UNITED STATES DEPARTMENT OF JUSTICE

Drug Enforcement Administration

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

ORDER DENYING INTERESTED PARTIES' PRELIMINARY OBJECTION AND MOTION FOR STAY

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

On March 16, 2022, the Interested Parties jointly filed their Opposed Preliminary Objection and Motion to Stay Rulemaking Pending Updated HHS Evaluation (Preliminary Objection). The Interested Parties seek to stay the current proceedings until DEA obtains updated scientific and medical evaluations from the Department of Health and Human Services (HHS), pursuant to 21 U.S.C. § 811(b). *See* Prelim. Obj. at 1 ("mov[ing] to stay proceedings pending DEA requesting and obtaining an updated HHS evaluation under 21 U.S.C. § 811(b)); *id*. at 8 ("Movants object to these proceedings, request the Court suspend the rulemaking, and remand them to the Administrator so she can request an updated evaluation from HHS…").

The Interested Parties' central argument is that, as a procedural matter, allowing DEA to proceed on HHS evaluations and recommendations drafted in 2012 (nearly ten years before DEA's Eight-Factor Analysis), violates the statutory "order of operations" (Prelim. Obj. at 3), and constitutes "an end-run around the reticulated dual-agency process required by the CSA" (*id*. at 5). *See also* Reply at 2 (proceedings should be stayed "so that DEA can comply with the procedures mandated by the CSA and the [Administrative Procedure Act] [APA]").[1] The Interested Parties claim that, given this procedural error, proceeding on the 2012 HHS evaluations and recommendations will prejudice them in how they present their case, will prejudice their ability to cross-examine the Government's witnesses, and might affect their access to underlying data. *See, e.g.*, Prelim. Obj. at 6; Reply at 8, 11-12.

The Government opposes. While the Government acknowledges that this tribunal "undoubtedly has broad authority to regulate the course of this hearing" and thus authority to issue a stay, it contends that this tribunal lacks jurisdiction to grant the relief requested—a remand to the Administrator with instructions to update the HHS evaluations and recommendations. Gov't Opp'n at 8-9.

In their Reply,[2] despite the express language in their Preliminary Objection, the Interested Parties shift their argument, claiming that "the Motion does not request the Tribunal to order anyone to do anything," offering the argument that, in the face of a stay, the Administrator "might choose to do nothing." Reply at 3. In terms of this tribunal's authority, the Interested Parties cite the following: (1) 21 U.S.C. § 875 (power of Attorney General to hold administrative hearings); (2) 28 C.F.R. pt. 0, subpart R, app. § 4(b) (authority of Administrative Law Judge to issue subpoenas); (3) 21 C.F.R. § 1316.41 (DEA regulations governing administrative hearings); (4) *id.* § 1316.52 (presiding officer duties); and (5) 5 U.S.C. § 556(c) (authority of presiding officer, under the APA, to regulate the course of the hearing). Reply at 2-3.

[1] The Interested Parties emphasize that this is a procedural issue. They note, however, that "[i]f the proceedings do proceed, Movants may later move for summary disposition. This procedural issue is a pure legal issue where there is no dispute on any material fact." Reply at 12 n.7.

[2] The Interested Parties filed Movants' Reply in Support of Preliminary Objection and Motion to Stay on April 6, 2022 (Reply). Interested Parties Hamilton Morris and Jason Wallach filed a separate Reply, but joined the Interested Parties' Reply on the instant issue. Accordingly, citations to the Interested Parties' Reply refers to the Reply filed by Interested Parties Mindstate and Tactogen, Panacea, and Amy Rising.

DISCUSSION

"A stay is not a matter of right, even if irreparable injury might otherwise result. It is instead an exercise of judicial discretion, and the propriety of its issue is dependent upon the circumstances of the particular case." *Nken v. Holder*, 556 U.S. 418, 433 (2009) (internal quotations and citations omitted); *see also United States v. Breyer*, 41 F.3d 884, 893 (3d Cir. 1994); *Fitzhugh v. DEA*, 813 F.2d 1248, 1252 (D.C. Cir. 1987); *PATCO v. Fed. Lab. Rels. Auth.*, 685 F.2d 547, 588 (D.C. Cir. 1982). "The party requesting a stay bears the burden of showing that the circumstances justify an exercise of that discretion." *Nken*, 556 U.S. at 433-34; *see also* 21 C.F.R. § 1316.56 (as the parties seeking relief, the Interested Parties have the burden of proof).

The Interested Parties fail to bear their burden of proving that, under the particular circumstances of this case, a stay is warranted. To begin, the Interested Parties do not articulate a legal mechanism by which this tribunal can order the remedy they undeniably seek: a "remand" to the Administrator in the rulemaking context, with instructions for the Administrator to obtain updated HHS evaluations and recommendations.[3] *See* Prelim. Obj. at 1, 8. The citations relied upon by the Interested Parties (Reply at 2-3) simply set forth this tribunal's general authority to regulate administrative hearings; none of those provisions support the remedy they seek.

Even if there were a mechanism, a stay would not be warranted in these circumstances. The Interested Parties do not demonstrate any prejudice. They argue, for example, that the procedural foul "infects these proceedings with error," including "missing evidence required by statute that makes for a statutorily incomplete hearing." Reply at 8. Moreover, they contend, "Movants are statutorily entitled to use and cross-examine a *current* recommendation," and the

[3] In their Reply, the Interested Parties' claim that "the Motion does not request the Tribunal order anyone to do anything." Reply at 3. This position cannot be reconciled with the express language in their Preliminary Objection or the substantive argument contained in both the Preliminary Objection and Reply, to wit, that it is improper to proceed without updated HHS evaluations and recommendations. Moreover, the notion that this tribunal could simply stay the order and the Administrator could obtain updated HHS evaluations and recommendations or simply "choose to do nothing" (*id*.) is untethered from any legal citation or legal mechanism. Nor do the Interested Parties provide any plan for how they would compel or convince DEA or HHS to update the HHS evaluations and recommendations. Indeed, granting a stay in this matter without a clear legal mechanism to compel action by the Administrator, and in the face of the Government's opposition, raises the possibility of an extended delay, without a clear purpose or resolution. This would run counter to the Interested Parties' reliance on APA § 555(b) (Reply at 5-8), which requires this tribunal to act, "within a reasonable time . . . to conclude a matter presented to it." 5 U.S.C. § 555(b).

age of the HHS evaluations and recommendations will affect "how Movant's will present and argue their case." *Id.* at 11-12. They also argue that the "prejudice caused by DEA's delay is manifest" because some data underlying the HHS evaluations and recommendations may no longer exist. Prelim. Obj. at 6. But these are all issues that can be explored at a merits hearing, at which the Interested Parties will have an opportunity to challenge the sufficiency of the Government's evidence through cross-examination and presentation of their own expert witnesses and documentary evidence. The Interested Parties also offer broader, policy-based arguments for prejudice, *i.e.*, that proceeding on the 2012 HHS evaluations and recommendations will undermine the "confidence that the agency conducted itself in a fair and impartial manner." Reply at 14. But this too can be addressed in a fair and impartial merits hearing, in which the Interested Parties can put the Government to its proof.

For the foregoing reasons, the Interested Parties' Preliminary Objection and Motion for a Stay is herein **DENIED.**

Dated: April 19, 2022

TERESA WALLBAUM
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Date: 2022.04.19 14:43:42 -04'00'

TERESA A. WALLBAUM
Administrative Law Judge

CERTIFICATE OF SERVICE

This is to certify that the undersigned, on April 19, 2022, caused a copy of the foregoing to be delivered to the following recipients:

(1) John E. Beerbower, Esq., Counsel for the Government, via email at John.E.Beerbower@dea.gov and to the DEA Government Mailbox at dea.registration.litigation@dea.gov;
(2) David Heldreth, CEO of Panacea Plant Sciences, via email at davidh@panaceaplantsciences.net;
(3) John T. Hunter, Esq., Counsel for Jason Wallach and Hamilton Morris, via email at john@hljdefense.com;
(4) Matt Baggott, Tactogen Inc., via email at matt@tactogen.com;
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Bella Mapeso
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