UNITED STATES DEPARTMENT OF JUSTICE

Drug Enforcement Administration

In the Matter of

Schedules of Controlled Substances: Placement of 2,5-dimethoxy-4iodoamphetamine (DOI) and 2,5dimethoxy-4-chloroamphetamine (DOC) in Schedule I Docket No. 24-24

ORDER GRANTING PANACEA PLANT SCIENCES' SECOND MOTION TO STAY PROCEEDINGS

On April 2, 2024, this tribunal issued an Order for Prehearing Statements ("OPHS") in the above-captioned matter, setting deadlines for the parties to file motions related to standing in these proceedings and to file prehearing statements, and setting a prehearing conference ("PHC") date for May 3, 2024 at 12:00 noon Eastern Time ("ET"). OPHS at 3-4.

On April 8, 2024, Petitioner Panacea Plant Sciences ("Panacea") filed Panacea Plant Sciences Motion for Injunction, Stay and to Compel ("Panacea First Motion to Stay"), requesting: (1) "the ALJ/judge to issue an injunction against the DEA to stop the rule-making due to errors/violations under the Administrative Procedure Act, Regulatory Flexibility Act and Tribunal Consultation Executive Orders;" (2) "a stay of the proceedings and halt to all Drug Enforcement Administration activity on rulemaking regarding DOI and DOC from the Tribunal/ALJ due to DEA lack of providing documents which have been ordered under a FOIA and which relate to this hearing as well as compelling the DEA to turnover the FOIA documents;" and (3) a stay based on "an impending challenge to the constitutionality of the DEA ALJ process." Panacea First Mot. to Stay at 1.

On April 10, 2024, the tribunal issued an Order Regarding Panacea Plant Sciences Motion for Injunction, Stay and to Compel ("Order Regarding Panacea First Motion to Stay"), ordering that Panacea's motion and any responses thereto be held in abeyance until after the prehearing conference and notifying Panacea that any motions to stay based on constitutional

challenges will not be considered unless notice is provided to the tribunal that Panacea has filed a case in federal district court. Order Regarding Panacea First Mot. to Stay at 1-2.

On Friday, April 12, 2024, the tribunal received from Panacea a copy of a complaint filed by Panacea in the U.S. District Court for the Western District of Washington ("the District Court"). The copy of the complaint was also served on the Government and other Petitioners in this case. The complaint was not accompanied by any motion by Panacea seeking a stay or any other relief regarding the instant administrative proceedings.

On Monday, April 15, 2024, the tribunal issued an Order Regarding Copy of Complaint Filed by Panacea Plant Sciences in Federal District Court ("Order Regarding Complaint"), indicating that should Panacea seek any action by this tribunal based on its federal district court filing, it must file a motion requesting such action no later than 2:00 p.m. Eastern Time ("ET") on April 18, 2024. Order Regarding Complaint at 2. The order further set a deadline of 2:00 p.m. ET on April 23, 2024, for responses from the Government and/or other Petitioners to any motion filed by Panacea related to the complaint. *Id*.

On April 16, 2024, the Government filed Government's Unopposed Motion to Stay ("Government Motion to Stay"), requesting that the tribunal "stay its April 2, 2024, Order for Prehearing Statements," or, in the alternative, grant the Government "a continuance of 30 days to provide its Prehearing Statement (PHS), currently due on April 17, 2024." Gov't Mot. to Stay at 1. On April 17, 2024, the tribunal issued an Order Granting in Part Government's Unopposed Motion to Stay ("Order Granting in Part Government Motion to Stay"), modifying the OPHS and setting new deadlines for parties to file motions related to standing and continuing the deadline for the Government to file its prehearing statement. Order Granting in Part Gov't Mot. to Stay at 3.

On April 17, 2024, Panacea filed Panacea Plant Sciences Motion for Stay ("Panacea Second Motion to Stay"), referencing its challenge to the constitutionality of these administrative proceedings filed in District Court and requesting "the ALJ/judge to issue a stay of these proceedings until an associated challenge to the proceedings in federal court can be completed." Panacea Second Mot. to Stay at 1. In its motion, Panacea referenced two other DEA cases pending in U.S. District Courts with constitutional challenges to DEA administrative

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¹ Panacea's Second Motion to Stay is dated April 16, 2024, but was filed after 5:00 p.m. ET and thus is deemed filed by Panacea on April 17, 2024. *See* 21 C.F.R. § 1316.45.

proceedings and where the associated administrative proceedings were stayed. *Id.* at 1-2. No responses to Panacea's Second Motion to Stay were filed by the Government or the other Petitioners in these administrative proceedings.

The Agency has adopted the legal standards articulated by the Supreme Court in *Nken*² in evaluating the merits of requests to stay in DEA administrative proceedings. *See Jennifer L. St. Croix, M.D.*, 86 Fed. Reg. 30,494, 30,495 (2021). As articulated by the Supreme Court, "[a] stay is not a matter of right, even if irreparable injury might otherwise result," and is "instead an exercise of judicial discretion, and the propriety of its issue dependent upon the circumstances of the particular case." *Nken v Holder*, 556 U.S. 418, 433 (2009) (internal quotations and citations omitted). Furthermore, the Agency has consistently found that parallel criminal, civil, or administrative proceedings, standing alone, seldom justify a stay of DEA administrative proceedings. *See Grider Drug #1 & Grider Drug #2*, 77 Fed. Reg. 44,070, 44,104 n.97 (2012); *see also Newcare Home Health Servs.*, 72 Fed. Reg. 42,126, 42,127 n.2 (2007); *Charles Szyman, D.O.*, 81 Fed. Reg. 64,937, 64,938 (2016); *Kenneth N. Woliner, M.D.*, 83 Fed. Reg. 7223, 7224 n.2 (2018).

In thus exercising its discretion to consider whether a stay is warranted, the tribunal considers:

(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the [stay] applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceedings; and (4) where the public interest lies.

Nken, 556 U.S. at 434; Jennifer St. Croix, 86 Fed. Reg. at 30,495. "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. Furthermore, in weighing the four factors, "[t]he first two factors of the traditional standard are the most critical." Id. at 434. In the event the requesting party "satisfies the first two factors, the traditional stay inquiry calls for assessing the harm to the opposing party and weighing the public interest." Id. at 435. When the Government is the opposing party, the third and fourth factors merge. Id.

On consideration of Panacea's motion, the lack of opposition thereto, and the ongoing constitutional examination of administrative proceedings by the federal courts, I find that a stay

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² Nken v. Holder, 556 U.S. 418 (2009).

is appropriate. Panacea's District Court complaint presents a challenge to this tribunal's authority based on *Axon*,³ which allows federal district courts to review interlocutory constitutional challenges to the structure of a federal agency. As acknowledged by the Supreme Court, claims wherein a litigant alleges that it is being subjected to unconstitutional agency proceedings represent a "here-and-now" injury, which is "impossible to remedy once the proceeding is over." *Axon Enterprise, Inc. v. Federal Trade Commission*, 598 U.S. 175, 191 (2023) (internal quotations and citations omitted). While Panacea's likelihood of success on the merits is difficult to ascertain at this time, the potential that Panacea may face irreparable injury absent a stay of the present administrative proceedings weighs significantly in favor of granting Panacea's motion.

Furthermore, no responses were filed in opposition to Panacea's Second Motion to Stay. As the substances at issue remain unscheduled, it is unlikely that a stay of these administrative proceedings would substantially injure the remaining Petitioners contesting DEA's proposed scheduling. The Government likewise presented no argument that it would be substantially injured in the event of a stay, and indeed seemed to concede to an impending stay in its own motion. *See* Gov't Mot. to Stay at 2. Although the public interest may lie in an expeditious and efficient resolution to these proceedings, the public interest also lies in ensuring parties are not potentially subjected to an adjudication process found unconstitutional. On the balance, and in deference to the authority of the District Court, the four *Nken* Factors favor granting Panacea's request for a stay.

Accordingly, it is hereby **ORDERED** that Panacea's unopposed Second Motion to Stay is **GRANTED**. It is further **ORDERED** that these administrative hearing proceedings, including the hearing set for June 10, 2024,⁴ are **STAYED**⁵ until the District Court renders its decision in the parallel litigation, and the prehearing conference scheduled for May 3, 2024 is **CANCELED**. The Government is directed to publish in the Federal Register either this order or

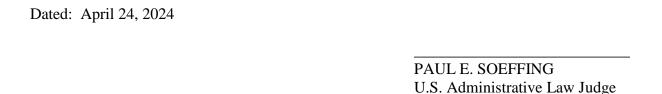
³ Axon Enterprise, Inc. v. Federal Trade Commission, 598 U.S. 175 (2023).

⁴ This date was set by an announcement published in the Federal Register. 89 Fed. Reg. 24,750 (2024).

⁵ See 21 C.F.R. § 1316.52(a) (the presiding officer has the power to "[a]rrange and change the date, time, and place of hearings").

some other notice apprising the parties and the public that the hearing set for June 10, 2024 is canceled and the proceedings are stayed.

It is further **ORDERED** that Panacea and the Government file with the tribunal, and serve on all other parties to this case, a joint status report update every sixty (60) days (commencing 60 days from the issuance of this order) until the date that either party is served with a decision by the District Court regarding the above-referenced parallel litigation. To ensure that this tribunal acts in consonance with the directives of the District Court, Panacea and the Government (either or both) are further directed to forthwith file with the tribunal, and serve on all parties to this case, any orders issued by the District Court and/or transcripts prepared in connection with the parallel litigation within ten (10) days of issuance. Either Panacea or the Government may file a single joint status report for both parties so long as it reflects the agreed understanding of both parties, but this obligation to have a joint status report filed by either party extends to both parties. Either party may file, but one party must file.⁶



⁶ The parties are reminded that these administrative proceedings are stayed, not dismissed or terminated. Therefore, failure to timely file a joint status report in compliance with the directions provided may result in a sanction, including (but not limited to) vacatur of stay.

CERTIFICATE OF SERVICE

This is to certify that the undersigned, on April 24, 2024, caused a copy of the foregoing to be delivered to the following recipients: (1) Frank W. Mann, Esq., Counsel for the Government, via email at Francis.W.Mann@dea.gov and to the DEA Government Mailbox at dea.registration.litigation@dea.gov; (2) Kayla L. Kreinheder, Esq., Counsel for the Government, via email at Kayla.L.Kreinheder@dea.gov and to the DEA Government Mailbox at dea.registration.litigation@dea.gov; (3) Alexis B. Attanasio, Esq., Counsel for the Government, via email at Alexis.B.Attanasio@dea.gov and to the DEA Government Mailbox at dea.registration.litigation@dea.gov; (4) David Heldreth, CEO of Panacea Plant Sciences, via email at davidh@panaceaplantsciences.net; (5) Brett J. Phelps, Esq., Counsel for Science Policy Council, Students for Sensible Drug Policy, via email at brett@brettphelpslaw.com; and (6) Robert T. Rush, Esq., via email at rrush@rrushlaw.com.

Tayonna A. Eubanks
Secretary (CTR)
Office of Administrative Law Judges