue of standing may properly be factored into the weight accorded to its presentation in this recommended decision. This requestor's access-for-seniors focus may by enhanced by consideration of presentation consolidation with other requestors focused on seeking marijuana access for specific groups (*e.g.*, veterans).

<u>The National Transportation Safety Board (NTSB)</u>

The POR filed by the NTSB provides the following account of its background, status, and mission:

> The NTSB is an independent federal agency charged by Congress with investigating every civil aviation accident in the United States and significant events in the other modes of transportation—railroad, transit, highway, marine, pipeline, and commercial space.

NTSB POR at 1. According to NTSB, under current law, rescheduling marijuana to Schedule III would place it outside the parameters of authorized drug testing, "prevent[ing] testing for marijuana use by safety-sensitive employees in commercial transportation operations, such as truck drivers, rail conductors, pipeline/hazardous materials operators, air traffic controllers, flight attendants, and airline pilots, among many others." *Id.* at 2. In NTSB's view, this result would "create a safety blind spot that could endanger the public, contrary to NTSB's public safety mission." *Id.* at 3. NTSB's POR expresses additional concerns related to the effect of increasing marijuana use in public, due to what it characterizes as "performance-impairing effects" on humans who operate by, with, and in the public transportation sphere. *Id.*

Inasmuch as its representations depict the potential for (in its view) a profound impact on its mission and its ability to safeguard the public in the transportation space, this requestor has established standing under Article III, and its position militates strongly in favor of standing under SC One (aggrievement, adverse impact or Article III standing).

With respect to SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR is responsive, and consistent with the Preliminary Order and the procedural directives of the Agency. Likewise, the subject matter of the POR is squarely within the proper scope of the NPRM (SC Three). On the issue of SC Four (Meaningful Assistance/Consolidation Potential) as the lead agency in evaluating major traffic incidents and the relevance and extent of any attendant impairment issues, it is likely that this requestor has access to experts in the field that could meaningfully assist in the adjudication of this NPRM. Additionally, the Administrator's approval of NTSB as a DP warrants significant deference.

Accordingly, inasmuch as all four of the SCs favor standing, NTSB has **ESTABLISHED STANDING AND MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. This requestor could potentially benefit by considering consolidation with another requestor whose focus is concerns over the potential limitations the NPRM may inflict upon testing for public safety.

<u>The Doc App, Inc., d/b/a My Florida Green (DocApp)</u>

In its POR, DocApp describes itself as "a company that supports over 43,000 medical marijuana patients in Florida [which] provides a HIPAA-compliant platform offering real-time analytics, data-driven insights, and treatment support for marijuana patients." DocApp POR at 2.

Even a cursory reading of this Designated Participant's POR reveals that the DocApp's primary interest in these proceedings' rests solely on the utilization of its platform in future actions involving the possible rescheduling of marijuana to Schedule III. To be sure, input into the process is only enhanced by entities with a potential commercial perspective in the proposed rescheduling action. Here, however, in place of expressing a position on the NPRM, the POR characterizes the NPRM as a "positive step," and emphasizes that it is essential that marijuana patients maintain "flexibility to select what best meets their needs, guided by real-time data on strain options, effects, and availability." *Id.* at 3. This emphasis stands in some tension with the CSA's implementing regulations, which unambiguously provide that "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." 21 C.F.R. § 1306.04(a). Furthermore, the Supreme Court has made clear that medical standards are a function of a state's police powers, not the DEA. *Gonzales*, 546 U.S. at 274. Patient control (as contrasted with input to his/her prescriber/pharmacist) is inconsistent with the regulatory dynamic of prescribing controlled substances, and setting a federal standard for the dispensing and prescribing of controlled substances is well beyond the CSA's statutory mandate. *Id.* at 272, 274-75.

A reading of this DP's POR reflects, at best, mild positivity regarding the NPRM and does not indicate any manner in which it, its customers, or its business interests would be even marginally affected by the proposed rescheduling. Accordingly, consideration of SC One (aggrievement, adverse impact or Article III standing) does not inure to this requestor's benefit in any perceivable way.

Under SC Two (compliance with procedural directives), the RFH was apparently timely, and POR provided identifying and mission information. Beyond that, this DP did not comply with the DEA Administrator's directives to state with particularity its interest in the proceeding, state with particularity the objections or issues concerning which it desires to be heard, and state its position regarding objections or issues. 89 Fed. Reg. at 70149. Likewise although responding to the Preliminary Order, the POR did not state "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." Prelim. Ord. at 3. Thus, SC Two does not militate in favor of APA standing.

With respect to SC Three (within the scope of the NPRM), as discussed, *supra*, inasmuch as this POR seeks relief that is beyond the NPRM (*to wit*, the adoption of regulations focused on the inclusion of its software or something like it), and even beyond the regulations and the proper scope of the CSA as determined by the Supreme Court, consideration of this factor does not at all support APA Standing.

Regarding SC Four (Meaningful Assistance/Consolidation Potential), as also discussed, *supra*, input from commercial interests are a proper and valuable area of consideration in deciding whether to reschedule marijuana or any other drug, but this DP is not raising a single issue that could or should be addressed by the NPRM. To be sure, the Administrator has identified this requestor as a DP, but the POR filed is so bereft of any demonstration of standing (or even relevance) has **NOT DEMONSTRATED STANDING AND MAY <u>NOT INDEPENDENTLY</u> CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. This requestor should expeditiously consider potential consolidation with another, similarly aligned, commercially-motivated requestor. The Administrator's designation is an essential element to be afforded (as evident in the balance of this order) to powerful (and generally controlling) deference regarding participation. But the Administrator did not have the benefit of the POR filed by this DP, and deserves, at a minimum, the analysis offered here. To be clear, based on the content of its POR, this DP has not demonstrated a sufficient (standing or evidentiary) basis to participate in this hearing in the absence of sponsorship by or consolidation with a DP who has demonstrated at least sufficient grounds to be heard.

<u>The State of Nebraska (Nebraska)</u>

In its POR, pertinent to SC One (aggrievement, adverse impact or Article III standing) Nebraska asserts that because under state law, marijuana is "illegal in all circumstances," rescheduling to Schedule III will "supercharge the marijuana industry" and "will increase the many costs and expenditures by Nebraska's law enforcement agencies, its judiciary, and its penal system directly related to or arising from marijuana industry." Neb. POR at 1-2. Inasmuch as its representations depict the potential for pecuniary costs and (in its view) public safety challenges,

this requestor has established standing under Article III, and this militates strongly in favor of standing under SC One.[30]

With respect to SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR is responsive, and consistent with the Preliminary Order and the procedural directives of the Agency. Likewise, the subject matter of the POR is entirely within the proper scope of the NPRM (SC Three). On the issue of SC Four (Meaningful Assistance/Consolidation Potential) it is self-evident that the official view of a state regarding the impact of the NPRM on its pecuniary and enforcement issues is a vital consideration that could benefit the NPRM process. Additionally, the Administrator's approval of Nebraska as a DP warrants significant deference.

Accordingly, inasmuch as all four of the SCs favor standing, Nebraska has **ESTABLISHED STANDING AND MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. This requestor's enforcement-related interests may by best served by considering presentation consolidation with other enforcement-motivated requestors.

Ari Kirshenbaum, PhD

In his POR, Dr. Kirshenbaum identifies himself as a PhD researcher and Psychology professor emeritus who is presently engaged in "research related to cannabis-related impairment of the skills needed for motor vehicle operation." Kirshenbaum POR at 1. The requestor indicates that the current placement of marijuana in Schedule I presents mandatory procedural steps that can result in delays in conducting research. *Id.* at 2. Dr. Kirshenbaum's POR states that he is currently "co-leading a research study out of the University of California San Francisco (Medical School) that has been delayed for over a year due to the regulatory hurdles necessitated by [marijuana's] Schedule I designation." *Id.*

[30] Nebraska's alternative argument that standing under the APA, the CSA, and the CSA's implementing regulations is satisfied exclusively by virtue of the fact that the Administrator designated it as a participant misperceives the recommended decision hearing structure. Analogously, although all DEA immediate suspension enforcement hearings commence with the issuance of a charging document by the Administrator, assigning controlling weight to that preliminary decision and binding the ALJ thereby would render the hearing process under the APA as illusory. 21 U.S.C. § 811(a). That cannot be the intent of Congress. To be sure, decisions regarding standing (like all rulings and decisions made by an ALJ) are subject to the Administrator's review, but a final order that is consistent with the recommended decision is stronger than when the contrary occurs. *See generally, Morall v. DEA*, 412 F.3d 165, 177 (D.C. Cir. 2005) ("The Agency's departures from the ALJ's findings are vulnerable if they fail to reflect attentive consideration to the ALJ's decision.").

Dr. Kirshenbaum supports the rescheduling of marijuana into Schedule III so that his studies can be conducted more expeditiously. On the issue of SC One (aggrievement, adverse impact or Article III standing), Dr. Kirshenbaum does not specify how he would be "adversely affected or aggrieved" by the *promulgation* of the proposed rescheduling rule. Not only would the proposed rescheduling not adversely affect or aggrieve this requestor, but he wants it to happen quickly. Accordingly, consideration of SC One does not inure to this requestor's benefit.

With respect to SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR is responsive, and consistent with the Preliminary Order and the procedural directives of the Agency. Likewise, the subject matter of the POR is within the scope of the NPRM (SC Three). Under SC Four (Meaningful Assistance/Consolidation Potential) Dr. Kirshenbaum offers his own testimony, which could potentially bring a knowledgeable and relevant perspective from academia. Additionally, the Administrator's approval of Dr. Kirshenbaum as a DP warrants significant deference.

Upon a thoughtful balance of the four SC Factors, Dr. Kirshenbaum has not demonstrated that promulgation of the NPRM will adversely affect or aggrieve him. Placing appropriate weight on Factor One, this requestor has **NOT DEMONSTRATED STANDING BUT MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. Consideration of the other SC Factors (in particular, SC Four, in light of the Administrator's designation) lend some support to allowing this requestor's participation in these proceedings, but the issue of standing may properly be factored into the weight accorded to his presentation in this recommended decision. Dr. Kirshenbaum may wish to consider the prospect of presentation consolidation with other academic/medical professional requestors who are supportive of the NPRM.

<u>Office of Cannabis Ombudsman, State of Connecticut (OCO)</u>

In its POR, OCO defines itself as "the first-in-the-nation independent state agency with a mission to protect and preserve the needs of medical cannabis patients." OCO POR at 1-2. The POR explains that OCO is statutorily created and its focus is to provide assistance to

> Connecticut residents [as] they navigate the [m]edical cannabis system through direct assistance; outreach and educational activities; meetings, facility visits and continuous communication with current and future suppliers; assessing and implementing needed improvements; and working with research centers,

> universities and advocates to monitor and improve [the state] system and bring best-in-class standards to [Connecticut].

Id. at 2. OCO represents that it "generally supports the [NPRM] and removing marijuana from [S]chedule I" due to criminal and other consequences that stem from that designation. But it also says that it "has concerns with a [S]chedule III placement" because state residents seeking medical marijuana could be "confused if cannabis becomes akin to Tylenol 3 and other pharmaceuticals in [S]chedule III." *Id.* at 3. Confusingly, OCO also expresses additional "concerns" that existing regulations (which apply to all Schedules) "could increase the price and decrease the availability of medicinal cannabis if enforced by DEA, which is currently not the case."[31] *Id.* Lastly, OCO is apparently also opposed to quotas and other controls that could be required to bring a Schedule III-marijuana in line with the terms of the Single Convention. *Id.* Thus, OCO is apparently "generally" supportive of rescheduling marijuana, but not supportive of controls that could be required to comply with U.S. treaty obligations.

While Connecticut is doubtless a relatively populous state, the true number of OCO's beneficiaries cannot be readily ascertained from its POR. Consequently, OCO's position on the NPRM renders the issue of associational standing irrelevant. The POR does not specify how OCO or any of the state residents that utilize its services would be "adversely affected or aggrieved" by the *promulgation* of the proposed rescheduling rule. In fact, although OCO has taken an arguably nuanced view of the NPRM, it has made it clear that it is "generally" supportive. Accordingly, consideration of SC One (aggrievement, adverse impact or Article III standing) does not inure to this requestor's benefit.

With respect to SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR is responsive, and consistent with the Preliminary Order and the procedural directives of the Agency. Likewise, the subject matter of the POR is generally within the proper scope of the NPRM (SC Three). The POR's demonstration under SC Four (Meaningful Assistance/Consolidation Potential) supplies little insight into whether it has sources of authoritative information at its disposal that could prove helpful in the decision the Agency must make beyond the perspective of this independent agency within the State of Connecticut,[32] but as an independent agency with a mission that is so closely aligned with the

[31] Enforcement (or past/future Congressional riders precluding enforcement) is not an issue within the scope of the NPRM.

[32] It is unclear as to whether OCO is authorized to speak on behalf of the State of Connecticut.

subject of the NPRM, its input certainly carries with it the potential to render a valuable contribution. Beyond all that, the Administrator's approval of OCO as a DP warrants significant deference.

Upon a thoughtful balance of the four SC Factors, OCO has not demonstrated that promulgation of the NPRM will adversely affect or aggrieve its own interests or the interests of those on whose behalf it advocates. Placing appropriate weight on Factor One, this requestor has **NOT DEMONSTRATED STANDING BUT MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. Consideration of the other SC Factors (in particular, SC Four, as evidenced by the Administrator's designation) lend some support to allowing this requestor's participation in these proceedings, but the issue of standing may properly be factored into the weight accorded to its presentation in this recommended decision. This requestor may wish to consider presentation consolidation with other DPs focused on enhancing marijuana access to specific groups and who support promulgation of the NPRM.

Tennessee Bureau of Investigation (TBI)

> TBI's POR provides the following account of its duties and mission:
>
> The [TBI] is Tennessee's lead investigative agency with original jurisdiction over drug enforcement and the primary agency for forensic science services for law enforcement in the State. This includes operating the Tennessee Dangerous Drugs Task Force, which collaborates with federal agencies (including the DEA) to combat drug crimes across the State. TBI both investigates and enforces federal and state drug-related offenses, including marijuana offenses.

TBI POR at 1. Additionally, TBI represents that its forensic crime labs process over 30,000 drug submissions annually, many of which involve marijuana. *Id.* at 2. TBI posits that the proposed rescheduling would increase the prevalence of marijuana, would strain its drug-enforcement activities, and result in an immediate and adverse impact on TBI's mission. More specifically, according to TBI, the promulgation of the NPRM would result in "significant time and resources to reassess enforcement priorities, personnel assignments, and adjust asset allocations …." *Id.* at 3.

Inasmuch as its representations depict the potential for pecuniary costs and (in its view) public safety challenges, this requestor has established standing under Article III, and its position militates strongly in favor of standing under SC One (aggrievement, adverse impact or Article III standing).

With respect to SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR is responsive, and consistent with the Preliminary Order and the procedural directives of the Agency. Likewise, the subject matter of the POR is squarely within the proper scope of the NPRM (SC Three). On the issue of SC Four (Meaningful Assistance/Consolidation Potential) it is self-evident that the official view of the primary drug law enforcement entity in a state regarding the impact of the NPRM on its pecuniary, training and enforcement issues is a vital consideration that could benefit the NPRM process. Additionally, the Administrator's approval of TBI as a DP warrants significant deference.

Accordingly, inasmuch as all four of the SCs favor standing, TBI has **ESTABLISHED STANDING AND MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. This requestor may be well served to consider presentation consolidation with other enforcement focused DPs who oppose the proposed rescheduling.

Village Farms International (VFI)

According to its POR, VFI is a large-scale supplier of products who either is or seeks to be a supplier of marijuana. The requestor broadly describes its mission as seeking "to improve life's journey for the wellbeing of humankind and the earth on which we live." VFI POR at 1. Very broad, to be sure. As its basis for APA standing, VFI represents that it intends to enter the U.S. marijuana market and that the proposed rescheduling of marijuana to Schedule III would "facilitate its goals of researching, manufacturing, importing, and exporting marijuana for scientific and medical purposes consistent with state and federal law …" and that those goals are hindered by the current Schedule I placement. *Id.* at 4. In VFI's view, numerous, specific regulatory barriers would soften if the NPRM succeeds, and those barriers would include easier access to research, gentler requirements for inventory, export, and ordering. *Id.* at 4-5. These ameliorations, in this requestor's opinion, would result in higher profits and more efficiencies.

The POR has convincingly outlined how placing marijuana in Schedule III would be helpful to its commercial interests, and is likewise clear that its ultimate objective is descheduling or scheduling to an even less restrictive level than Schedule III. The requestor views the NPRM as "an incremental step toward optimizing the U.S.'s legal approach to marijuana" (read: legalization). *Id.* at 6. None of VFI's expanded objectives are contemplated by the present NPRM. The POR regarding this requestor does not specify how it would be

"adversely affected or aggrieved" by the *promulgation* of the proposed rescheduling rule, but rather, outlines how its research and pecuniary interests would be advanced by rescheduling. This is a requestor who aspires to pursue the purported benefits of marijuana for commercial use. Thus, this requestor has not demonstrated that it would be adversely affected or aggrieved by promulgation of the NPRM, but that it will not accrue the potential benefits it aspires to upon the failure of the NPRM. Rescheduling presents a potential benefit to this requestor, but declining to do so will not adversely affect its interests beyond the status quo. Accordingly, consideration of SC One (aggrievement, adverse impact or Article III standing) does not inure to this requestor's benefit.

Under SC Two (compliance with procedural directives), the RFH was apparently timely, and the POR is clear in its support of the proposed rescheduling (albeit as an incremental measure), discusses the issues upon which it desires to be heard, and adequately outlines its position. On the whole, this requestor has complied with the relevant Preliminary Order and the procedural directives of the Agency in the NPRM. Thus, SC Two does not disfavor APA standing. Similarly, inasmuch as the POR is mostly focused on the rescheduling depicted in the NPRM and its potential impact on its commercial interests, SC Three (within the scope of the NPRM) militates in favor a grant of APA standing for this requestor.

Regarding SC Four (Meaningful Assistance/Consolidation Potential), a reasonable reading of the POR depicts an enterprise with considerable experience in supplying agricultural products on a large scale, a likely result of rescheduling marijuana into medicine. Such input has the potential to bring valuable perspectives to the rescheduling equation. Beyond that, the Administrator has identified this requestor as a DP.

Upon a thoughtful balance of the four SC Factors, VFI has certainly not adequately demonstrated that promulgation of the NPRM will adversely affect or aggrieve its interests within the unambiguous, directive terms of the regulations. Upon consideration of the powerful Factor One, this requestor has **NOT DEMONSTRATED STANDING BUT MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**.[33] Analyzing the other SC Factors (in particular, SC Four, as evidenced by the nature and scale of this requestor's business,

[33] VFI's unsupported accusation that the DEA is an improper advocate or sponsor of its own NPRM adds nothing to the standing equation (at least on the present record and at this procedural juncture). The issues at stake in these proceedings are too important to devote time and attention to *ad hominem* distractions. This accusation has also been set forth in a separate motion, which will be addressed in a separate order.

as well as the Administrator's designation) militate in favor of VFI's participation in these proceedings, but the issue of standing may properly be factored into the weight accorded to its presentation in this recommended decision. Inasmuch as VFI shares a pecuniary and commercial concerns with other requestors, it may be prudent for this requestor to a consolidation of presentations with other commercially-motivated DPs who also support the NPRM.

Smart Approaches to Marijuana (SAM)

SAM's POR describes the organization as "a bipartisan alliance of organizations and individuals dedicated to a health-first approach to marijuana … comprised of medial doctors, lawmakers, treatment providers, preventionists, teachers, law enforcement officers who seek a middle road between incarceration and legalization." SAM POR at 1. It defines its mission as "equip[ing] policymakers with commonsense proposals, based in reputable science, to promote public health and decrease marijuana use and its consequences." *Id.*

By the terms of its POR, SAM presents itself as an advocacy organization. The POR references "organizations," but has made no representations that would sustain associational standing. Thus, the standing justification of this requestor are exclusively founded in its claim that it would be aggrieved and adversely affected by the potential affect rescheduling would have on its training and advocacy expenditures as a marijuana-skeptical material and lecturing source.[34] Inasmuch as this requestor has adequately demonstrated that promulgation of this

[34] SAM's alternate theory, *to wit*, that it is somehow magically endowed with APA standing by virtue of the fact that the Administrator sent a DP letter is singularly unpersuasive. SAM POR at 2. First, the regulations apply to DEA – all of DEA. While it is possible to apply to the Administrator "for an exception to the application of any [regulation] by filing a written request . . . stating the reasons for such an exception," no such written request granted by the Administrator is part of the present record. 21 C.F.R. § 1307.03. Beyond that, SAM's theory misperceives the structure of adjudications under the APA, the CSA, and the CSA's implementing regulations. As discussed elsewhere in this order, Congress was crystal clear in placing APA proceedings as a condition precedent to rescheduling by the Agency. 21 U.S.C. § 811(a). Determinations as to standing fixed by the Administrator at the outset of the hearing would obstruct the ALJ's authority to issue a report including a statement of all "findings and conclusions, and the reasons or basis therefor, on all the material issues of fact, law, or discretion as presented on the record [and] the appropriate rule …." 5 U.S.C. § 557(c). Analogously, although all DEA immediate suspension enforcement hearings commence with the issuance of a charging document by the Administrator, assigning controlling weight to that preliminary decision and binding the ALJ thereby would render the hearing process under the APA as illusory. 21 U.S.C. § 811(a). That cannot be the intent of Congress. To be sure, decisions regarding standing (like all rulings and decisions made by an ALJ) are subject to the Administrator's review, but a final order that is consistent with the recommended decision is stronger than when the contrary occurs. *See generally, Morall v. DEA*, 412 F.3d 165, 177 (D.C. Cir. 2005) ("The Agency's departures from the ALJ's findings are vulnerable if they fail to reflect attentive consideration to the ALJ's decision.").

NPRM would adversely affect its budget and mission, SC One (aggrievement, adverse impact or Article III standing) militates in favor of APA standing.

With respect to SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR is responsive, and consistent with the Preliminary Order and the procedural directives of the Agency. Likewise, the subject matter of the POR is within the proper scope of the NPRM (SC Three). On the issue of SC Four (Meaningful Assistance/Consolidation Potential) it is self-evident that the official view of an advocacy entity that purports to have wide-ranging, bipartisan support and can show adverse impact as a direct result of the proposed rescheduling action has the potential for significant, relevant input here. Further, the Administrator's approval of SAM as a DP (while not necessarily controlling) warrants significant deference.

Accordingly, inasmuch as all four of the SCs favor standing, SAM has **ESTABLISHED STANDING AND MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. This requestor may wish to consider the option of presentation consolidation with other DP advocacy groups who do not favor the proposed rescheduling.

National Cannabis Industry Association (NCIA)

The POR filed by NCIA describes itself as "the oldest, largest, and most inclusive [tax-exempt non-profit] trade association representing the legal cannabis industry." NCIA POR at 2. The POR further represents that NCIA's "membership is composed of hundred of businesses from all sectors of the industry—from state-licensed cannabis businesses to legal hemp product manufacturers to the wide range of ancillary businesses serving the industry" and styles itself as "the voice of Main Street Cannabis." *Id.*

NCIA has put forward its APA standing argument in essentially two prongs. The first is not persuasive, but much of the second prong is. Both prongs are underpinned by an associational standing theory. That is, that its standing derives from its theory that one or more of its members would have standing to sue in their own right, the interests to be protected are germane to the organization's purpose, and the result the organization is pursing requires the participation of individual members in the lawsuit. *Fund Democracy*, 278 F.3d at 25 (citing *Friends of the Earth*, 528 U.S. at 181).

The first prong is that it (and presumably its members) support rescheduling into Schedule III because that action "would both lessen criminal penalties and preclude the application of [Internal Revenue Code § 280E] … to marijuana businesses" that are not currently operating in violation of applicable state laws. NCIA POR at 6. Inasmuch as this prong supports the proposed rescheduling action, it would not, at least in this regard adversely affect or aggrieve its membership, and does not further its standing argument under SC One (aggrievement, adverse impact or Article III standing).

The other theory of standing is both more nuanced and more persuasive. NCIA posits that a number of its members would be adversely affected by a new definition of tetrahydrocannabinol which is incorporated into the NPRM. Without engaging in a deep dive into the merits of this issue, NCIA argues that the NPRM definition "could cause currently unscheduled [n]on-[i]ntoxicating [c]annabinoids to be designated as prohibited Scheduled I controlled substances without [additional] scheduling actions" on the part of DEA. NCIA POR at 4. A significant weakness in this position is that NCIA has not specifically alleged that any of its members are currently utilizing any particular substances that would be affected (a deficit that could conceivably undermine its standing argument in this regard). However, NCIA's POR contains the following representation:

> NCIA is adversely affected or aggrieved by the [NPRM] because the simultaneous scheduling of certain [n]on-intoxicating [c]annabinoids as Schedule I substances through the [NPRM's] proposed revisions to the definition of THC would make one or more NCIA members' businesses federally illegal for the first time.

Id. at 3 (internal quotation marks omitted). Thus, based on the fact that this requestor has alleged that it is properly in a position to exercise associational standing with several of its members who could potentially have their present business enterprises rendered illegal by promulgation of the NPRM, SC One favors standing on this narrow issue.[35]

With respect to SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR is responsive, and consistent with the Preliminary Order and the procedural directives of the Agency. Likewise, the subject matter of the POR is somewhat within the proper scope of the NPRM (SC Three). On the issue of SC Four (Meaningful

[35] Contrariwise, NCIA's more speculative arguments regarding what the Agency may do in the future, based on its pronouncements in the past and other interpretations, are unpersuasive and beyond the scope of the NPRM. See e.g., *Id.* at 5.

Assistance/Consolidation Potential), as described in its POR, it seems that NCIA would have the means at its disposal to provide qualified witnesses among its large and diverse membership, and that the commercial perspective available to it would be helpful to the adjudication of this NPRM. That said, its commercial perspective may lend itself readily and effectively to a consolidation with other DPs. Additionally, the Administrator's approval of NCIA as a DP warrants significant deference.

Accordingly, inasmuch as all four of the SCs favor standing, NCIA has **ESTABLISHED STANDING AND MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. Inasmuch as this requestor shares a pecuniary and commercial concerns with other requestors, it may by prudent to a consolidation of presentations with other commercially-motivated DPs who also support the NPRM.

Ellen Brown

While Ellen Brown's POR references her position as Research Subcommittee Chair of the Massachusetts Cannabis Advisory Board (MCAB), there is no indication therein that she is authorized (or seeking) to speak for that body.[36] Indeed, the POR is written in the first person, and focuses, not on the MCAB, but on her own experiences. Ms. Brown indicates that her position on the MCAB Research Subcommittee has provided her with some exposure to veterans, but evidently, she is not in a group authorized to speak on any behalf beyond her own. Ms. Brown further provides that she is a veteran, and as one under the care of the Veteran's Administration (the VA), she has "personally been aggrieved" by marijuana's current Schedule I placement and is in favor of the proposed rescheduling action set forth in the NPRM. Brown POR at 2.

Ms. Brown's POR does not specify how she would be "adversely affected or aggrieved" by the *promulgation* of the proposed rescheduling rule. It is her stated position that she and other veterans would markedly benefit by DEA's embracement of the NPRM and rescheduling of marijuana to Schedule III, thereby opening marijuana treatment avenues. *Id.* Thus, this requestor has not demonstrated that she would be adversely affected or aggrieved by

[36] To the extent this conclusion is incorrect and Ms. Brown is indeed authorized to speak for MCAB, that body or Ms. Brown may file a clarification within five (5) business days from the receipt of this order with a request to reconsider.

promulgation of the NPRM. Rescheduling presents a potential benefit to this requestor and (at least in her view) other veterans. Accordingly, consideration of SC One (aggrievement, adverse impact or Article III standing) does not inure to this requestor's benefit.

With respect to SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR is generally responsive, and in some respects consistent with the Preliminary Order as well as the procedural directives of the Agency. Likewise, the subject matter of the POR is within the proper scope of the NPRM to some extent (SC Three). The POR's demonstration under SC Four (Meaningful Assistance/Consolidation Potential) is difficult to gauge. Although Ms. Brown represents that she has spoken to some veterans interested in exploring the benefits of marijuana as medicine, there is no indication about the number of veterans or anything beyond some limited anecdotal, generalized representations. That the Administrator approved Ms. Brown status as DP's is entitled to significant deference, but balancing the powerful SC One and the other SC Factors, Ms. Brown has not made a sufficient (standing or evidentiary) presentation to warrant her participation in these proceedings.

Upon a thoughtful balance of the four SC Factors Ms. Brown has not demonstrated that promulgation of the NPRM will adversely affect or aggrieve her own interests and has noticed little beyond her own experience and expectations about the potential benefits of rescheduling marijuana as sought by the DEA. Placing appropriate regulatory emphasis on the powerful Factor One, this requestor has **NOT DEMONSTRATED STANDING AND MAY <u>NOT INDEPENDENTLY</u> CONTINUE TO PARTICIPATE IN THESE PROCEEDNGS**. Ms. Brown's POR efforts and input may be better suited to consolidation with another DP who has presented a sufficient showing to warrant participation.

<u>Drug Enforcement Association of Federal Narcotics Agents (DEAFNA)</u>

The POR filed on behalf of DEAFNA describes the association as a "[l]aw [e]nforcement [f]raternal [o]rganization representing active and retired DEA Special Agents, Diversion Investigators, Intelligence Research Specialists, and other DEA [p]ersonnel." DEAFNA POR at 2.

DEAFNA's basis for standing is that the rescheduling "has a direct impact on [its] members' ability to implement the necessary regulatory controls which will take years to implement and will come at an unreasonable financial cost." *Id.* This requestor is against the proposed rescheduling because it would present "a significant shift in federal drug policy with

significant implications for … the ability of law enforcement agencies to protect the public." *Id.* at 3. As noted *supra*, "[a]n association only has standing to bring suit on behalf of its members when its members would otherwise have standing to sue in their own right, the interests [the association] seeks to protect are germane to the organization's purpose, and neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Fund Democracy*, 278 F.3d at 25 (citing *Friends of the Earth*, 528 U.S. at 181). Here, inasmuch as DEAFNA's members, as specialized public servants engaged in the regulation and enforcement actions under the CSA, could potentially demonstrate adverse effect from the promulgation of the NPRM, the action is clearly germane to DEAFNA's purpose, and the members of the organization are not required participants in the action. Here, the interests cited by DEAFNA, at least as articulated as adverse (that is—at least in its view—the potentially adverse impact rescheduling could have on the law enforcement efforts to enforce driving and other impairment-related and fit-for-duty laws regularly enforced by many of its members), could conceivably be adversely impacted by promulgation of the NPRM. Accordingly, SC One favors standing in this case.

With respect to SC Two (compliance with procedural directives), as proffered, the RFH was apparently timely, and the POR is responsive, and consistent with the Preliminary Order as well as the procedural directives of the Agency. Likewise, the subject matter of the POR is within the proper scope of the NPRM (SC Three). On the issue of SC Four (Meaningful Assistance/Consolidation Potential), this requestor organization (at least as noticed in its POR) specializes in law enforcement in the field of controlled substances. It would be reasonable to assume that this requestor has access to members with the potential to speak authoritatively on the listed issues of concern, a law enforcement perspective (particularly this highly-specialized law enforcement perspective) is quite valuable, and even beyond all that, that the Administrator approved DEAFNA's status as DP's is entitled to significant deference.

Accordingly, inasmuch as all four of the SCs favor standing, this DP has **ESTABLISHED STANDING AND MAY CONTINUE TO PARTICIPATE IN THESE PROCEEDINGS**. This requestor should strongly consider the option of presentation consolidation with other enforcement-motivated DPs who also disfavor the NPRM.

On Procedure

In accordance with my authority to regulate the course of the hearing,[37] the following procedures are herein implemented to ensure fair and orderly proceedings. While the Government, as the burdened party, may present multiple witnesses, each of the remaining DPs (absent leave to the contrary granted by this tribunal) may present the testimony of a single witness. Documentary evidence and proposed witnesses from all the Parties must be disclosed in advance in a written disclosure (Prehearing Statement) as outlined below. No evidence will be admitted to the record without a proper foundation presented at the hearing on the merits.

Within the discretion of the tribunal, and to the extent practicable, each of the Parties will present testimonial and documentary evidence as set forth below.

The Government, as the burdened party, will present its evidence first. Those DPs who support the NPRM (Pro-Rescheduling DPs) will present evidence following the conclusion of the Government's case. The DPs who oppose the NPRM (Anti-Rescheduling DPs) will present evidence following the conclusion of the Pro-Rescheduling DPs' presentations. All DPs (Pro and Anti) will be limited to a single witness each, with direct examination limited to no more than approximately ninety (90) minutes (excluding cross-examination). Anti-Rescheduling DPs may cross-examine all Government witnesses and all Pro-Rescheduling witnesses. Witnesses presented by the Anti-Rescheduling DPs may be cross-examined by the Government and Pro-Rescheduling DPs. In all cases, cross-examination will be limited to approximately twenty (20) minutes per witness for each authorized cross-examiner. Within the further discretion of the tribunal, presentations may be grouped (or even consolidated) by the tribunal in accordance with commonly-expressed viewpoints as set forth in the Parties' respective PORs.

Any Party (to include the Government) who is unprepared to proceed on the date(s) scheduled at the preliminary hearing (with the input of that Party) may forfeit his/her/its ability to present the scheduled evidence or examination.

It is herein **ORDERED** that the Parties, no later than **2:00 p.m. Eastern Time (ET) on November 26, 2024**, shall electronically file with this tribunal and serve on each other, a Prehearing Statement[38] containing the following sections:

[37] 5 U.S.C. § 556(c)(5); 21 C.F.R. § 1316.52.

[38] Absent advance leave by this tribunal on a motion supported by good cause, all filed documents (other than noticed proposed exhibits offered by either party on the merits) *shall be limited to fifty (50) pages* (utilizing 12-point characters and 1-inch margins).

1. **Witnesses.** Names, *curriculum vitae*, and current addresses of all witnesses whose testimony is sought to be presented by each of the Parties.

2. **Summary of Testimony.** Brief summary of the testimony of each witness. The summaries are to state what the testimony will be, rather than merely list the areas to be covered. Testimony not disclosed may be subject to exclusion.

3. **Documents.** A list noticing all documentary evidence, including affidavits and other proposed exhibits, intended to be offered into evidence, specifying the number of pages in each. Each proposed exhibit is to be marked for identification and numbered as follows: ("[name of Party]-Exh. No. ## (ID)").

4. **Hearing Date Availability.** The NPRM and GNoH in this matter fixes the place of hearing as the DEA Hearing Facility in Arlington, Virginia. The Government and the Parties are expected to provide their representatives' and their witnesses' availability for the months of January through February 2025[39] at the Preliminary Hearing.

5. **District Court Intervention**. To the extent practicable, each Party should indicate whether he/she/it presently intends to seek the intervention of a U.S. District Court in accordance with *Axon Enterprise, Inc. v. FTC*, 598 U.S. 175 (2023).

It is further **ORDERED** that, in accordance with 21 C.F.R. § 1316.64, **a Preliminary Hearing[40] in this matter will be conducted on December 2, 2024, at 9:30 a.m. ET in the North Courtroom[41] at the DEA Hearing Facility**, at 700 Army Navy Drive, Arlington, Virginia, 22202.[42]

It is further **ORDERED** that all proceedings will be governed by the provisions of 21 C.F.R. §§ 1316.41-1316.68.[43] Your attention is specifically directed to 21 C.F.R. § 1316.45, which provides, *inter alia*, that "[d]ocuments shall be dated and deemed filed upon receipt by the

[39] 21 C.F.R. § 1301.45.
[40] 21 C.F.R. § 1316.
[41] As set forth in the Preliminary Order, the courtrooms at the DEA Hearing Facility are spacious and modern, but not unlimited. Accordingly, in view of the potentially high number of hearing participants, it is anticipated that admission to the preliminary hearing will be limited to representatives (no more than two, preferably one) and credentialled media as designated by the Agency. The Administrator has directed the proceedings will be livestreamed to afford those physically outside the courtroom an opportunity to observe the proceedings. Naturally, witnesses will be admitted to the courtroom to testify at the merits hearings at times where their testimony is scheduled. No cell phone use by anyone will be permitted in the courtroom at any hearing conducted in this matter. The highest level of decorum will be maintained at all times during all hearings, and court attire is required for anyone participating in any capacity. All representative appearances will be live (not virtual) throughout, and all representatives must plan to arrive sufficiently early to allow security processing through the DEA Visitor Center, which is collocated with the DEA Hearing Facility at 700 Army Navy Drive, Arlington, Virginia, 22202.
[42] Logistical issues will be coordinated by Law Clerk Laila Mogharabi, Esq., who can be contacted at (202) 307-8188 and at ECF-DEA@dea.gov.
[43] Additional helpful information regarding DEA administrative proceedings may be found at the OALJ website, https://www.dea.gov/administrative-law-judges.

Hearing Clerk." Documents (other than proposed exhibits) may be filed electronically or by hard copy. Only one method of document filing may be utilized.

Electronic Filing: The strongly preferred method of filing correspondence in these proceedings is as a PDF attachment via email to the DEA Judicial Mailbox (**ECF-DEA@dea.gov**). The forwarding email on all electronically filed correspondence must indicate that it was simultaneously served on the opposing party via email. The Respondent must ensure that all documents filed with the DEA Judicial Mailbox are simultaneously served on the Government Mailbox at (**dea.registration.litigation@dea.gov**). Any request(s) to modify email addresses of a party or counsel must be made on notice to this tribunal and the opposing party. The email receipt date reflected by the DEA Judicial Mailbox server shall conclusively control all issues related to the date of service of all filed correspondence, provided however, that correspondence received after 5:00 p.m., local Washington, D.C. time, will be deemed to have been received on the following business day. Note: While email is utilized as the method to forward documents for filing—as attachments—no substantive matter communicated through the body of a forwarding email will be considered. The parties are directed to refrain from including social security numbers or personally identifiable information in electronically-filed documents. Proposed evidentiary exhibits will not be accepted via electronic filing. Details regarding evidentiary exhibit filing will be the subject of a subsequent order.

Hard Copy Filing: Alternatively, correspondence may be filed in hard-copy form. Hard-copy filings must be served in triplicate and addressed to my attention at: **The DEA Office of Administrative Law Judges, 8701 Morrissette Drive, Springfield, Virginia 22152**. Because the DEA Hearing Facility is not physically collocated with the DEA mailing address, hard copy filings must be posted sufficiently in advance of the due date to assure timely receipt by this office.

Failure to timely file a prehearing statement that complies with the directions provided above may result in a sanction, including (but not limited to) a waiver of hearing and an implied withdrawal of a request for participation. Prehearing statements should not include motions, which should be filed separately.[44]

[44] A prehearing ruling setting deadlines will be issued after the prehearing conference.

It is further **ORDERED** that any requests for extension of time to file must be made by written motion sufficiently in advance of scheduled deadlines to be considered and ruled upon.

Dated: November 19, 2024

JOHN MULROONEY

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Date: 2024.11.19 17:25:51 -05'00'

JOHN J. MULROONEY, II
Chief Administrative Law Judge

CERTIFICATE OF SERVICE

This is to certify that the undersigned, on November 19, 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) Shane Pennington, Esq., Counsel for Village Farms International, via email at spennington@porterwright.com; and 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) Andrew J. Kline, Esq., Counsel for Hemp for Victory, AKline@perkinscoie.com; and Abdul Kallon, Esq., Counsel for Hemp for Victory, via email at and AKallon@perkinscoie.com; (7) Erin Gorman Kirk for the State of Connecticut, via email at erin.kirk@ct.gov; (8) Ellen Brown for Massachusetts Cannabis Advisory Board, via email at ellen@greenpathtraining.com; (9) Shanetha Lewis for Veterans Initiative 22, via email at info@veteransinitiative22.com; (10) Jason Castro, Esq., Counsel for The Doc App., Inc. d/b/a My Florida Green, via email at jasoncastro@myfloridagreen.com; (11) Kelly Fair, Esq., Counsel for The Commonwealth Project, via email at Kelly.Fair@dentons.com; (12) Rafe Petersen, Esq., Counsel for Ari Kirshenbaum, via email at Rafe.Petersen@hklaw.com; (13) 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 Impacts of Cannabis, and National Drug and Alcohol Screening Association, via email at thinkon908@aol.com; (14) 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; (15) Stephanie E. Masker, Esq., Counsel for National Transportation Safety Board, via email at stephanie.masker@ntsb.gov; (16) 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; (17) Gene Voegtlin for International Association of Chiefs of Police, via email at voegtlin@theiacp.org; (18) Gregory J. Cherundolo for Drug

Enforcement Association of Federal Narcotics Agents, via email at executive.director@afna.org; (19) 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 (20) Jim Skinner for National Sheriff's Association, via email at sheriffskinner@collincountytx.gov and ykaraman@sheriffs.org.

QUINN FOX

Digitally signed by QUINN FOX
Date: 2024.11.19 17:27:19 -05'00'

Quinn Fox
Staff Assistant to the Chief Judge
Office of Administrative Law Judges