

IN THE 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

PARTY'S OPPOSITION TO THE GOVERNMENT'S MOTION TO DISMISS IN PART

Government contends that Panacea Plant Sciences is not an interested party and does not have standing in the current administrative court hearings regarding the action to schedule 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT, and thus move to dismiss.

Panacea Plant Sciences would like to provide evidence in support of Panacea Plant Sciences standing in the hearing and in opposition to the DEA motion to dismiss, the party states as follows:

Factual Background

1. Panacea Plant Sciences first believes the DEA has in their possession communication from the company regarding our research on these items. In December of 2021, prior to any DEA publication of notice on rulemaking on these substances, Panacea Plant Sciences contacted the DEA in order to get written clarification on the assumed uncontrolled status of 4-OH-DiPT, 5-MeO-MiPT and 5-MeO-DET among other items. Panacea Plant Sciences at that point alerted the DEA to our research into these and related compounds and simply sought the written clarification in order to provide to customs in the United States and Canada as the company is seeking to import compounds for such research. DEA responded without providing clarification on the status or any mention of a pending scheduling attempt. Weeks later, on January 14, 2022 the DEA filed the scheduling notice in the federal register and this scheduling process began.

2. Panacea Plant Sciences as DEA states in their response does not hold a DEA license directly itself. Due to this Panacea Plant Sciences has instead been focused by necessity on research which utilizes items such as 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET and DiPT. Panacea Plant Sciences is utilizing these and other compounds as analogs of scheduled compounds in order to research the mechanisms behind these in such ways as looking at their effects on animal and cell models of disease. Panacea Plant Sciences is currently collaborating with Dr. Gary Ostroff of the University of Massachusetts on the development of medical therapies with tryptamines, phenethylamines and other compounds which have 5-HT_{2A} receptor activity to treat things like depression and PTSD. Due to the expenses, hassle, time and complexity of DEA licensing our research with Dr. Ostroff is solely focusing on uncontrolled analog compounds. Our work with Dr. Ostroff was originally intended to be directed to looking at 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET and DiPT but due to the potential of conflict and future scheduling Panacea Plant Sciences was forced to discontinue that project and focus on other lead compounds with research partnerships with that University. This has cost us time and money put towards the initial projects.

3. Panacea Plant Sciences is also contracting with other universities, companies and conducting research on 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET and DiPT directly toward developing medical treatments. If these compounds are moved to schedule 1 it would require that Panacea Plant Sciences apply for both manufacturing and research licensing from the DEA which would cost thousands of dollars in application costs, and additional security and related infrastructure would cost hundreds of thousands of dollars more in order to come into compliance with DEA rules and regulations at the locations and groups with which Panacea Plant Sciences is working with on these items. It would also cost months and months or years of delays

in awaiting DEA approvals as they review applications. This would be a direct harm to Panacea Plant Sciences and a further barrier to research of psychedelics, medicine and neuroscience in general.

4. Panacea Plant Sciences would also like to state for the record that the company has patent filings which cover 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET and DiPT manufacturing and medical uses which our company has conducted research on and are expected to be published in the federal register in 2023. In order to keep a competitive advantage in business and not disclose company IP, Panacea Plant Sciences will not be admitting those to record here. Further control of these items would directly harm Panacea Plant Sciences by increasing the cost of research and development as well as manufacturing for potential medical therapies which our company is focused on developing and licensing to other entities.

5. Panacea Plant Sciences is collaborating with Philippe Henry and the company Egret Bioscience which are based in Canada, on developing medical therapies related to compounds such as tryptamines and phenethylamines. 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET and DiPT are some of the targets of that research and the companies have been in contact with Health Canada, some of that communication was provided to the DEA in December of 2021, in order to attempt to smooth over cross border collaboration and shipment of items through customs as we try to expand collaborative research on 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET and DiPT and other compounds. If these items are scheduled it will impose greater costs on importation, research, development and manufacturing which will be new costs and burdens created solely by the DEA action to schedule these items.

Argument

6. Panacea Plant Sciences has provided several examples of the companies work and interests in the scheduling status of 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET and DiPT. These include collaboration with Dr. Gary Ostroff, Egret along with patents and IP which has been developed already. This along with the cited examples of damages from direct and indirect costs of DEA licensing including legal representation, registration fees, security requirements and more demonstrate that Panacea Plant Sciences is an interested party and has standing the case.

CONCLUSION

For the foregoing reasons, party requests the Tribunal find Panacea Plant Sciences is an interested party, has standing in the case and to deny the government's motion to dismiss in part.

Date: April 20, 2022

Respectfully submitted,

/s/ David Heldreth

David Heldreth

PANACEA PLANT SCIENCES

davidh@panaceaplantsciences.net

14321 SE 49th St.

Bellevue, WA 98006

For Panacea Plant Sciences

CERTIFICATE OF SERVICE

On April 20, 2022, I served a copy of this motion on via email to the DEA Judicial Mailbox (**ECF-DEA@dea.gov**) and the Government Mailbox at (**dea.registration.litigation@dea.gov**).

/s/ David Heldreth