IN THE UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

IN THE MATTER OF	§	
Schedules of Controlled Substances:	§	
Placement of 2,5-dimethoxy-4-	§	Docket No. 24-24
iodoamphetamine (DOI) and 2,5-dimethoxy-4	§	
-Chloroamphetamine (DOC) in Schedule 1	§	
	§	

PANACEA PLANT SCIENCES MOTION FOR
INJUNCTION, STAY AND TO COMPEL

Panacea Plant Sciences (PPS) requests: 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.

Additional Information:

a) The DEA did not follow regulatory requirements under the Regulatory Flexibility Act or the Tribal Consultation Executive Orders. Due to this, the rule-making must be withdrawn. We ask the ALJ to issue an injunction against the DEA and order the DEA to withdraw the rule-making.
b) the DEA to provide records that they have not produced under an approved FOIA request made nearly 4 months ago related to this rulemaking, hearing and docket. Additionally, PPS won an appeal of a DEA denial of the records and is still awaiting the records to be delivered. The FOIA is related to matters of this rule-making and whether or not the DEA followed regulatory and other rules/laws such as the APA. As

such if the hearing is not stayed it would be a grave miscarriage of justice and judicial procedure.

PPS requires the FOIA documents for PPS to prepare for any hearing and to prepare and provide that which the judge is asking such as to file a prehearing statement by May 1. As the government has not provided PPS the FOIA documents we request a stay in the hearing and request all deadlines and dates be moved back the number of days between the judge's notice on April 2 and the date with which we are provided the FOIA documents in full. For example, if the documents are provided by April 9 then the DEA deadline should move from April 17 to April 24, and our prehearing statement moved from May 1 to May 8, and the hearing moved from June 10 to June 17.

c) PPS is currently preparing a filing for a challenge to the constitutionality of this tribunal, this Administrative law judge and the entire DEA ALJ process. We plan to file the challenge in the Western District of Washington State before the end of April. 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).

Additionally, there are currently 2 other challenges to the constitutionality of the DEA ALJ process:

1) Inmar RX Solutions, Inc. v. M 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, and UNITED STATES DRUG ENFORCEMENT ADMINISTRATION; and

2) Ascent Pharmaceuticals, Inc., v. MERRICK B. GARLAND, in his official capacity as U.S. Attorney General, UNITED STATES DEPARTMENT OF JUSTICE, UNITED STATES DRUG ENFORCEMENT ADMINISTRATION, ANNE MILGRAM, in her official capacity as Administrator of DEA, TERESA A. WALLBAUM, in her official capacity as an Administrative Law Judge of DEA, and THE UNITED STATES OF AMERICA.

In both of these cases the DEA ALJ stayed the hearings.

As such PPS asks for an indefinite stay of the hearing and rulemaking process until 60 days following the termination or completion of such case. Once that date has arrived however, the hearing should remain stayed until the FOIA records are also delivered.

As additional good cause for the requests, Panacea Plant Sciences states as follows:

1. DEA originally filed a rule-making to schedule DOI and DOC on April 11, 2022.

2. DEA withdrew that rule-making on August 29, 2022.

3. DEA filed rulemaking and published in the federal register to schedule DOI and DOC on December 13, 2023.

4. To start there are apparent errors in the rulemaking process, in that the DEA did not consult with tribal governments as required under Executive Order 13175.

5. The rulemaking references active Executive Order 13175 - Consultation and Coordination with Indian Tribal Governments – however, it asserts that no such consultation with tribal governments is necessary, or as stated directly below:

6. *"This proposed rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes."*

7. This statement is incorrect as this rulemaking will change the status of a substance under federal law to Schedule 1 which will then as such require tribal law enforcement to enforce this new law as reservations are regulated as federal lands and many tribal law codes reference federal law and the Controlled Substances Act. As such the current rulemaking will create a situation in which tribal governments and law enforcement will be required to train law enforcement on the new laws and this alone will impose direct costs on tribal entities and governments. Additionally, the costs of any enforcement of these new laws incurred from arrests, testing, jailing, etc. which falls on tribal governments again represent burdens and reasons for the DEA/Department of Justice to conduct a tribal consultation prior to rulemaking as is required under EO 13175. From the text:

8. *"To the extent practicable and permitted by law, no agency shall promulgate any regulation that has tribal implications, that imposes substantial direct compliance costs on Indian tribal governments, and that is not required by statute, unless:*

9. *(1) funds necessary to pay the direct costs incurred by the Indian tribal government or the tribe in complying with the regulation are provided by the Federal Government; or*

10. *(2) the agency, prior to the formal promulgation of the regulation,*

11. *(A) consulted with tribal officials early in the process of developing the proposed regulation;*

12. *(B) in a separately identified portion of the preamble to the regulation as it is to be issued in the* ***Federal Register*** *, provides to the Director of OMB a tribal summary impact statement, which consists of a description of the extent of the agency's prior consultation with tribal officials, a summary of the nature of their concerns and the agency's position supporting the need to issue the regulation, and a statement of the extent to which the concerns of tribal officials have been met; and*

13. *(C) makes available to the Director of OMB any written communications submitted to the agency by tribal officials."*

14. Additionally, under the current DOJ tribal consultation policy, the DEA ande DOJ are tasked to not narrowly define when it is necessary to consult tribal governments, but to do so in a way that is widely encompassing and to err on the side of consulting, rather than not. From the DOJ's own tribal consultation policy:

15. *"The requirements of Executive Order 13175 and this Policy Statement generally will be construed liberally in favor of Consultation on any given policy as defined above with Tribal implications. Consultations may be organized in a variety of ways, from a single group discussion to a more iterative process involving a series of discussions. All decisions regarding whether and how to conduct a Consultation, or whether a given policy or topic has Tribal implications, will be coordinated with the Department's Office of Tribal Justice."*

16. The next issue at hand that must be dealt with is, the DEA's current rulemaking references the Regulatory Flexibility Act. However, the DEA finds that there is not a significant impact on small entities.

17. From the text of the rulemaking:

"The Administrator of DEA, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–612, has reviewed this proposed rule, and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities.

18. We find fault with the DEA assessment that there will not be a substantial impact on small businesses and small entities from this rule-making. Panacea Plant Sciences itself is a small business that qualifies under the Regulatory Flexibility Act to have consultation. Currently, the compounds DOI and DOC are not contained in any federal drug schedule and as such are unregulated essentially. As such there are not any regulations that would require a small business or other small entity to disclose that they are utilizing DOI and DOC for research or for any other business development. Due to this, I am unsure how the DEA measured or even attempted to measure the impact to small business. Additionally, I wonder if this rule was shared with the Small Business Administration to ascertain any possible impacts or from my understanding it wasn't and the DEA administrator made a convenient finding that would allow her to move forward without following the requirements of the Regulatory Flexibility Act.

19. The Regulatory Flexibility Act allows this, but also as it says below requires the administrator to provide such certification and statement to the Chief Counsel for Advocacy of the Small Business Administration. We are curious if this step was done as the rule making does NOT mention. We have sent a FOIA request to ascertain if this requirement was fulfilled.

20. *"(b) Sections 603 and 604 of this title shall not apply to any proposed or final rule if the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. If the head of the agency makes a certification under the preceding sentence, the agency shall publish such certification in the Federal Register at the time of publication of general notice of proposed rulemaking for the rule or at the time of publication of the final rule, along with a statement providing the factual basis for such certification. The agency shall provide such certification and statement to the Chief Counsel for Advocacy of the Small Business Administration."*

21. "*If finalized, this action would impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess), or propose to handle DOI and DOC."*

22. The DEA provides a wide scope of activity that will be impacted by this rule-making. DOI and DOC are widely used as standards for comparing the activity

of a compound on the 5-HT2A receptor which is found in the human body and animals. This is because in order to validate the data you need to have a standard with which to calibrate and compare. The same principle occurs when using a known weight to calibrate a scale. DOI and DOC are also widely used in animal trials in which it is necessary to study the 5-HT2A system in animals or humans. Additionally, DOI and DOC have recently shown benefits for asthma, pain and inflammation in preliminary studies and follow-up studies are needed. All of this would be illegal without first obtaining a DEA license/permit if the DEA gets its way and finalizes this rulemaking. A DEA permit/license which costs thousands of dollars and requires thousands of dollars more in security and regulatory costs. These regulatory costs and restrictions imposed by the current rulemaking will strangle and highly impact small business and other small entities.

23. There are roughly 4,000 universities that would qualify under the Regulatory Flexibility Act as small entities and each of those has hundreds or thousands of students who could be studying DOI or DOC or using them in research. In 2023 alone there were 178 studies using DOI and DOC found among scholarly journals on Google Scholar. That's 178 small entities. Additionally, there could be any number of small businesses, such as Panacea Plant Sciences throughout the U.S. We believe this high volume of use and high volume of impacted small entities and businesses is indicated by the volume of comments which the DEA has received on this rulemaking. As such the DEA is statutorily bound to follow the regulations of the Regulatory Flexibility Act.

24. From the Regulatory Flexibility Act:

"§ 602. Regulatory agenda

(a) During the months of October and April of each year, each agency shall publish in the Federal Register a regulatory flexibility agenda which shall contain —

(1) a brief description of the subject area of any rule which the agency expects to propose or promulgate which is likely to have a significant economic impact on a substantial number of small entities;

(2) a summary of the nature of any such rule under consideration for each subject area listed in the agenda pursuant to paragraph (1), the objectives and legal basis for the issuance of the rule,

and an approximate schedule for completing action on any rule for which the agency has issued a general notice of proposed rulemaking, and

(3) the name and telephone number of an agency official knowledgeable concerning the items listed in paragraph (1).

(b) Each regulatory flexibility agenda shall be transmitted to the Chief Counsel for Advocacy of the Small Business Administration for comment, if any.

(c) Each agency shall endeavor to provide notice of each regulatory flexibility agenda to small entities or their representatives through direct notification or publication of the agenda in publications likely to be obtained by such small entities and shall invite comments upon each subject area on the agenda.

(d) Nothing in this section precludes an agency from considering or acting on any matter not included in a regulatory flexibility agenda, or requires an agency to consider or act on any matter listed in such agenda."

24. We would like to let it be known that this rulemaking was not included on the DOJ or DEA Regulatory Flexibility ACT. We would like the rulemaking withdrawn until this can be done.

25. Additionally, we believe that under the Regulatory Flexibility Act requirements that the DEA does not need to conduct this rule making in order to achieve the goals it states while also not impacting small entities and businesses. Currently, under the Analog Act any compound which is substantially similar to a controlled substance may also be found illegal for human consumption and related uses. However, the use of that same substance is and would be legal if it were to be used for in vitro studies, cell studies, animal trials of related uses. That is the current status quo. Under the current state of things there is as the DEA states in their own 8-factor analysis no apparent illicit diversion of DOI and DOC. As such there is no danger or need for a regulatory change and the only way to reduce or prevent impact on small entities and business under the Regulatory Flexibility Act is to have this rulemaking withdrawn and not resubmitted.

26. Due to the Regulatory Flexibility Act and Tribal Consultation errors, Panacea Plant Sciences requests the rulemaking at hand be:

a. Withdrawn; and either
b. No further action on DOI or DOC scheduling by DEA; or

c. Small business and entity consultation which begins with a publication to that end prior to rulemaking in 2024 and potential final rulemaking in 2025.

27. DEA filed original rulemaking for DOI/DOC in April 2022 and withdrew the rulemaking in August 2022.
28. DEA filed new rulemaking to Schedule DOI and DOC on December 13, 2023.
29. 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)
30. DEA denied/closed the FOIA for these records on February 6, 2024.
31. PPS/David Heldreth filed an appeal to the DEA FOIA denial on February 6, 2024.
32. DEA denial of FOIA is overturned by the Department of Information Policy on February 20, 2024 and is attached as Exhibit 1.
33. DEA sends hearing notice for DOI/DOC on March 29, 2024.
34. DEA assigns Judge Soffling on April 1, 2024.
35. Judge Soffling sends order for prehearing statements on April 2, 2024
36. 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.
37. 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 Ascent to participate in an unconstitutional DEA administrative proceeding. Ascent seeks declaratory and injunctive relief to prevent the irreparable harm it would suffer if subjected to such an unconstitutional proceeding.

38. 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.

39. 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.

40. 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."

41. 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.

42. A federal court filing, and forcing the DEA withdrawal of rules and/or stay by this ALJ 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).

43. 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.

44. PPS is currently in possession of both DOI and DOC physically and utilizes the compounds in 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.

45. Currently, there are, as stated previously, 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.

46. The combined lack of DEA providing the FOIA documents, APA/Regulatory Flexibility/Tribal Consultation errors, and the pending constitutional challenge provide ample reason for a stay(s) to be issued and orders to compel and an injunction against the DOI and DOC rule-making as requested.

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Date: April 8, 2024

Respectfully submitted,

/s/ David Heldreth

David Heldreth

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For Panacea Plant Sciences

CERTIFICATE OF SERVICE

On April 8, 2024, I served a copy of this motion via email to the DEA Judicial Mailbox (**ECF-DEA@dea.gov**), and

- Paul A. Dean, Esq., Counsel for the Government, via email at Paul.A.Dean@dea.gov;
- The DEA Government Mailbox at dea.registration.litigation@dea.gov;
- Robert T. Rush, Esq., Counsel for Respondent Ramos, et al, via email at rrush@rrushlaw.com; and
- Elijah Ullman, for Respondent Students for Sensible Drug Policy, via email at ezu321@gmail.com.

/s/ David Heldreth