UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON

Panacea Plant Sciences, Inc., and David Heldreth representing Panacea Plant Sciences, Inc.; **Plaintiff(s),** **v.** **MERRICK B. GARLAND, in his official capacity as U.S. Attorney General, UNITED STATES DEPARTMENT OF JUSTICE, ANNE M. MILGRAM, in her official capacity as Administrator of the Drug Enforcement Administration, UNITED STATES DRUG ENFORCEMENT ADMINISTRATION, PAUL E. SOEFFING, in his official capacity as an Administrative Law Judge of DEA,** ***Defendants***.	CASE NO. _____

COMPLAINT AND REQUEST FOR TEMPORARY RESTRAINING ORDER, DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Panacea Plant Sciences, Inc. (PPS), by this complaint against the United States Department of Justice, Attorney General Merrick B. Garland, the Drug Enforcement Administration, its Administrator Anne M. Milgram, and its Administrative Law Judge Paul E. Soeffing, allege as follows:

INTRODUCTION

1. This action for injunctive and declaratory relief arises from Defendants' attempt to subject Panaea Plant Sciences (PPS) to unconstitutional proceedings before a DEA administrative law judge (ALJ).

2. On April 11, 2022 Defendant DEA issued a rule-making notice to move DOI and DOC into Schedule 1, which PPS challenged.

3. On August 29, 2022, DEA withdrew the rule-making for DOI/DOC.

4. On April 14, 2023 the Supreme Court ruled in Axon that administrative proceedings do not need to be completed before a challenge to the constitutionality may be made.

5. Nearly 16 months after withdrawing the original rule, on December 13, 2023, defendant DEA issued a new rule-making notice to move DOI and DOC into Schedule 1. Panacea Plant Sciences and others again challenged the rule-making and asked for it to be withdrawn in comments via the Federal Register and Regulations.gov.

6. Then on March 29, 2024, DEA announced a hearing in an administrative DEA court to determine the scheduling status of DOI and DOC. However, the ALJ is not an Article III court.

7. On April 8, 2024, PPS filed a motion in the DEA ALJ proceedings to request: a) 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 Tribal Consultation Executive Orders, b) 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, c) an impending challenge to the constitutionality of the DEA ALJ process.

8. On April 10, 2024, DEA ALJ Soeffing replied to PPS motion with an order to hold any decisions in abeyance until after turning over prehearing documents and the prehearing conference.

9. The hearing and scheduling poses a significant threat to the company. PPS conducts research and development on medical technologies which include the use of DOI or DOC for development and as products themselves. Currently, DOI and DOC are not controlled.

10. Under the Controlled Substances Act (CSA) and its implementing regulations, PPS will be required to turn over to law enforcement or destroy our stock of DOI and DOC which means the rule-making acts as an effective taking of property.

11. As a result, when PPS received the hearing notice from DEA, it was faced with a stark choice: either default and lose automatically or defend itself against the DEA's attempts to schedule DOI and DOC and its use of an ALJ-overseen adjudication. PPS is thus compelled to participate in the DEA's adjudicatory proceedings.

12. That does not mean the ALJ proceedings should go forward. Under binding precedent, those proceedings violate Article II of the Constitution of the United States. As the Fifth Circuit held in Jarkesy v. SEC, 34 F.4th 446 (5th Cir. 2022), the two-layer, for-cause removal restrictions applicable to ALJs impermissibly impair the President's constitutional charge to take care that the laws are faithfully executed. The same restrictions on for-cause removal at issue in Jarkesy are at issue here. Specifically, Sections 7521(a) and 1202(d) of Title 5 of the United States Code prevent the President and Attorney General from removing DEA ALJs unconditionally. Rather, ALJs may be removed only for "good cause" as "determined" by the Merit Systems Protection Board ("MSPB"), whose members themselves can be removed by the President only on certain limited "good cause" grounds. This degree of insulation is unconstitutional. Indeed, because DEA ALJs do not satisfy either narrow recognized exception to the President's unrestricted removal power, any degree of insulation is unconstitutional.

13. The DEA's scheduling hearings has stakes that extend beyond PPS. DOI and DOC are widely used in research and development for pharmaceutical drugs related to the mind and other bodily systems. They are also key compounds for the research into schizophrenia and other related illnesses. Removing access to these compounds through legal channels and/or making their access more difficult would severely limit science and reduce the reproducibility of experiments and ability to compare to past research. This would lead to reduced development of new treatments and less understanding of medical conditions, which could lead to increased deaths and suffering in the United States and beyond over time. In addition, the unconstitutional taking of property by the government without access to an Article III court would set an illegal, and dangerous precedent.

14. PPS should not, however, be forced to defend itself under the DEA's constitutionally illegitimate regime. As the Supreme Court has recognized, being subjected to an unconstitutional proceeding is an independent, immediate, "here-and-now" injury—one that cannot be remedied through normal channels of appeal. See Axon Enter., Inc. v. Fed. Trade Comm'n, 598 U.S. 175, 191-92 (2023).

15. The DEA, for its part, has no immediate need to proceed with a constitutionally defective process. The items DOI and DOC are already controlled for human consumption under the Analog Act. Additionally, it has been nearly 2 years since the DEA began this process, with more than a year between the previous attempt and this attempt to schedule the items.

16. Panacea Plant Sciences moves accordingly for all necessary relief to enjoin the DEA's administrative action regarding the ALJ proceedings for DOI and DOC, including a temporary restraining order preventing DEA or DEA ALJ Soeffing from continuing the ALJ proceedings while this case is heard, an immediate stay of the ALJ proceedings, as well as any scheduling of DOI and DOC until the constitutional defects in its enforcement regime can be remedied.

PARTIES

17. Plaintiff Panacea Plant Sciences is a medical research company which is incorporated in Washington State and has main offices in Bellevue, Washington. Founded in 2017, the company has focused much of its research around compounds with activity on the 5-ht2a receptor system and related biological systems.

18. The company is developing therapies and IP which involve DOI, DOC and related drugs.

19. Plaintiff David Heldreth is CEO of Panacea Plant Sciences, and Pro Se self-representing in this case. He also resides in Bellevue, Washington.

20. Defendant Merrick B. Garland is named in his official capacity as the Attorney General of the United States. By statute, the Attorney General has the authority to enforce the CSA. The Attorney General has delegated relevant enforcement authority to the DEA Administrator. See 28 C.F.R. § 0.100. The address of the Office of the Attorney General is 950 Pennsylvania Avenue NW, Washington, DC 20530.

21. Defendant United States Department of Justice is an executive department of the United States. See 5 U.S.C. § 101; 28 U.S.C. § 501. The head of the Department of Justice is the Attorney General. See 28 U.S.C. § 503. The address for the DOJ is 950 Pennsylvania Avenue NW, Washington, DC 20530.

22. Defendant Anne M. Milgram is named in her official capacity as the Administrator of the DEA. The Attorney General's authority to enforce the CSA has been delegated to her. See 28 C.F.R. § 0.100. The Address of the Office of DEA Administrator is 8701 Morrissette Drive, Springfield, Virginia 22152.

23. Defendant Drug Enforcement Administration is a component of the United States Department of Justice. The DEA was created by Executive Order 11,727. 38 Fed. Reg. 18357 (July 10, 1973). It has jurisdictional authority across the United States. The address for the DEA is 8701 Morrissette Drive, Springfield, Virginia 22152.

24. Defendant the Honorable Paul E. Soeffing is an ALJ of DEA. He is sued in his official capacity.

Jurisdiction and Venue

25. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1337, and 1346 because this action arises under the Constitution and laws of the United States concerning commercial regulation. The United States has waived its sovereign immunity from this lawsuit in 5 U.S.C. § 702.

26. This action arises under Article II of the United States Constitution and the Declaratory Judgment Act. This Court has subject-matter jurisdiction under 28 U.S.C. § 1331 because the action arises under the laws of the United States.

27. Venue is proper in this district under 28 U.S.C. § 1391(e) because (i) one or more Defendants is an officer or employee of the United States or any agency thereof acting in his official capacity or under color of legal authority, or is an agency of the United States, or is the United States and (ii) Plaintiff resides in this District.

STATEMENT OF CLAIMS

FACTUAL ALLEGATIONS

28. DEA files Federal Register notice on controlled substances manufacturing quotas on September 2, 2021. https://www.federalregister.gov/documents/2021/09/02/2021-18935/proposed-adjustments-to-the-aggregate-production-quotas-for-schedule-i-and-ii-controlled-substances

29. On September 3, 2021, Panacea Plant Sciences and David Heldreth contacted the DEA after the DEA submitted Docket 688A to the Federal Register on levels of controlled substance manufacturing on September 2, 2021. The Federal Register listing indicated that a Regulations.gov website was live for comments on the government action. This is required under administrative law. PPS made the contact to alert the DEA that the phone

number and email which was provided for contact regarding the rule-making was incorrect and was not being returned or answered. For 2 weeks approximately the DEA still did not correct the errors and so PPS contacted them repeatedly. However, PPS also contacted Regulations.gov and was told that in fact the Regulations.gov team could not fix the error or make the pages live for comment as only the DEA was in charge of this and that DEA was well aware of their control of this feature. In response PPS alerted the DEA to this issue and DEA still did not have the comment page operational for more than 24 hours.

30. Then September 17, 2021, Panacea Plant Sciences published a press release informing the public of these facts in order to increase public comment and requests for DEA action to make the comment page live. With no surprise, once public was made aware of DEA blatant and willful negligence of following administrative law the DEA somehow was able to make the page live for viewing within next 12 hours. However, even after DEA made public listing for Docket 688A the agency did not immediately turn on comments and took another day to do so. The text of the press release PPS released can be found here: https://www.einnews.com/pr_news/551479837/panacea-plant-sciences-submits-comments-on-psychedelics-cannabis-to-dea.

31. During this time members of DEA staff were dismissive and aggressive regarding the situation in verbal communication on calls.

32. PPS filed a variety of FOIA requests on November 4, 2021 on DEA records related to DEA drug scheduling actions. The agency declined the FOIA request on December 3, 2021. This appears to be in response and retaliation for my activity which exposed DEA attempt to subvert administrative process and reduce public comment in order to more easily push through their goals with less public awareness or activity against them.

33. Panacea Plant Sciences was/is working on biosynthetic pathway development regarding the use of yeast and bacteria for the creation of therapies 4-OH-DiPT, 5-MeO-AMT, 5-

MeO-MiPT, 5-MeO-DET, DiPT, DOI, DOC and other compounds with Philippe Henry and his companies which include or included Egret and Alvarius Research, among others, which are all Canadian-based entities.

34. In order to facilitate research with these compounds Panacea Plant Sciences and our partners sought to obtain written confirmation of what we knew which was that these items were legal for possession and research purposes from Health Canada and DEA in order to provide directly to US and Canadian Customs officials and others in order to reduce timetable and potential for misunderstanding of compound identities and legality during shipments of these items from Canada to the United States or the United States to Canada.

35. DEA and Office of National Drug Control Policy (ONDCP)have issued multiple statements, particularly on this day regarding their support to reduce barriers to research of schedule 1 drugs and items such as cannabis and psychedelics. However, this current scheduling process which was started a month later is exactly the type of movement which will restrict and reduce access and ability for research while increasing costs and adding barriers. - https://www.marijuanamoment.net/dea-backs-white-house-plan-to-streamline-research-on-marijuana-psychedelics-and-other-schedule-i-drugs/.

36. Philippe Henry and Panacea had been in contact with Health Canada, some of that communication was provided to the DEA on December 31, 2021, in order to attempt to smooth over cross border collaboration and shipment of 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET and DiPT and other compounds. DEA responded without providing clarification on the status or any mention of a pending scheduling attempt and directed us to contact other DEA staff at the ODLP regarding the discussion and sent emails to Panacea Plant Sciences on January 4, January 7.

37. On January 14, 2022 the DEA filed the scheduling notice in the federal register and the scheduling process began for 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET

and DiPT. https://www.federalregister.gov/documents/2022/01/14/2022-00713/schedules-of-controlled-substances-placement-of-4-hydroxy-nn.

38. On April 11, 2022 Defendant DEA issue a rule-making notice to move DOI and DOC into Schedule 1, which PPS challenged.

39. On June 30, 2022 DEA lawyer John Beerbower during an administrative law hearing said that the DEA administrator told him to violate ALJ Judge Teresa Wallbaum's orders regarding publishing of hearing dates for the 5 tryptamines case.

40. On July 6, 2022, DEA filed a notice for the public hearing for the 5 tryptamines for August 22, 2022.

41. On July 11, 2022, a status conference was held in which she told the DEA to answer for the claims that the DEA administrator may have broke APA or other laws.

42. On July 19, 2022, the DEA removed Beerbower from the 5 tryptamine case and on July 21 DEA stated that Beerbower had agreed to a "transfer" out of the DEA to another DOJ location due to an arrangement made prior to the June 30 conference.

43. On July 21, 2022, PPS served the DEA and ALJ with a motion to dismiss and stop rulemaking due to APA violations and potential signs of tampering by DEA administrator Milgram.

44. On July 27, 2022, the DEA withdrew the rulemaking for the 5 tryptamines before an ALJ order could be drafted.

45. On August 29, 2022, DEA withdrew the rule-making for DOI/DOC.

46. On April 14, 2023 the Supreme Court ruled in Axon that administrative proceedings do not need to be completed before a challenge to the constitutionality may be made.

47. DEA filed new rulemaking to Schedule DOI and DOC on December 13, 2023.

48. PPS/David Heldreth filed a FOIA request on December 27, 2023 for: Any records regarding Docket No. DEA 1156 rulemaking titled "Placement of 2,5-dimethoxy-4-iodoamphetamine (DOI) and 2,5-dimethoxy-4-chloroamphetamine (DOC) in Schedule I," or regarding mention of 2,5-dimethoxy-4-iodoamphetamine (DOI) or 2,5-dimethoxy-4-chloroamphetamine (DOC) which was sent to the Department of Justice's Office of Tribal Justice from the DEA or DEA administrator/administrator's office; and any records related to or showing the DEA sent this rule making to the Chief Counsel for Advocacy for the Small Business Administration (from December 1, 2021 to December 31, 2023)

49. DEA denied/closed the FOIA for these records on February 6, 2024.

50. PPS/David Heldreth filed an appeal to the DEA FOIA denial on February 6, 2024.

51. DEA denial of FOIA is overturned by the Department of Information Policy on February 20, 2024.

52. DEA sends hearing notice for DOI/DOC on March 29, 2024.

53. DEA assigns Judge Soffling on April 1, 2024.

54. Judge Soffling sends order for prehearing statements on April 2, 2024

55. On April 8, 2024, PPS filed a motion in the DEA ALJ proceedings to request: a) 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 Tribal Consultation Executive Orders, b) 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, c) an impending challenge to the constitutionality of the DEA ALJ process.

56. On April 10, 2024, DEA ALJ Soeffing replied to PPS motion with an order to hold any decisions in abeyance until after turning over prehearing documents and the prehearing conference.

57. The DEA, for its part, has no immediate need to proceed with a constitutionally defective process. The items DOI and DOC are already controlled for human consumption under the analog act. Additionally, it has been nearly 2 years since the DEA began this process, with more than a year between the previous attempt and this attempt to schedule the items.

58. The United States Supreme Court has found that an ALJ appointment process nearly identical to that used by DEA is unconstitutional. DEA, however, has done nothing to conform its ALJ appointment process to constitutional requirements. Moreover, statutory restrictions on an ALJ's removal violate the President's Article II executive power. DEA nonetheless seeks to compel PPS to participate in an unconstitutional DEA administrative proceeding. PPS seeks declaratory and injunctive relief to prevent the irreparable harm it would suffer if subjected to such an unconstitutional proceeding.

59. DEA ALJs are executive "officers" for purposes of Article II's Appointments Clause. They hold continuing positions, established by law, in which they exercise significant authority and discretion presiding over DEA administrative hearings and adjudicating adversarial proceedings.

60. Under the Appointments Clause, inferior Article II "officers" such as DEA's ALJs must be appointed either by the President or the Head of their Department, the Attorney General of the United States. U.S. Const. art. II, § 2, cl. 2. DEA ALJs, however, are appointed by neither. On information and belief, the DEA ALJ presiding over the administrative hearing was selected from a pool of candidates and appointed by the DEA Administrator upon recommendation from DEA's Chief ALJ.

61. In June 2018, the United States Supreme Court confirmed that this ALJ appointment process is unconstitutional in Lucia v. S.E.C., 138 S. Ct. 2044 (2018). Although the Court's decision specifically addressed the appointment of ALJs for the Securities and Exchange Commission ("SEC"), its reasoning equally applies to the appointment of DEA's ALJs. The Solicitor General explicitly acknowledged this fact in a memorandum addressed to all agency general counsels made public following the Supreme Court's decision in Lucia. In that memorandum, the Solicitor General stated that "SEC ALJs, and other ALJs who exercise similar powers, are inferior officers and must be appointed as such."

62. The framework for removal of DEA's ALJs is similarly unconstitutional. Article II vests "[t]he executive Power" in the President, including ultimate authority to remove officers to ensure that the law is "faithfully executed." U.S. Const. art. II, § 1, cl. 1; id. § 3. The Supreme Court has held that, because the executive power is vested in the President, Article II requires inferior officers, such as ALJs, to be answerable to the President, and not separated from the President by attenuated chains of accountability. See Free Enter. Fund v. Pub. Co. Acct. Oversight Bd., 561 U.S. 477, 492-98 (2010) ("Free Enterprise"). Statutory prohibitions found in Sections 7521(a) and 1202(d) of Title 5 of the United States Code prevent the President and Attorney General from removing DEA ALJs. Rather, they may be removed only for "good cause" as "determined" by the Merit Systems Protection Board ("MSPB"), whose members themselves can only be removed by the President on certain limited "good cause" grounds. This scheme—creating two layers of "for cause" protection between the President (or Attorney General) and his inferior officer ALJs—deprives the President (or Attorney General) from exercising his executive oversight duties and therefore is violates Article II. Id. at 492.

63. This court is PPS' only opportunity for meaningful judicial review that could prevent a deprivation of its constitutional rights. PPS cannot wait until a DEA ALJ conducts a hearing and reaches a determination before seeking review in an Article III court, because PPS would then have already suffered a constitutional harm. PPS thus seeks protection from an "illegitimate proceeding, led by an illegitimate decisionmaker." Axon Enter., Inc. v. Fed. Trade Comm'n, 598 U.S. 175, 191 (2023).

64. Under the Supreme Court's decision earlier this year in Axon, PPS is entitled to seek relief in a District Court now to address its constitutional challenges to avoid compounding the "here-and-now injury" from being subjected to this illegitimate proceeding—a harm that is "impossible to remedy once the proceeding is over, which is when appellate review kicks in." 598 U.S. at 192.

65. PPS is currently in possession of both DOI and DOC physically and utilizes the compounds in the research and development of business activities. The current rule-making amounts to an attempt to seize or take property from PPS as the change in regulatory status will require the company, which does NOT have a Schedule 1 license to destroy or turn over our possessed DOI/DOC to law enforcement upon initiation of the law. As such this rule-making and the ALJ process are unconstitutionally keeping PPS from Article III court review of the taking of property (DOI/DOC) from our company. All attempts to take property from a person or a company require Article III review under the constitution. As such there is no constitutional way for the DEA ALJ to hold this hearing currently. If PPS waits until the ALJ process is finalized, the company may be forced to destroy or remove the chemicals which would result in the loss of the company's standing for an appeal or case, and would again result in the taking of property via a non-Article III court.

66. Currently, there are 2 other DEA ALJ proceedings/hearings that have been stayed pending their district court challenges to the constitutional nature of the DEA ALJ. This shows evidence that the current request should similarly be granted.

CAUSES OF ACTION

COUNT ONE

(Application for Injunctive Relief)

67. PPS repeats and realleges each and every allegation in the statement of claim, as if fully set forth here.

68. Without injunctive relief from this Court, PPS will be required to continue to submit to an unconstitutional proceeding led by an unconstitutional decisionmaker which constitutes a "here-and-now injury" that is "impossible to remedy once the proceeding is over, which is when appellate review kicks in" under Axon, 598 U.S. at 191. This, in and of itself, constitutes irreparable harm to Plaintiff unless the Administrative Proceeding is enjoined.

69. Furthermore, if the DEA Administrator, upon recommendation from the presiding DEA ALJ, finds that DOI and DOC should be moved into Schedule 1, the harm will be severe and irreversible. PPS business will be forced to discontinue research and also to dispose of or turn over to law enforcement our property, DOI and DOC. Moreover, Plaintiff could not obtain meaningful judicial review in time to prevent this outcome. Nor can this harm be remedied after-the-fact with money damages, as numerous immunity doctrines would prevent PPS from obtaining a financial damages award from DEA.

70. PPS seeks a temporary restraining order on the DEA administrative proceedings for DOI and DOC, an injunction barring the Defendants from continuing rule-making to schedule DOI or DOC and requiring the current rule-making to be rescinded/withdrawn, AND preliminary and permanent injunctive relief barring Defendants from administrative adjudicatory proceedings before any DEA ALJ, so long as the unconstitutional removal restrictions applicable to the ALJ have not been rectified.

71. PPS seeks an injunction forcing the Defendants to turn over records sought by PPS and David Heldreth in all FOIAs filed.

COUNT TWO

(Declaratory Judgment)

72. PPS repeats and realleges each and every allegation in the statement of claim, as if fully set forth here.

73. PPS requests a declaratory judgment that the statutes, regulatory provisions, and policies providing for the appointment of DEA ALJs are unconstitutional as applied by DEA and DOJ.

74. PPS further requests a declaratory judgment that the statutes, regulatory provisions, and policies providing for the removal of DEA ALJs are unconstitutional as applied by DEA and DOJ.

PRAYER FOR RELIEF

For the foregoing reasons, Panacea Plant Sciences, Inc. respectfully requests that this Court enter judgment for PPS on its claims and order the following relief:

A. Declarations that the statutes, regulatory provisions, and policies providing for removal of DEA ALJs are unconstitutional as applied by the DEA and DOJ;

B. A temporary restraining order against defendants barring any further administrative proceedings or scheduling attempts on DOI or DOC, and staying any hearings or deadlines in the administrative proceedings until this case is heard;

C. Preliminary injunctive relief requiring defendants to issue a stay in the administrative proceedings;

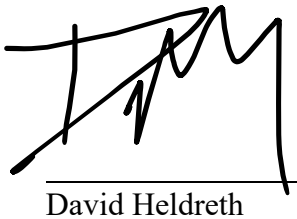
D. Preliminary and permanent injunctive relief barring Defendants from administrative adjudicatory or regulatory proceedings before any DEA ALJ, so long as the unconstitutional removal restrictions applicable to the ALJ have not been rectified;

E. Injunctive relief barring Defendants from continuing rule-making to schedule DOI or DOC and requiring the current rule-making to be rescinded/withdrawn; and

F. Such further and other relief as this Court may deem just and proper.

Date: April 10, 2024

Respectfully submitted,



David Heldreth
PANACEA PLANT SCIENCES
davidh@panaceaplantsciences.net
14321 SE 49th St.
Bellevue, WA 98006