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 MOTIONS FOR SUMMARY DISPOSITION

This is a scheduling case under 21 U.S.C.§ 811(a), in which Panacea Plant Sciences (Panacea), Hamilton Morris and Jason Wallach, Kykeon Biotechnologies Inc. (Mindstate) and Tactogen Inc. (Tactogen) (collectively the Interested Parties) have requested a hearing challenging the Drug Enforcement Administration's (DEA) decision to schedule five hallucinogenic substances. Mindstate and Tactogen and Panacea move for summary disposition on the grounds raised in the Interested Parties' unsuccessful motion requesting a stay of these proceedings and based on new arguments.[1] The Government has opposed these motions. For the reasons set forth in detail below, both motions for summary disposition are **DENIED**.

BACKGROUND AND PROCEDURAL HISTORY

Under 21 U.S.C. § 811(a), the Attorney General may make a rule adding a drug or other substance to one of the five schedules of the Controlled Substances Act (CSA) if "he finds that such drug or other substance has a potential for abuse, and makes with respect to such drug or other substance the findings prescribed by [21 U.S.C. § 812(b)] for the schedule in which such drug is to be placed." Rulemaking proceedings "may be initiated by the Attorney General (1) on

[1] To avoid confusion, the phrase "Interested Parties" will be used to refer both to the parties who filed the Opposed Preliminary Objection and Motion to Stay Rulemaking Pending Updated HHS Evaluation (joined by all parties) and the motions for summary disposition (Mindstate, Tactogen, and Panacea). If successful, the motions for summary disposition would dismiss the entire proceeding and thus provide relief to all of the Interested Parties. Therefore, it is unnecessary to distinguish between those who joined the summary disposition motions and those who did not.

his own motion, (2) at the request of the Secretary [of Health and Human Services (HHS)],[2] or (3) on the petition of any interested party." 21 U.S.C. § 811(a).

The statute creates a system in which HHS and DEA work together to determine whether a substance should be controlled and, if so, which schedule is the most appropriate fit for the substance. The statute sets forth eight factors relevant in this analysis:

> (1) [The drug or other substance's] actual or relative potential for abuse.
> (2) Scientific evidence of its pharmacological effect, if known.
> (3) The state of current scientific knowledge regarding the drug or other substance.
> (4) Its history and current pattern of abuse.
> (5) The scope, duration, and significance of abuse.
> (6) What, if any, risk there is to public health.
> (7) Its psychic or physiological dependence liability.
> (8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

Id. § 811(c).

After gathering the necessary data, but prior to initiating proceedings, the Attorney General must request "a scientific and medical evaluation" and "recommendations, as to whether such drug or other substance should be controlled" from the Secretary of HHS. *Id.* § 811(b). The Secretary must "consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection (c) and any scientific or medical considerations involved in paragraphs (1), (4), and (5) of such subsection" when making the evaluation and recommendation. *Id.* The Secretary must also recommend the appropriate schedule, if any, in which the drug or substance should be placed. *Id.* The Secretary's recommendations regarding scientific and medical matters are "binding on the Attorney General[.]" *Id.* Moreover, "if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance." *Id*. In other words, "[t]he Attorney General cannot control a substance if the Secretary disagrees." *Gonzales v. Oregon*, 546 U.S. 243, 265 (2006) (first citing 21 U.S.C. § 811(b); and then citing Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91-1444, 91st Cong., 2nd Sess. (1970) reprinted in 1970 U.S.C.C.A.N. 4566, 4600 (§ 811(b) "is not intended to authorize the Attorney General to undertake or support medical and scientific research [for the purpose of scheduling], which is within the competence of [HHS]…")).

[2] Prior to 1980, HHS was known as the Department of Health, Education, and Welfare.

If, after reviewing the "facts and all other relevant data[,]" the Attorney General determines that "substantial evidence of potential for abuse" warrants control "he shall initiate proceedings for control…under subsection (a) of this section." *Id.* The Attorney General may only make a rule placing a drug or other substance in a schedule after the rule is "made on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by" the Administrative Procedure Act (APA). *Id.* § 811(a). The Attorney General must consider the eight factors in § 811(c) to make the findings required under 21 U.S.C. §§ 811(a) and 812(b). *Id.* § 811(c).

On January 14, 2022, DEA published a Notice of Proposed Rulemaking (NPRM), 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 CSA. *Id.*

The NPRM indicates that DEA gathered the necessary data on the five tryptamines pursuant to 21 U.S.C. § 811(b) and requested scientific and medical evaluations and scheduling recommendations for the five tryptamines from the former Assistant Secretary of HHS on December 19, 2008. *Id.* at 2378. On March 29, 2012, HHS provided its evaluation and scheduling recommendation for 5-MeO-AMT, titled "Basis for the Recommendation to Control 5-Methoxy-alphamethyltryptamine (5-MeO-AMT) and its Salts in Schedule I of the Controlled Substances Act (CSA)." *Id.* Additionally, on May 17, 2012, HHS sent the evaluations and scheduling recommendations to DEA for 4-OH-DiPT, 5-MeO-MiPT, and 5-MeO-DET, and they were each respectively titled: "Basis for the Recommendation to Control 4-Hydroxy-N,N-diisopropyltryptamine (4-OH-DIPT) and its Salts in Schedule I of the Controlled Substances Act (CSA);" "Basis for the Recommendation to Control N-Isopropyl-5-Methoxy-N-Methyltryptamine (5-MeO-MIPT) and its Salts in Schedule I of the Controlled Substances Act (CSA);" and "Basis for the Recommendation to Control N,N-Diethyl-5-methoxytryptamine (5-MeO-DET) and its Salts in Schedule I of the Controlled Substances Act (CSA)." *Id.* Lastly, on August 14, 2012, HHS sent an evaluation and scheduling recommendation to DEA for DiPT, titled "Basis for the Recommendation to Control N,N-Diisopropyltryptamine (DIPT) and its Salts in Schedule I of the

Controlled Substances Act (CSA)." *Id.* After considering the eight factors and findings related to each of the tryptamine's potential for abuse, legitimate medical use, and dependence liability, HHS recommended that each tryptamine be placed in schedule I of the CSA under 21 U.S.C. § 812(b). *Id.*

Next, DEA considered the HHS scientific and medical evaluations and scheduling recommendations and "all other relevant data," *see* 21 U.S.C. § 811(b), and completed its own eight-factor analysis pursuant to 21 U.S.C. § 811(c). NPRM, 87 Fed. Reg. at 2378. DEA's eight-factor analysis is dated as August 2021 and titled "Schedule 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) into schedule I" (DEA's Eight-Factor Analysis). In conducting its analysis, DEA relied not only upon the 2012 HHS evaluations and scheduling recommendations, but also upon "all other relevant data," (NPRM, 87 Fed. Reg. at 2378) and ninety-three "References"—listed in DEA's Eight-Factor Analysis—which included scientific studies and publications that post-dated the 2012 HHS evaluations and recommendations. *See* DEA's Eight-Factor Analysis.[3] The NPRM noted two areas in which DEA had updated the data. First, DEA "confirmed with HHS" that two statements in their 2012 evaluations were "still applicable": none of the substances are approved drug products by the Food and Drug Administration (FDA) and HHS was still "unaware of any country in which their use is legal." NPRM, 87 Fed. Reg. at 2378; *see also* DEA Eight-Factor Analysis at 4-5 (DEA confirmed this information in June 2020). Second, for Factor Five (the scope, duration, and significance of abuse), DEA queried the National Forensic Laboratory Information System (NFLIS) data on August 17, 2021. NPRM, 87 Fed. Reg. at 2380 & n.4.

Based on its analysis, including the HHS evaluations and recommendations, DEA issued the NPRM proposing that each of the five tryptamines be placed in schedule I. *Id.* The NPRM summarizes HHS and DEA's analysis of the eight factors for each tryptamine and determination that each be placed in schedule I. *Id.* at 2378-81. Relying on the HHS scientific and medical evaluations and all other data, DEA concluded that all five tryptamines have a high potential for

[3] As the NPRM notes, the supporting documents, including DEA's August 2021 Eight-Factor Analysis, were published at https://regulations.gov, under docket number DEA-623. In an Order issued on May 6, 2022, this tribunal took official notice of these documents.

abuse (Factor One), have neurochemical effects on the serotonergic system in the central nervous system (Factor Two), share structural similarities with schedule I tryptamine hallucinogens (Factor Three), have been encountered by law enforcement entities in the U.S. and have no legitimate medical use (Factor Four), are available, trafficked, and abused in the U.S. (Factor Five), pose a risk to public health due to their hallucinogenic properties that usually occur quickly (Factor Six), may lead to psychological dependence (Factor Seven), and are not immediate precursors of any substances already controlled under the CSA (Factor Eight). *Id.*

The NPRM concludes with DEA's decision that the five tryptamines be placed in schedule I, pursuant to 21 U.S.C. § 812(b)(1). *Id.* at 2381. DEA considered the HHS evaluations and recommendations and all other available data and concluded that the five tryptamines each: (1) have high potential for abuse; (2) have no accepted medical use in the U.S.; and (3) lack accepted safety for use under medical supervision. *Id.*

On March 16, 2022, the Interested Parties jointly filed their Opposed Preliminary Objection and Motion to Stay Rulemaking Pending Updated HHS Evaluation (Preliminary Objection), seeking to stay the proceedings until DEA requested and received updated scientific and medical evaluations from HHS.[4] On March 30, 2022, the Government filed its Opposition to the Opposed Preliminary Objection and Motion to Stay Rulemaking (Government's Opposition), opposing the Interested Parties' Preliminary Objection and requesting that these proceedings continue. On April 6, 2022, Interested Parties Panacea, Mindstate, and Tactogen filed their Reply in Support of Preliminary Objection and Motion to Stay (Stay Reply). That same day, Interested Parties Hamilton Morris and Jason Wallach jointly filed their Reply in Support of Preliminary Objection and Motion to Stay (Morris & Wallach Stay Reply), where they joined and adopted Interested Parties Panacea, Mindstate, and Tactogen's Reply and put forth an additional argument in support of the Preliminary Objection. [5] In the Stay Reply, the Interested Parties indicated that, if the stay

[4] Amy Rising also requested a hearing and was included as an Interested Party in early pleadings. On May 6, 2022, however, this tribunal granted the Government's motion to dismiss Ms. Rising as a party for her failure to establish that she met the regulatory definition of "interested person." Thus, while Ms. Rising's name appears in the early pleadings and in the Order Denying Interested Parties Preliminary Objection and Motion for Stay, she is no longer a party in this case and her name is omitted when summarizing the procedural history.

[5] Interested Parties Hamilton Morris and Jason Wallach filed a separate stay reply arguing that the Administrator's action of initiating scheduling proceedings approximately ten years after receiving the HHS evaluations "[i]nvites an [u]nconstitutional [i]nterpretation of the [s]tatute[.]" Morris &

were denied, they would lodge the same objection as a substantive motion to summarily dismiss the proceedings. Stay Reply at 12 n.7. This tribunal denied that stay request on April 19, 2022 and, in a separate Briefing Order, set a deadline of April 28, 2022 for the summary disposition motion. Pursuant to that Order, on April 22, 2022, Panacea filed its Motion for Summary Disposition (Panacea's Summary Disposition Motion), in which it adopted the arguments raised in the Preliminary Objection and Stay Reply and raised new arguments. Panacea Summ. Disp. Mot. at 1. On April 28, 2022, Mindstate and Tactogen filed their Motion for Summary Adjudication (Summary Adjudication Motion), in which it also adopted the arguments set forth in the Preliminary Objection and Stay Reply with some expansion. Summ. Adjud. Mot. at 1. No other party filed any summary disposition motion or joined one of the existing summary disposition motions. On May 9, 2022, Mindstate and Tactogen filed a Revised Supplement to Motion for Summary Disposition (Revised Supplement),[6] and the Government filed its Consolidated Opposition to the Movant's Motions for Summary Disposition.

Wallach Stay Reply at 1. Morris and Wallach did not re-file this pleading as a substantive motion for summary disposition. In any event, as Morris and Wallach acknowledge, this constitutional issue "is beyond the scope of this tribunal to determine," (*id*.), as administrative agencies have "no authority to entertain a facial constitutional challenge to the validity of a law," *Jones Bros., Inc. v. Sec'y of Lab.*, 898 F.3d 669, 673 (6th Cir. 2018).

[6] Mindstate and Tactogen originally filed its Supplement to Motion for Summary Disposition on Sunday, May 8, 2022, which under the rules of this tribunal means the pleading was filed on May 9, 2022, the same day the Government's response to the summary disposition motions was due. This tribunal rejected Mindstate and Tactogen's motion because it had an incorrect service date and did not allege good cause for why this tribunal should accept a supplement well past the April 28, 2022 filing deadline. Mindstate and Tactogen filed their Revised Supplement to Motion for Summary Disposition on May 9, with a correct certificate of service, and noting that Interested Parties Wallach and Morris "have indicated they will adopt Mindstate and Tactogen's Motion." Revised Suppl. at 1, 3 n.2. Mindstate and Tactogen's alleged "good cause" was that "the deadline for filing a motion for summary disposition was April 28, before the government's May 2 disclosure" and "upon learning of the disclosure, Mindstate and Tactogen worked diligently to prepare and file this supplement as soon as possible in light of that disclosure and competing schedules of counsel." *Id*. at 1. From this proffer of good cause, it is still unclear why Mindstate and Tactogen required six days to file a three-page pleading that primarily revisits arguments made in other pleadings. Even if I were to accept this as good cause, it would not change the outcome of this Order. *See infra* at notes 13, 16.

DISCUSSION

A. Summary Disposition Standard

"[A]n agency may ordinarily dispense with a hearing when no genuine dispute exists." *Veg-Mix, Inc. v. U.S. Dep't of Agric.*, 832 F.2d 601, 607 (D.C. Cir. 1987). Indeed, "[c]ommon sense suggests the futility of hearings where there is no factual dispute of substance." *Id.*; *see also Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 621 (1973); *Puerto Rico Aqueduct & Sewer Auth. v. EPA*, 35 F.3d 600, 606 (1st Cir. 1994); *NLRB v. Int'l Ass'n of Bridge, Structural & Ornamental Ironworkers, Local 433*, 549 F.2d 634, 639 (9th Cir. 1977); *Citizens for Allegan Cnty., Inc. v. Fed. Power Comm'n*, 414 F.2d 1125, 1128-29 (D.C. Cir. 1969). Moreover, under DEA precedent, "it is well-settled that when no question of material fact is involved, a plenary, adversary administrative proceeding involving evidence and cross-examination of witnesses is not obligatory.'' *Michael Jones, M.D.*, 86 Fed. Reg. 20728, 20729 (2021) (quoting *Michael G. Dolin, M.D.*, 65 Fed. Reg. 5661, 5662 (2000)). This precedent is based on the principle that "Congress did not intend administrative agencies to perform meaningless tasks." *Id.* (quoting *Sandra J.S. Tyner, M.D.*, 63 Fed. Reg. 56223, 56223 (1998)); *see also Richard Jay Blackburn*, *D.O.*, 82 Fed. Reg. 18669, 18672 (2017).

Thus, "[t]he central inquiry when deciding a motion for summary disposition is whether there is 'a genuine issue for trial.'" *Jones*, 86 Fed. Reg. at 20729 (quoting *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 249 (1986)). The moving party bears the burden of proving there are no material issues of fact and judgment must be issued as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-25 (1986); *see also Jones*, 86 Fed. Reg. at 20729 ("party moving for summary disposition must show, with materials of appropriate evidentiary quality, that every state of facts is excluded save that which entitles [it] to relief.") (quotations omitted). "To be considered material, a fact must be 'outcome determinative.'" *Jones*, 86 Fed. Reg. at 20729 (quoting *Int'l Shortstop, Inc. v. Rally's, Inc*., 939 F.2d 1257, 1264 (5th Cir. 1991)). "In other words, a material fact is a fact that has the potential to affect the outcome of the case." *Id*. "An issue is genuine if the evidence resolving the issue is sufficient to support a ruling in favor of the party opposing summary judgment. An issue must be 'real and substantial' to be considered genuine." *Id.* (citation and quotations omitted).

Once the moving party meets its burden of proof, the burden shifts to the non-moving party to identify the genuine issues of material fact. *Celotex*, 477 U.S. at 323-25; *see also Liberty Lobby*,

477 U.S. at 248-49. To meet its burden, the non-moving party, to survive the motion for summary disposition, must demonstrate specific, material facts that give rise to a genuine issue of fact. *Celotex*, 477 U.S. at 324. Under this standard, "[t]he mere existence of a scintilla of evidence" in favor of the non-movant's position is insufficient to withstand the summary judgment motion. *Liberty Lobby*, 477 U.S. at 252. "Likewise, conclusory allegations or denials, without more, are insufficient to preclude granting the summary judgment motion." *Tom v. Hosp. Ventures LLC*, 980 F.3d 1027, 1037 (4th Cir. 2020).

Whether a party is entitled to judgment "as a matter of law" involves applying a standard that "mirrors the standard for a directed verdict under Federal Rule of Civil Procedure 50(a), which is that the trial judge must direct a verdict if, under the governing law, there can be but one reasonable conclusion as to the verdict." *Liberty Lobby*, 477 U.S. at 250. Thus, a "party is entitled to a judgment as a matter of law because the nonmoving party has failed to make a sufficient showing on an essential element of her case with respect to which she has the burden of proof." *Celotex*, 477 U.S. at 323 (quotations omitted).

B. Mindstate and Tactogen's Summary Adjudication Motion

1. Genuine Issues of Material Fact

There is no dispute that the written HHS evaluations and recommendations were issued in 2012. In its Opposition to the Preliminary Objection, however, the Government claimed that DEA "reaffirmed its evaluations" prior to the Administrator initiating the scheduling proceedings. Gov't Opp'n at 10 (citing the NPRM, 87 Fed. Reg. at 2378). The NPRM indicates that HHS confirmed that the 2012 evaluations were still accurate with respect to two points: (1) there are no FDA approved uses for any of the five tryptamines; and (2) there were no legal uses in other countries. 87 Fed. Reg. at 2378. The NPRM does not expressly state that DEA confirmed with HHS that all other statements in the evaluations are still applicable. Moreover, DEA's Eight-Factor Analysis states specifically that DEA consulted HHS on the two points in June 2020. DEA Eight-Factor Analysis at 4-5. Thus, there is no genuine issue of fact as to the narrow point presented here: the HHS evaluations and recommendations were issued in 2012, and DEA updated two specific points (the domestic and foreign authorized medical use of the five tryptamines) in June 2020.[7]

[7] The NPRM also indicates that DEA updated information on Factor Five, which falls within DEA's purview. NPRM, 87 Fed. Reg. at 2380 & n.4. Given the Government's position on this matter, whether the NPRM updated the other factors may be an unresolved issue of fact, but given

2. Dismissal as a Matter of Law

The only issue presented, therefore, is whether the Interested Parties are entitled to summary disposition as a matter of law. To prevail, they must establish that there is only one outcome based on their legal arguments—the NPRM must be ruled invalid. The Interested Parties' rationale for *why* DEA's reliance on the ten-year old evaluations is a fatal defect, however, evolved between the Preliminary Objection and the Stay Reply and is refined again in the Summary Adjudication Motion. The Summary Adjudication Motion, and by incorporation the Preliminary Objection and Stay Reply, is based on the theory that allowing DEA to proceed on HHS evaluations and recommendations drafted 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).

In their Preliminary Objection, the Interested Parties argue that this delay is fatal because the CSA requires DEA to have *current* HHS evaluations prior to initiating scheduling proceedings, a natural consequence (they argue) of the statutory scheme that "HHS makes binding determinations on all scientific and medical matters." Prelim. Obj. at 5 (first citing H.R. Rep. No. 91-1444, reprinted in 1970 U.S.C.C.A.N. at 4589; then citing *United States v. Spain*, 825 F.2d 1426, 1428 (10th Cir. 1987); and then citing *Gonzales v. Oregon*, 546 U.S. 243, 260 (2006)); *see also* Stay Reply at 9 ("On scientific and medical matters, HHS leads; its recommendations and conclusions are dispositive"). In their Stay Reply, the Interested Parties shifted their focus from a statutory interpretation of the CSA to the procedural requirements of the APA, arguing that the APA requires agencies to act within a "reasonable amount of time." Stay Reply at 5-8. In their Summary Adjudication Motion, Mindstate and Tactogen refine this argument as, essentially, absent a more current HHS evaluation and recommendation, the parties do not know if HHS still holds the same views regarding scheduling. Summ. Adjud. Mot. at 2. And here, again, Mindstate and Tactogen emphasize the language that "[t]he recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters." *Id.* at 3 (quoting 21 U.S.C. § 811(b)).

Thus, the Interested Parties' Preliminary Objection, Reply, and Summary Adjudication Motion argue that the NPRM violates the statutory requirements of the CSA and the delay violates

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this tribunal's analysis, the unresolved issue of fact would not alter the outcome. Therefore, that fact is not material to this Order. *See Jones*, 86 Fed. Reg. at 20729.

the APA. As the moving party, the Interested Parties bear the burden of justifying the relief they seek—summary dismissal. 21 C.F.R. § 1316.56. I find that the Interested Parties have not met their burden.

The Controlled Substances Act Claims

The Interested Parties advance two arguments that the NPRM violates § 811 such that dismissal of the NPRM is required as a matter of law. Those claims are grounded in: (1) the language in § 811(c) that two of the statutory factors require "current" information; and (2) the statutory language establishing HHS's role in the process, including the provision in § 811(b) that HHS's evaluation is "binding" on the Attorney General.

First, according to the Interested Parties, the NPRM's reliance on HHS evaluations and recommendations from 2012 violates the "statutory order of operations," (Prelim. Obj. at 3), and is "an end-run around the reticulated dual-agency process required by the CSA," (*id.* at 3), under which DEA and HHS "act in tandem," (Stay Reply at 4), and "act as partners, like a marriage," (*id*. at 9-10). As part of that statutory marriage, the Interested Parties argue, the statute requires that HHS evaluations and recommendations on all scientific and medical matters must be "current." Prelim. Obj. at 4-5; Stay Reply at 1-3; Summ. Adjud. Mot. at 1.

The Interested Parties repeatedly frame this as a statutory requirement that an *entire* evaluation and recommendation be "current." Prelim. Obj. at 3, 4; Stay Reply at 1-2, 4, 9, 11, 13; Summ. Adjud. Mot. at 2-4. But, in fact, the statute nowhere contains the word "current" when discussing the HHS evaluation and recommendation.[8] *See* 21 U.S.C. § 811(b). The only other

[8] The Interested Parties cite the previous scheduling proceeding of methoxetamine (MXE) where DEA sent additional data to HHS after requesting an evaluation in support of their argument that DEA should have done so in this matter. Prelim. Obj. at 5 (citing *Schedules of Controlled Substances: Placement of Methoxetamine (MXE) in Schedule I*, 86 Fed. Reg. 69187, 69188 (2021). In that case, prior to initiating scheduling proceedings, DEA provided HHS with "additional scientific and updated information on [MXE]" in April 2017. *Placement of Methoxetamine (MXE) in Schedule I*, 86 Fed. Reg. at 69188. DEA had previously requested an evaluation from HHS in December 2014, but HHS did not complete it until after DEA sent the additional information. *Id*. The MXE scheduling proceedings are distinguishable from these proceedings for two reasons. First, DEA did not seek an updated evaluation after HHS had already completed one; DEA provided additional information to HHS prior to HHS completing its evaluation. Second, the additional information that DEA provided to HHS in April 2017 included that the United Nations Convention on Psychotropic Substances had scheduled MXE. *Id*. at 69188. Accordingly, DEA was required to control MXE, but, here, no such statutory obligation exists. *See* 21 U.S.C. § 811(d).

temporal language in § 811(b) is imposed on HHS, as the statute requires that an HHS evaluation and recommendation be submitted to the Attorney General, in writing, "within a reasonable time." *Id.* No such requirement is imposed on the Attorney General. In fact, the word "current" appears only twice, in § 811(c), which sets forth the eight factors to be considered by the Attorney General. Specifically, "current" appears in Factor Three, which requires "current scientific knowledge" and Factor Four, which requires the "current pattern of abuse." 21 U.S.C. § 811(c)(3)-(4). Of those two factors, only Factor Three falls within HHS's bailiwick; Factor Four involves information obtained directly by DEA. *See* 21 U.S.C. § 811(b). The word "current" is noticeably absent from the other six factors.[9]

"[W]hen 'Congress includes particular language in one section of a statute but omits it in another'—let alone in the very next provision—this Court 'presume[s]' that Congress intended a difference in meaning." *Loughrin v. United States*, 573 U.S. 351, 358 (2014) (quoting *Russello v. United States*, 464 U.S. 16, 23 (1983)). Accordingly, the plain language of § 811 requires only that *one factor* of the HHS evaluation and recommendation reflect current information, not the entire evaluation and recommendation. As a result, the Interested Parties' corollary argument—that failure to obtain a more recent evaluation and recommendation is a procedural foul so serious that it requires summary dismissal of these proceedings—must fail.[10]

The Interested Parties also argue that DEA's reliance on more recent data in its own 2021 Eight-Factor Analysis violates the statutory procedure. Prelim. Obj. at 4-5; Summ. Adjud. Mot. at 3. Again, they offer no compelling argument for why the age of the HHS evaluations and

[9] In their Summary Adjudication Motion, the Interested Parties reframe this argument slightly and claim that a more current evaluation is necessary because HHS "*could* decide that evidence or policy could veto scheduling—which could be the case here where one or more of the substances are actively involved in the research and development of groundbreaking medicine and the evidence of abuse is almost non-existent." Summ. Adjud. Mot. at 2 (emphasis original). This, of course, is a hypothetical, and it is particularly unpersuasive given that DEA consulted with HHS about the continued validity of their evaluation on the two points noted above. Moreover, whether the Interested Parties' research is developed enough to merit consideration is an issue of fact not yet determined.

[10] The Interested Parties also emphasize that a different Agency administration requested the HHS evaluations than the current administration which initiated these proceedings. Prelim. Obj. at 4; Summ. Adjud. Mot. at 2. Their argument that the delay "means the agency determined that the facts and other relevant data as presented did not constitute substantial evidence of a potential for abuse to warrant control," (Summ. Adjud. Mot. at 2) is, at a minimum, a genuine issue of material fact.

recommendations necessitate dismissal as a matter of law. In their Summary Adjudication Motion, the Interested Parties claim that, by relying on a ten-year old HHS recommendation, "DEA bypasses this procedural safeguard that carefully balances power in both agencies." Summ. Adjud. Mot. at 2. But that conclusion does not automatically flow from the age of the evaluations and recommendations. DEA requested and received HHS's evaluations and recommendations, as required by statute. DEA also consulted with HHS on the current validity of the information on current domestic and foreign authorized medical use. NPRM, 87 Fed. Reg. at 2378; DEA Eight-Factor Analysis at 4-5. In so doing, DEA complied with the statutory framework. Moreover, the information post-dating the HHS evaluations is not inconsistent with HHS's findings, but only bolsters the evaluations. Gov't Opp'n at 12. Thus, this is not a case in which DEA conducted its "own research [because it] was dissatisfied with [the] scientific and medical evaluation." Summ. Adjud. Mot. at 3 (quoting Robert L. Bogomolny et al., A HANDBOOK OF THE 1970 FEDERAL DRUG ACT 72 (1975)). Nor is it a case in which DEA is attempting to schedule the substances against the 2012 recommendation of HHS. 21 U.S.C. § 811(b). This cuts against the argument that DEA has usurped HHS' role.[11]

Second, the Interested Parties argue that using the 2012 HHS evaluations violates the CSA because "[t]he recommendations of the Secretary to the Attorney General *shall be binding* on the Attorney General as to such scientific and medical matters." Summ. Adjud. Mot. at 3 (emphasis added in Mot.) (quoting 21 U.S.C. § 811(b)); *see also id*. at 4 (again quoting the language in

[11] The Interested Parties' reliance on *NAACP v. USPS*, 496 F. Supp.3d 1, 7 (D.D.C. 2020) and *Touby v. United States*, 500 U.S. 160, 170-71 (1991), does not assist their argument. *See* Summ. Adjud. Mot. at 3. In *NAACP*, the statutory framework required the Postal Service to seek an advisory opinion from the Postal Regulatory Commission and to provide an opportunity for notice and comment before implementing changes that have a nationwide impact on mail delivery. *NAACP*, 496 F. Supp.3d at 7-8. Since nothing in § 811(a) requires the entire evaluation and recommendation be "current," *see supra* pp. 10-11, DEA followed the statutory framework by obtaining the 2012 HHS evaluation and recommendation. In *Touby*, the Supreme Court held, in a criminal case, that § 811(h)—which governs temporary scheduling and does not require HHS input—was constitutional despite the Congressional delegation to the Attorney General to schedule a substance that subsequently formed the basis for criminal prosecution. *Touby*, 500 U.S. at 163, 166-67. The language in Justice Marshall's concurrence, which the Interested Parties quote, stands for Justice Marshall's opinion that there are Due Process limits on the extent to which the Executive Branch could allocate power within a single Branch, specifically, the extent to which "prosecutorial and other functions may be combined in a single actor." *Id.* at 170-71 (Marshall, J., concurring).

§ 811(b)); Prelim Obj. at 5.[12] The Interested Parties fail to establish that summary disposition is required as a matter of law in part because they do not fully address the Administrator's decision in *Schedules of Controlled Substances: Placement of Carisoprodol into Schedule IV*, 76 Fed. Reg. 77330, 77333-36 (2011) (*Carisoprodol Scheduling Decision*), in which the Administrator addressed the very language relied upon by the Interested Parties, all in the context of whether an interested party could challenge the HHS evaluation at the merits hearing, and found 21 U.S.C. § 811 contains seemingly contrary provisions. The Interested Parties do not address how the Administrator's prior interpretation of the statute affects their statutory analysis in support of summary disposition.

To be sure, in their Summary Adjudication Motion, the Interested Parties acknowledge the *Carisoprodol Scheduling Decision*, but do so indirectly and with little analysis. Summ. Adjud. Mot. at 3-4. Specifically, the Interested Parties select one quote from the *Carisoprodol Scheduling Decision*, *i.e.*, that the HHS Secretary "is the *expert* as to the scientific and medical matters at issue in the scheduling decision." *Id*. at 4. (emphasis added in Mot.) (citing *Carisoprodol Scheduling Decision*, 76 Fed. Reg. at 77335). They then incorporate that quote (without clear attribution) in the following argument: "Most important, at the hearing they [the Interested Parties] cannot introduce or examine evidence from the 'expert' at the hearing that that (sic) 'shall be binding' on the Administrator." *Id.* (quoting 21 U.S.C. § 811(b)).[13] But those two sentences omit any reference

[12] In their Stay Reply, however, the Interested Parties concede that "[w]hile DEA is correct that it is "not bound by HHS's recommendation to schedule a drug or to place [a drug] in any particular schedule, . . . at a minimum, HHS findings may call into question whether DEA has met its burden of proof in the rulemaking." Stay Reply at 11. This appears to undercut the Interested Parties' initial argument.

[13] In their Revised Supplement, the Interested Parties again cite the *Carisoprodol Scheduling Decision*, as follows:

> Dr. Carbonaro therefore cannot offer expert testimony that adds to or is distinct from the HHS recommendations. The agency is bound to the HHS recommendation. *See also* 76 Fed. Reg. 77,334 (Dec. 12, 2011) ([Administrative Law Judge (ALJ)] noting "the plain language and legislative history … and federal case law indicate [that] Congress intended that the Secretary's scientific and medical fact-findings bind the [Agency] throughout the scheduling process."). Although agency precedent holds that these findings do not bind the agency throughout the proceeding, *see id*., the plain language forbids DEA from *sua sponte* supplementing its Eight Factor analysis with additional medical and scientific evidence.

to the Administrator's analysis of the statutory language upon which the Interested Parties now rely.

Moreover, the *Carisoprodol Scheduling Decision* considered the federal cases independently cited by the Interested Parties: *Gonzales*, 546 U.S. at 260 and *Spain*, 825 F.2d at 1428. Prelim. Obj. at 5. Importantly, when construing the very language the Interested Parties now repeatedly rely upon, the Administrator distinguished those two decisions. Certainly, as the Administrator acknowledged, *Gonzales* stands for the proposition that the CSA allocates authority so that "medical judgments" are left to HHS; however, the Administrator found that *Gonzales* cannot be interpreted to mean that HHS's medical judgments are final and immune from challenge in a scheduling context. *Carisoprodol Scheduling Decision*, 76 Fed. Reg. at 77334 (citing *Gonzales*, 546 U.S. at 260). As for *Spain*, the Administrator distinguished that case, because it "addressed the Attorney General's authority under 21 U.S.C. [§] 811(h), which authorizes the 'scheduling of a substance in schedule I on a temporary basis [when] necessary to avoid an imminent hazard to the public safety.'" *Id.* at 77334 n.5 (citing *Spain*, 825 F.2d at 1427). "Under this provision, the Attorney General is not required to obtain a scientific and medical evaluation from the Secretary before acting." *Id*. (citing *Spain*, 825 F.2d at 1428-29).[14]

Finally, the Interested Parties fail to address *Grinspoon v. DEA*, 828 F.2d 881, 897 (1st Cir. 1987) (cited approvingly by the Administrator, *Carisoprodol Scheduling Decision*, 76 Fed. Reg. at 77335), which rejected a challenge to the HHS evaluation and recommendation, holding that "[t]he CSA does not specify the steps to be taken by HHS; it simply requires the Administrator to request from the Secretary of HHS a scientific and medical evaluation." *See also id*. (flawed HHS evaluation did not "taint" the Administrator's decision, because it was not binding). Other courts have similarly held that a letter from HHS was sufficient so long as that letter stated the agency had considered the statutory factors and gave a recommendation. *United States v. Sullivan*, 967 F.2d 370, 373–74 (10th Cir. 1992) (although more detailed analysis "would have been preferable," letter was sufficient); *United States v. Lafoon*, 978 F.2d 1183, 1184 (10th Cir. 1992) (same); *United*

Revised Suppl. at 2 n.1. But, even if I were to consider this argument, it is unpersuasive because it fails to acknowledge that the Administrator rejected the ALJ's opinion.

[14] This tribunal further notes that the dicta in *Spain* is merely two lines: "The recommendations of the Secretary are binding on the Attorney General 'to such scientific and medical matters.' This 'binding' nature of the Secretary's recommendation makes the Secretary a partner in the delegation." *Spain*, 825 F.2d at 1428.

States v. Casey, 788 F. Supp. 725, 728 (S.D.N.Y. 1991) (letter from the Health Education and Welfare—the precursor agency to HHS—was sufficient given that it stated it had considered the statutory factors).[15] The Interested Parties fail to address why, if cursory and essentially *pro forma* HHS evaluations and recommendations are permissible, ten-year old HHS evaluations and recommendations fall short of the statutory requirement.

Because the Interested Parties fail to address, and distinguish, cases that run contrary to their interpretation of § 811, they have not met their burden of proving that summary disposition is the only available outcome here under the statutory framework of 21 U.S.C. § 811.

The Interested Parties' remaining arguments relate to factual disputes and the ultimate question of whether the HHS information is substantively outdated and whether its recommendation constitutes substantial evidence in favor of scheduling the five tryptamines. *See, e.g.*, Prelim. Obj. at 6; Stay Reply at 11; Summ. Adjud. Mot. at 4.[16] But those are issues properly explored at a merits hearing, at which the Government will have the burden of proof and at which the Interested Parties will be able to challenge the Government's proffered evidence on cross-examination and offer its own expert testimony, if they decide to do so. This does not, as the Interested Parties argue (Summ. Adjud. Mot. at 4), shift the burden of proof. Nor does it require the Interested Parties to prove a negative because the "expert evidence" is lacking and they cannot "speculate about what a current HHS evaluation might say about the data." Summ. Adjud. Mot. at 3-4. The Government has the burden of proof at a merits hearing.

The Administrative Procedures Act Claim

The Interested Parties also argue that the APA prohibits the Administrator from waiting ten years after receiving the HHS evaluations to initiate scheduling proceedings. Prelim. Obj. at 6. The Interested Parties cite 5 U.S.C. § 555(b), which requires that "within a reasonable time, each agency shall proceed to conclude a matter presented to it." Prelim. Obj. at 6; Stay Reply at

[15] Indeed, the Interested Parties appear to concede that the HHS evaluation could be a letter simply acknowledging consideration of the statutory factors. *See* Stay Reply at 13 (accepting, without disputing, the Government's statement that a letter from HHS could be sufficient if it stated "only that HHS had 'considered' the drugs at issue and paid specific attention to the statutorily enumerated factors").

[16] In their Revised Supplement, the Interested Parties also challenge whether Dr. Theresa Carbonaro can testify as an expert and supplement the HHS findings with her own research. Revised Suppl. at 2-3. Even if I were to consider this argument, it would not change the outcome here because this is an issue best addressed at the merits hearing.

6. The Interested Parties appear to argue both that DEA commenced rulemaking proceedings in this matter in December 2008 when DEA requested the HHS evaluations (Prelim. Obj. at 6) and that the "matter presented" to DEA is the 2012 HHS evaluations (Stay Reply at 6). Neither argument justifies summary disposition as a matter of law.

To begin, the Interested Parties (who, again, bear the burden here), offer no case or compelling argument for why APA § 555(b) applies to the deliberative period between DEA requesting an evaluation and recommendation from HHS or between HHS' written submission of its evaluation and recommendation and the Administrator's decision (as the Attorney General's delegate) that there is substantial evidence to warrant scheduling a substance. Section 811(a) envisions three avenues for scheduling a controlled substance: DEA initiates rulemaking proceedings, HHS requests that DEA initiate the proceedings, or a private party files a petition seeking to compel rulemaking. The instant case involves only the first scenario—DEA initiated the proceedings. It is the only relevant portion for purposes of the summary disposition motions.

Section 555(b) provides no support for the Interested Parties' argument that the 2012 HHS recommendation was the "matter presented" to DEA for consideration within a reasonable time. Section 555(b), titled "Ancillary matters," refers to a "person compelled to appear in person before an agency," and "an interested person." 5 U.S.C. § 555(b). But, when DEA initiates the process on its own accord, by definition there is no "interested person" until DEA decides to schedule a substance and proposes the scheduling in a notice of proposed rulemaking. *See* 21 C.F.R. § 1300.01(b) (defining "interested person" as "any person adversely affected or aggrieved by *any rule or proposed rule* issuable pursuant to … 21 U.S.C. [§] 811) (emphasis added).[17] Rather, when DEA requests an evaluation and recommendation from HHS, that period is an internal discretionary deliberative process, and the end of that process can be an internal, unpublished decision not to schedule a substance.[18] *Cf. Heckler v. Chaney*, 470 U.S. 821, 832 (1985) (in context of agency's refusal to take enforcement action, "recogniz[ing] that an agency's refusal to institute

[17] To be clear, this tribunal is addressing only the scenario before it and not the scenario in which a private party files a petition seeking to compel rulemaking.

[18] The Government makes a similar argument, relying upon an adverse inference from the holding in *In re American Rivers & Idaho Rivers United*, 372 F.3d 413 (D.C. Cir. 2004). *See* Gov't Opp'n at 14. The Interested Parties contest the Government's reading of that case. Stay Reply at 5-7. To be clear, in that decision, the court found that § 555(b) applies to an agency's failure to respond to a non-governmental petition for rulemaking which was allowed under the agency's own regulations. *In re Am. Rivers*, 372 F.3d at 418.

proceedings shares to some extent the characteristics of the decision of a prosecutor in the Executive Branch not to indict—a decision which has long been regarded as the special province of the Executive Branch.").[19]

Given the statutory scheme and posture of this case, the APA cases cited by the Interested Parties (Stay Reply at 7) are distinguishable and thus do not justify dismissing these proceedings. *See, e.g.*, *Cutler v. Hayes*, 818 F.2d 879, 895 & n.136 (D.C. Cir. 1987) (applying § 555(b) when the FDA, under a legislative directive to review over-the-counter (OTC) drugs after a statutory amendment, took affirmative action and, by regulation, created an OTC drug review panel); *Oil, Chem. & Atomic Workers Int'l Union v. Zegeer*, 768 F.2d 1480, 1481 (D.C. Cir. 1985) (applying § 555(b) to a non-governmental petition to compel the Mine Safety and Health Administration to reduce the permissible levels of radon daughters to which miners may be exposed); *Pub. Citizen Health Rsch. Grp. v. Comm'r, FDA*, 724 F. Supp. 1013, 1016, 1020 (D.D.C. 1989) (FDA came under a "duty to act" to issue tampon absorbency regulations after FDA's public acknowledgments of the risk of Toxic Shock Syndrome, a failed initial FDA regulation, and a petition from a citizen's group requesting a revised regulation).

The Interested Parties also argue that the APA prevents DEA from relying on the ten-year old HHS evaluations (Stay Reply at 5-8) because ten years "crosses far past the mandamus line for unreasonable delay." *Id.* at 5 (citing *In re Core Commc'ns, Inc.*, 531 F.3d 849, 850 (D.C. Cir. 2008); and then citing *In re United Mine Workers of Am. Int'l Union*, 190 F.3d 545, 547 (D.C. Cir. 1999)). The Interested Parties' mandamus argument is unpersuasive for two reasons. First, this is not a mandamus petition, and mandamus—an extraordinary equitable remedy—is

[19] For this reason, the Interested Party's conclusory, unsupported argument that DEA's *failure* to schedule the five tryptamines between 2012 and 2021 was itself a "final decision" *not* to schedule to substances (Prelim. Obj. at 7; Summ. Adjud. Mot. at 2) is without merit. The inference the Interested Parties seek to make is too attenuated, as there are any number of reasons why DEA may not have acted during that time frame. *Cf. John O. Dimowo, M.D.*, 85 Fed. Reg. 15800, 15810 n.M (2020) ("actions are distinct from [] inactions"); *Kwan Bo Jin, M.D.*, 77 Fed. Reg. 35021, 35025 (2012) ("[s]peculation is, of course, no substitute for evidence") (quotations omitted). Moreover, even in the face of a legislative mandate to act—which is *not* present here, "[a]n Agency has broad discretion to set its agenda and to first apply its limited resources to the regulatory tasks it deems most pressing." *Cutler v. Hayes*, 818 F.2d 879, 896 (D.C. Cir. 1987).

distinguishable because it requires a duty to act.[20] *See In re Am. Rivers & Idaho Rivers United*, 372 F.3d 413, 418 (D.C. Cir. 2004); *In re United Mine Workers*, 190 F.3d at 549. Here, the Interested Parties have identified no such duty when DEA, on its own accord, solicits an HHS evaluation and recommendation. To the contrary, in the context of a different argument, they appear to concede there is no duty to act, *i.e.*, they argue that, if this tribunal issued a stay, the Administrator "might choose to do nothing." Stay Reply at 3.

Second, the cases cited by the Interested Parties are all distinguishable because they identify a duty to act that finds no comparison in the CSA or the procedural history of this case. *See In re Core Commc'ns*, 531 F.3d at 850, 861-62 (six-year delay in responding to court's remand "to do nothing more than state the legal justification for its rules" warranted grant of mandamus); *In re Am. Rivers*, 372 F.3d at 418-19 (six-year delay in responding to a petition to engage in multi-agency consultation warranted mandamus because agency's regulations allowed for petitions for discretionary action); *In re United Mine Workers*, 190 F.3d at 546 (denying the writ for mandamus but retaining jurisdiction where the agency failed to issue a final rule eight years after issuing an NPRM).[21] In other words, none of these cases are relevant or helpful to the Interested Parties' argument.

Accordingly, the Interested Parties do not establish, as a matter of law, that the NPRM violates either the CSA or the APA.

C. Panacea's Summary Disposition Motion

In addition to adopting the arguments made in the Preliminary Objection and Stay Reply (addressed above), Panacea makes two new arguments. To begin, it asserts that, because of prior interactions between Panacea and DEA, "DEA apparently resurrected the scheduling/control process in response to Panacea Plant Sciences communications on the items and in response to the company's efforts to call attention to the agency's actions and urge transparency and policy change at the agency rather than due to an actual danger of these items." Panacea Summ. Disp. Mot. at 3;

[20] It is also well-established that DEA ALJs "lack the authority to exercise equitable powers." *Samson K. Orusa, M.D.*, 87 Fed. Reg. 2986, 3010 n. 42 (2022) (determining whether a registration is consistent with the public interest).

[21] The Interested Parties appear to cite *In re United Mine Workers*, 190 F.3d 545 (D.C. Cir. 1999), as a case where the court granted a writ of mandamus. Stay Reply at 5. It did not. *In re United Mine Workers of Am. Int'l Union*, 190 F.3d at 556. The case is also distinguishable from this matter because there was a statutorily imposed timetable for the agency to conclude rulemaking. *Id*. at 551-52.

see also id. at 5 (Agency has taken "direct responses to Panacea Plant Sciences communications, actions and business interests rather than due to public health or risk of items being looked at."). Those prior interactions involve Panacea: (1) notifying DEA that, on a prior agency action seeking notice and comment, the online comment function was not enabled; (2) issuing a press release that, in part, notified others of the inability to file online comments; (3) submitting a Freedom of Information Act (FOIA) request; and (4) communicating with DEA about a shipment of these substances to Canada and receiving a response that lacked "clarification on the status or any mention of a pending scheduling attempt" two weeks before publication of the NPRM. *Id*. at 1-2.

While some of the underlying facts might not be in dispute (*i.e.*, that Panacea filed a FOIA request), the inference that Panacea wishes to draw (DEA has proposed scheduling the five tryptamines as retaliation for Panacea's communications and actions) *is also a fact* Panacea wishes this tribunal to accept as undisputed and true. Panacea's submitted documents do not establish that fact; rather, at this time the claim is simply an allegation, which is insufficient to meet a movant's burden of proof for summary disposition. *Celotex*, 477 U.S. at 323.

Panacea also challenges DEA's Eight-Factor Analysis, including whether: (1) the identified deaths can properly be linked to the hallucinogens; (2) the analysis should have given more weight to its finding that there was no evidence of diversion by legitimate researchers; and (3) the analysis should have considered the benefits of 5-HT_{2A} agonism. Panacea Summ. Disp. Mot. at 3-4. Again, these are facts, and these facts go to whether there was substantial evidence supporting the Agency's proposal to schedule the tryptamines. Accordingly, summary disposition is not appropriate. *Celotex*, 477 U.S. at 323-25; *Jones*, 86 Fed. Reg. at 20729.

CONCLUSION

Therefore, upon consideration of Mindstate and Tactogen's Summary Adjudication Motion, I find that the Interested Parties do not establish that they are entitled to summary disposition as a matter of law. Upon consideration of Panacea's Summary Disposition Motion, I find that there are genuine issues of material fact that preclude summary disposition. Accordingly, both motions are herein **DENIED**.

Dated: May 11, 2022

TERESA WALLBAUM
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Date: 2022.05.11 08:25:37 -04'00'

TERESA A. WALLBAUM
Administrative Law Judge

CERTIFICATE OF SERVICE

This is to certify that the undersigned, on May 11, 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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(6) Graham Pechenik, Esq., Counsel for Tactogen Inc. and Kykeon Biotechnologies Inc., via email at graham@calyxlaw.com; and
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ANIAYAH BECKFORD
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Aniayah S. Beckford,
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