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. 24-24**

RESPONSE OF SMART APPROACHES TO MARIJUANA PURSUANT TO NOVEMBER 21, 2024 ORDER

In accordance with the Order of November 21, 2024, Smart Approaches to Marijuana (SAM) submits this Response to assertions relating to SAM raised in the Joint Motion Requesting Supplementation of the Record and Disqualification and Removal of DEA from the Role of Proponent of the Rule in these Proceedings filed by Hemp for Victory and Village Farms International, Inc. (Movants) on November 18, 2024. The assertions concerning SAM fail on their face to suggest any improper contacts between SAM and the DEA. Movants' requests for relief should be rejected.

STATEMENT

Movants' assertions related to SAM can and should be quickly dispensed with by this Tribunal. They fail on their face and under the applicable law.

First, as a matter of law, Movants raise no colorable assertions that would support the relief they are requesting. As Movants themselves acknowledge, albeit in a footnote, *see* Mot. at 16 n.24, the relevant prohibitions on *ex parte* communications with the DEA are triggered *at the earliest* when a Notice of Proposed Rulemaking (NPRM) is published in the Federal Register. Movants, however, do not even purport to provide any information suggesting any communications between SAM and anyone at the DEA *after* the rescheduling NPRM was

published on May 21, 2024. Standing alone, that deficiency itself is sufficient to dismiss Movants' speculation about supposed improper contacts.

Second, as a factual matter, Movants have greatly exaggerated the extent to which their key asserted fact—a May 6, 2024 X.com post by Dr. Sabet—indicated any significant inside knowledge about disagreement between DOJ and the DEA concerning the proposed rule. Long before May 6, the tension between DOJ and the DEA over the potential rescheduling of marijuana was widely reported, including in a March 9, 2024 article in *The Wall Street Journal*. The news outlet reported in March that "Federal officials are at odds over President Biden's push to loosen restrictions on marijuana," and that some officials "within the Drug Enforcement Administration are resistant [to rescheduling]."[1] *The Wall Street Journal* also reported in April 2024 that the Attorney General (and thus not the DEA) had sent a proposed rule to the White House for review. Moreover, Dr. Sabet was hardly the only advocate in this space posting online about agency activity prior to the NPRM's issuance. In fact, opponents of Dr. Sabet's views were tracking agency activity and posting accurate, though not yet public, information. For example, on April 17, 2024, rescheduling proponent Anthony Varrell posted: "My sources tell me the OLC legal opinion requested by the HHS is done and ready to be published. It's also validating the HHS recommendation in our favor regarding rescheduling."[2] Thereafter, on the morning of May 16, 2024, Mr. Varrell accurately predicted that DOJ would release the NPRM that day: "I have heard through the grapevine that the register might ring today."[3] If every tweet claiming insider knowledge of the events *leading up to* the formal publication of the NPRM were a basis for inquiry

[1] Sadie Gurman, *Biden Push to Ease Marijuana Restrictions Sparks Tensions*, THE WALL STREET JOURNAL (Mar. 9, 2024), https://www.wsj.com/politics/policy/biden-push-to-ease-marijuana-restrictions-sparks-tensions-051759f7.
[2] Anthony Varrell (@V_arrell), X (Apr. 17, 2024, 12:38 PM), https://x.com/V_arrell/status/1780636940703817748.
[3] Anthony Varrell (@V_arrell), X (May 16, 2024, 9:03 AM), https://x.com/V_arrell/status/1791092072377671778/. To be sure, the NPRM was not formally issued in the Federal Register until May 21, but DOJ revealed it publicly on the 16th. Press Release, *Justice Department Submits Proposed Regulation to Reschedule Marijuana*, DOJ (May 16, 2024) https://www.justice.gov/opa/pr/justice-department-submits-proposed-regulation-reschedule-marijuana

by this Court, that unnecessary sideshow would quickly overtake the merits, both here and in every similar proceeding.

In short, the Motion is a transparent effort to smear both SAM and the DEA in an attempt to eliminate from this proceeding one of the strongest voices opposing rescheduling of marijuana. The Tribunal should deny Movants' invitation to create a sideshow requiring SAM and its counsel to expend more time and funds defending against unfounded attacks and instead should permit SAM to focus on the merits of these proceedings.

I. As Movants Concede, No Provision of Law Prohibits Contacts Between DEA and Third Parties Prior to the Publication of the NPRM.

As a starting point, Movants provide no evidence of any communications between SAM and the DEA on or after the earliest day when relevant prohibitions on *ex parte* communications could have been triggered—namely, the day the NPRM was published in the Federal Register, May 21, 2024. The four X.com posts (and two replies) referenced by Movants are dated May 6, 2024,[4] May 16, 2024,[5] May 17, 2024,[6] and May 20, 2024[7]. Significantly, only the May 6 post mentions the receipt of any information. That post was issued 10 days before DOJ publicly released the NPRM on May 16, and 15 days before the NPRM was published.[8]

On these facts, Movants fail to assert the existence of any improper *ex parte* communications. As explained below, and as Movants themselves acknowledge, the relevant prohibitions in 5 U.S.C. § 557(d) and 21 C.F.R. § 1316.51(c) were triggered *at the earliest* when the NPRM was published in the Federal Register on May 21. Movants themselves concede that,

[4] Kevin Sabet (@KevinSabet) X (May 6, 2024, 3:44 PM), https://x.com/KevinSabet/status/1787569052782846142.
[5] Kevin Sabet (@KevinSabet) X (May 16, 2024, 3:38 PM), https://x.com/KevinSabet/status/1791191462597796137.
[6] Kevin Sabet (@KevinSabet) X (May 17, 2024, 2:19 PM), https://x.com/KevinSabet/status/1791533950948807061.
[7] Kevin Sabet (@KevinSabet) X (May 20, 2024, 4:31 PM), https://x.com/KevinSabet/status/1792654527486898626.
[8] Although the Motion discusses a June 2024 webinar in which SAM Executive Vice President Luke Niforatos participated, Movants do not assert that Mr. Niforatos engaged in any *ex parte* communication. As such, the fact that the webinar took place in June 2024 is of no consequence.

given the timing, any communication suggested by Dr. Sabet's postings was "perhaps not expressly barred by the DEA regulation barring *ex parte* communications" because it occurred "*before* DOJ published the Proposed Rule in the Federal Register." Mot. at 16 n.24 (emphasis in original).[9] That standing alone should end this matter.

To the extent Movants suggest that contacts *not* prohibited by the relevant statute and regulation are "nevertheless improper," *id.*, that suggestion should be rejected out of hand. The law sets specific restrictions on *ex parte* communications so that parties may know what is allowed and what is not. Communications that are not restricted cannot be arbitrarily branded "improper" after the fact.[10] As explained below, the relevant prohibitions do not apply here for at least two reasons. First, they are triggered at the earliest upon publication of the NPRM in the Federal Register. Second, they do not prohibit or require disclosure of contacts that concern procedural matters, such as the progress of an NPRM toward release and who signed the NPRM.

A. 5 U.S.C. § 557(d) Does Not Apply.

The first provision Movants cite, 5 U.S.C. § 557(d), states that prohibitions on *ex parte* communications do not apply until "such time as the agency may designate, but in no case shall they begin to apply later than the time at which a proceeding is noticed for hearing." 5 U.S.C. § 557(d)(1)(E). Because no DEA regulation designates an earlier start time for this provision, the statute does not apply to a DEA rulemaking until it is noticed for hearing, which did not occur in this case until August 29, 2024. Even if 21 C.F.R. § 1316.42 applied to Section 557(d) (which it

[9] It stands to reason that ex parte communication prohibitions would not be triggered until, *at the earliest*, the commencement of formal proceedings. As the D.C. Circuit has explained, "informal contacts between agencies and the public are the "bread and butter" of the process of administration." *Home Box Off., Inc. v. FCC*, 567 F.2d 9, 57 (D.C. Cir. 1977).

[10] Far from "improper," the Administrative Conference of the United States has written that pre-NPRM contacts "can help an agency gather essential information, craft better regulatory proposals, and promote consensus building among interested persons."). *See* ACUS, Administrative Conference Recommendation 2014-4: *Ex Parte Communications in Informal Rulemaking* (adopted June 6, 2014).

does not), it still would not suggest any improper communications here. That provision defines the term "proceeding" as used in DEA's own regulations to mean "all actions involving a hearing, commencing with the publication by the Administrator of the notice of proposed rulemaking." 21 C.F.R. § 1316.42. There is no indication that this definition of "proceeding" was intended to set the triggering date for Section 557(d), which does not even use the term "proceeding." But even if it did apply, section 1316.42 would trigger the prohibitions *at the earliest* on the date when the NPRM was published in the federal register.

In short, there are no assertions of *ex parte* communications occurring after either (i) the publication of the NPRM on May 21, 2024, or (ii) the day the hearing on this matter was noticed on August 29, 2024. Accordingly, Section 557(d) is not triggered.

In addition, even when Section 557(d) does apply, it prohibits only communications that meet two additional criteria—both of which are absent here. First, the communications must be "relevant to the merits." 5 U.S.C. § 557(d). It is well established that communications concerning the status or general background of a rulemaking are not "relevant to the merits" and are not prohibited by Section 557(d). *See, e.g.*, *Louisiana Ass'n of Indep. Producers & Royalty Owners v. FERC*, 958 F.2d 1101, 1112 (D.C. Cir. 1992); *Raz Inland Navigation Co. v. ICC*, 625 F.2d 258, 262 (9th Cir. 1980). Indeed, the definition of "*ex parte* communication" in the APA expressly provides that it does "not includ[e] requests for status reports on any matter or proceeding." 5 U.S.C. § 551(14); *see also, e.g.*, *PATCO v. FLRA*, 685 F.2d 547, 563 (D.C. Cir. 1982) ("Requests for status reports are thus allowed under the statute, even when directed to an agency decisionmaker rather than to another agency employee."). Dr. Sabet's post suggests nothing more than him having received an update on the status of the proposed rule, including who had signed

it—which decidedly does not go to the merits. Being provided such information does not constitute *ex parte* contact.

Second, to be an ex parte contact, the communications must be with "employee[s] who [are] or may reasonably be expected to be involved in the decisional process." 5 U.S.C. § 557(d). Movants provide no evidence that Dr. Sabet was in contact with any person concerning rescheduling who could reasonably be expected to be "involved in the decisional process." *Id.*

B. 21 C.F.R § 1316.51(c) Does Not Apply.

The second provision Movants cite, 21 C.F.R. § 1316.51(c), applies to "any substantive matter *which is the subject of any hearing*, at any time after the date on which the proceedings commence." 21 C.F.R. § 1316.51(c) (emphasis added). Relying on the use of the term "proceedings" in the second clause of that sentence, Movants argue that Section 1316.51(c) applies once an NPRM is published. Mot. at 16 & n.24. As noted above, Section 1316.42 of DEA's regulations defines "proceeding" to mean "all actions involving a hearing, commencing with the publication by the Administrator of the notice of proposed rulemaking."[11] The better understanding of Section 1316.51(c), however, is that it applies by its plain terms only while a matter "is the subject of any hearing" and thus is triggered only when a hearing is noticed. 21 C.F.R. § 1316.51(c). DEA's publication of an NPRM does not, in itself, make a rulemaking proceeding the subject of a hearing. Until a notice of hearing is published, the issuing agency is free to withdraw a proposed rule and avoid holding a hearing at all. *Env't Integrity Project v. McCarthy*, 139 F. Supp. 3d 25, 29 (D.D.C. 2015) (noting withdrawn NPRM prior to potential

[11] Movants cite 21 CFR § 1300.01, which does not apply here because by its text it is applicable only to terms "used in parts 1301 through 1308, 1312, and 1317 of this chapter." 21 CFR § 1300.01(b). The relevant definitions here are contained in Section 1316.42, which applies to Section 1316 Subpart D – "Administrative Hearings," *i.e.* Sections 1316.41 through 1316.68. 21 CFR § 1316.42 ("As used in this subpart, the following terms shall have the meanings specified . . .").

formal rulemaking). This understanding is buttressed by the title of Section 1316.51, which announces that the section addresses the "[c]onduct of hearing" and thus suggests that it would apply only when a hearing has been formally noticed. As a result, a rulemaking "is" not the subject of a hearing until a notice of hearing issues and the regulation on *ex parte* contacts does not apply before that point.

In any event, whether the relevant trigger is the publication of the NPRM or the notice of hearing, there is no evidence of any improper contacts here, because Movants have asserted only a contact that occurred *before* either of those dates.

In addition, once it comes into effect, Section 1316.51(c) does not operate to bar the contacts asserted here. Section 1316.51(c) contains two substantive provisions. First, the regulation requires all DEA officials to memorialize regulated *ex parte* contacts. This provision does not prohibit such contacts. Second, Section 1316.51(c) incorporates the restrictions of 5 U.S.C. § 554(d), by directing that "[t]he presiding officer and employees of the Administration shall comply with the requirements of 5 U.S.C. § 554(d) regarding ex parte communications and participation in any hearing." 21 C.F.R. §1316.51(c). Section 554(d), in turn, applies restrictions on ex parte contacts only to the employee presiding over a hearing and prohibits *that employee* from holding *ex parte* consultations "on a fact in issue." 5 U.S.C. § 554(d) ("[S]uch an employee may not . . . consult a person or party on a fact in issue . . . ."); *see also Butz v. Economou*, 438 U.S. 478, 514 (1978) (noting both requirements). Section 554(d) applies distinct restrictions on agency "employees" with respect to participating in the hearing. Accordingly, the prohibition in section 554(d) does not apply to the only asserted contact here, because that contact was not with "the employee who presides at the reception of evidence." 5 U.S.C. § 554(d). Moreover, even if Section 1316.51 effectively extended all the restrictions of Section 554(d) to all "employees of the

Administration," which it does not, it still would prohibit only *ex parte* communications "on a fact issue" related to this hearing. Here, the asserted communication did not concern any fact issue in this hearing, and thus could not have run afoul of the restriction imposed by Section 1316.51.

II. The Substance of Mr. Sabet's X.com Posts Was Largely in the Public Record.

Finally, it bears noting the degree to which Movants overstate the significance of Dr. Sabet's posts in an effort to suggest that the posts revealed some unusual degree of inside knowledge. The basic import of what Dr. Sabet discussed—that it was DOJ rather than DEA that was moving the rescheduling proposed rule forward—had already been disclosed. Moreover, numerous individuals in and around the cannabis industry were similarly posting information about the status of internal agency activity before the NPRM was published, many claiming to have sources inside agencies. Mr. Sabet's posts were not unique.

In the months leading to DOJ's announcement of its proposed rule to reschedule marijuana, the Attorney General's unique level of involvement was well known. The rescheduling rule was initiated not as a response to a petition for rulemaking but rather by an official Statement from President Biden to the Secretary of HHS and Attorney General Garland. *See* Schedules of Controlled Substances: Rescheduling of Marijuana, 89 FR 44,597, 44,600 (May 21, 2024) ("On October 6, 2022, President Biden requested that the Attorney General and the Secretary of HHS initiate the administrative process to review expeditiously how marijuana is scheduled under federal law.") (quotations and citation omitted). Because the White House was a key stakeholder in these proceedings, the Attorney General was uniquely involved in the process of preparing the NPRM, a fact that was widely reported months before the NPRM was issued.

Specifically, on March 9, 2024, *The Wall Street Journal* published an article titled "Biden Push to Ease Marijuana Restrictions Sparks Tensions." Among other things, the March 9th news

article stated that "Federal officials are at odds over President Biden's push to loosen restrictions on marijuana" and "some [HHS] counterparts within the Drug Enforcement Administration are resistant [to rescheduling], saying the drug's medicinal benefits remain unproven and that it has a high potential for abuse."[12] Thereafter, in April 2024 *The Wall Street Journal* reported that the Justice Department—Attorney General Garland—had submitted a proposal rescheduling marijuana "for White House review."[13] The April article again characterized rescheduling as "a source of contention between officials at the Drug Enforcement Administration and the Department of Health and Human Services." *Id.*

Moreover, on May 6, in response to Dr. Sabet's post on X.com, the website Marijuana Moment reported that it had received a statement from DOJ public affairs *a week before* stating that "the Attorney General circulated a proposal to reclassify marijuana from Schedule I to Schedule III."[14] In other words, a pro-Marijuana organization *itself* already knew prior to May 6 that it was the Attorney General who had circulated the proposed rule, *not* the DEA Administrator.

Additionally, Dr. Sabet was hardly the only individual posting on X.com regarding internal inter- and intra-agency activity prior to the NPRM's issue. For example, on April 17, 2024 pro-rescheduling advocate Anthony Varrell posted information regarding the status *and conclusion* of DOJ's OLC opinion[15]:

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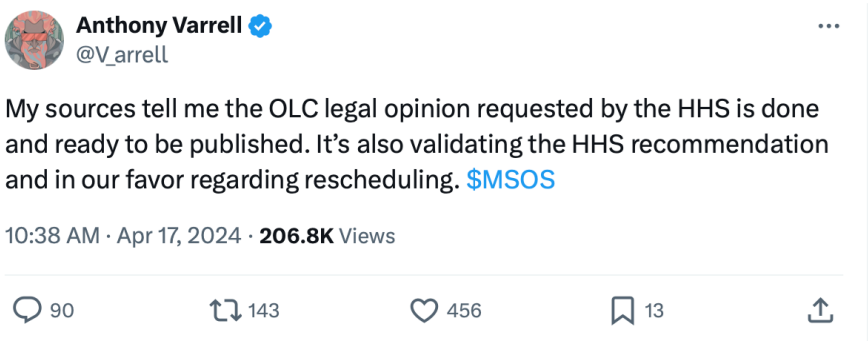
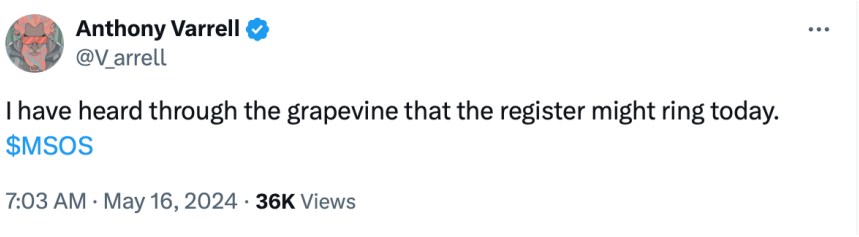
[12] Sadie Gurman, *Biden Push to Ease Marijuana Restrictions Sparks Tensions*, THE WALL STREET JOURNAL (Mar. 9, 2024), https://www.wsj.com/politics/policy/biden-push-to-ease-marijuana-restrictions-sparks-tensions-051759f7.
[13] Sadie Gurman and Liz Essley Whyte, *Biden Administration Aims to Reclassify Marijuana as Less Dangerous Drug*, THE WALL STREET JOURNAL (Apr. 30, 2024), https://www.wsj.com/politics/policy/biden-administration-wants-to-reclassify-marijuana-as-less-dangerous-drug-d6735b23?page=1.
[14] Ben Adlin, *DEA Administrator 'Did Not Sign Off' On Marijuana Rescheduling Order, Prohibitionist Group Says*, Marijuana Moment (May 6, 2024), https://www.marijuanamoment.net/dea-administrator-did-not-sign-off-on-marijuana-rescheduling-order-prohibitionist-group-says/
[15] Anthony Varrell (@V_arrell), X (Apr. 17, 2024, 12:38 PM), https://x.com/V_arrell/status/1780636940703817748/.

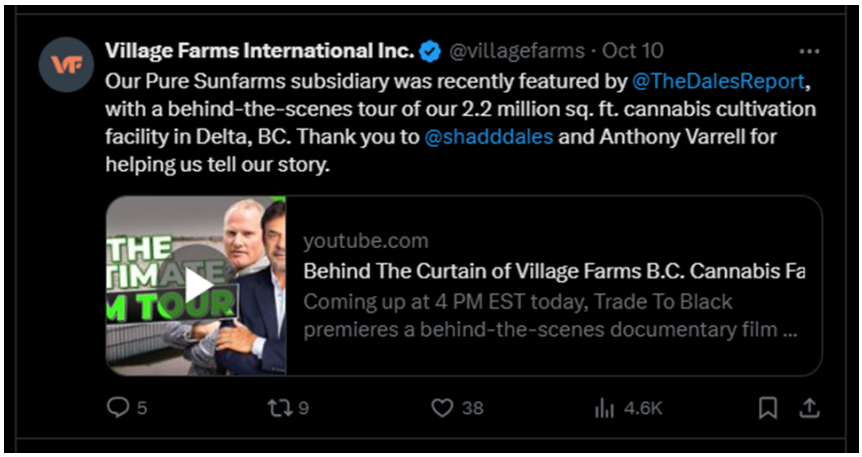


Further boasting his inside knowledge, Mr. Varrell previewed on the morning of May 16 that DOJ would publicly disclose its NPRM that day.[16]



Notably, Mr. Varrell appears to be an associate of Movant Village Farms International, Inc. For example, Mr. Varrell assisted Village Farms with producing a YouTube documentary regarding Village Farms' 2.2 million square foot cannabis cultivation facility in Canada. The Dales Report, *Behind The Curtain of Village Farms B.C. Cannabis Facility | Trade to Black on Location*, YouTube (Oct. 9, 2024) https://www.youtube.com/watch?v=mfkhDKkzoGE. Village Farms advertised its collaboration with Mr. Varrell on X.com:[17]

[16] Anthony Varrell (@V_arrell), X (May 16, 2024, 9:03 AM), https://x.com/V_arrell/status/1791092072377671778/.
[17] Village Farms International Inc. (@villagefarms), X (Oct. 10, 2024, 11:03 AM) https://x.com/villagefarms/status/1844393245696196679.



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These are just a few examples of the array of individuals, on both sides of the issue, who were following the rescheduling efforts and who obtained information on the status of the draft rule *before* the NPRM was published. SAM does not believe that any of this suggests improper contacts because, as explained above, the relevant prohibitions on *ex parte* communications had not yet been triggered. For the reasons explained above, no further inquiry and no discovery into supposed improper contacts is warranted. Yet if Movants are right that supplementation of the record is appropriate, under their own reasoning the supplementation order would need to extend well beyond SAM (and the DEA), also to encompass any pro-rescheduling entities that were posting allegedly non-public information. It is firmly SAM's position that none of that is necessary, it is not supported by law, and it is not in the public interest.

CONCLUSION

SAM respectfully submits that Movants' request should be denied.

November 25, 2024

Respectfully submitted.

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