UNITED STATES DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

In the Matter of **Scheduling of Controlled Substances: Placement of 2,5-dimethoxy-4- iodoamphetamine (DOI) and 2,5-dimethoxy-4-chloroamphetamine (DOC) in Schedule I.**	**Docket No. 24-24** ADMINISTRATIVE LAW JUDGE PAUL E. SOEFFING

PETITIONERS SCIENCE POLICY COUNCIL, SSDP AND DR. RAUL RAMOS'S JOINT PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

I. Introduction

Petitioners Science Policy Council, Students for Sensible Drug Policy ("SSDP") and Dr. Raul A. Ramos (collectively, "Petitioners") submit this post-hearing brief to oppose the proposed placement of 2,5-dimethoxy-4-iodoamphetamine (DOI) and 2,5-dimethoxy-4-chloroamphetamine (DOC) in Schedule I of the Controlled Substances Act ("CSA"). This proposal, if enacted, would have far-reaching implications for scientific research, public health policy, and the equitable application of drug enforcement regulations. The Drug Enforcement Administration ("DEA") has not met its statutory burden of demonstrating that these substances satisfy the criteria for Schedule I (i.e., high potential for abuse, no accepted medical use and no accepted safety even under medical supervision) placement under 21 U.S.C. § 811 and 21 C.F.R. § 1308.11. Furthermore, the evidence presented by Petitioners underscores the critical role these substances play in advancing scientific understanding and potential therapeutic breakthroughs.

The CSA was designed not merely as a mechanism for restricting drug abuse but as a nuanced framework for balancing public safety with the imperative of scientific progress. Rather

than viewing the CSA as a beginning or an end, it is better conceived as an evolving regulatory tool intended by Congress to embody sufficient flexibility to adapt to changes in the knowledge as science and research evolve. The nature of the CSA as an evolving regulatory tool is reflected in Congress's creation of a procedure by which changes in scheduling could be affected. *See National Organization for Reform of Marijuana Laws (Norml) v. Drug Enforcement Administration, U.S. Dept. of Justice,* 559 F.2d 735 (D.C. Cir. 1977*).* The best reading of the CSA allows it to serve as a vehicle for discernment and continuous renegotiation of essential concepts such as "abuse liability" as the understanding of science evolves. As such, it is crucial for the DEA's scheduling determinations to be rooted in robust evidence and to reflect the broader societal and scientific context. Unfortunately, the Government's proposed scheduling of DOI and DOC falls short on all counts.

II. STATEMENT OF THE ISSUE

Whether the substances 2,5-Dimethoxy-4-iodoamphetamine (DOI) and 2,5-Dimethoxy-4-chloroamphetamine (DOC) should be placed into schedule I of the Controlled Substances Act (CSA) (21 U.S.C. § 801 *et seq.*).

III. BURDEN OF PROOF AND EVIDENTIARY STANDARD

As the proponent of the proposed scheduling, the government has the burden of proof in this proceeding. 21 CFR § 1316.56

The burden of proof at this administrative hearing is a preponderance-of-the-evidence standard. *See Steadman v. SEC*, 450 U.S. 91, 100-01 (1981).

IV. PROPOSED FINDINGS OF FACT

DOI AND DOC DO NOT MEET CSA'S CRITERIA FOR SCHEDULE I, AND THEREFORE SHOULD REMAIN UNSCHEDULED.

A. Potential for Abuse

In order to place a substance in a Schedule under the CSA, a finding must be made that the substance has a "potential for abuse." Then the substance's relative potential for abuse must be determined. Substances with a "high" potential for abuse are to be placed in either schedule I or II. Those with less than a "high" potential for abuse are to be placed in Schedules III, IV, or V. The statute itself provides no further direct guidance as to what it meant by "potential for abuse." However, the provisions of 21 U.S.C. § 811(C), and the legislative history of the Controlled Substances Act do provide important additional guidance. See infra pp.

1. Eight Factors to be Considered

The provisions of 21 U.S.C. § 811(C) mandate the DEA consider eight specific factors in making "any finding" in determining the Schedule in which to place a drug. These eight factors are as follows:

> (1) Its actual or relative potential for abuse.
>
> (2) Scientific evidence of its pharmacological effect, if known.
>
> (3) The state of current scientific knowledge regarding the 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 controlled substance.

21 U.S.C. § 811(C)

Thus, the DEA must take into account all of the above factors in making a determination with respect to potential for abuse and relative potential for abuse. The most important lesson that

21 U.S.C. § 811(C) teaches with respect to the current proceeding is that the DEA is not free to make a determination concerning a drug's relative potential for abuse without considering the history and current pattern of abuse of that drug relative to experience with other controlled drugs; the scope, duration and significance of abuse of a particular drug relative to that of other drugs; the risk to the public health posed by abuse of a particular drug relative to that of other drugs; and a drug's psychic or physiological dependence liability relative to that of other scheduled drugs.

In short, petitioners argue that the provisions of 21 U.S.C. § 811(C) mean that the DEA may not make a determination of relative potential for abuse based exclusively on theoretical similarities between drugs based on chemical structure or pharmacological effect. Rather, the DEA is mandated by statute to take into account the actual experience "on the streets" with the drug when making a determination of its relative potential for abuse. Furthermore, the Act's legislative history confirms this interpretation.

2. Legislative History on "Potential for Abuse"

The legislative history of the CSA provides very important guidance in defining the term "potential for abuse." In order to discuss the legislative history of the Controlled Substances Act, it is necessary to describe briefly the evolution of the Act. The Administration originally submitted a bill that was introduced in both the House and the Senate. The Senate passed S. 3246, The Controlled Dangerous Substances Act of 1969, on January 28, 1970. 116 Cong. Rec. Sl671 (1970). The Senate-passed bill was essentially the Administration bill.

The House Subcommittee on Public Health and Welfare of the House Committee on Interstate and Foreign Commerce then held eleven days of hearings in February and March, 1970. Subsequently, the House Subcommittee drafted a clean bill amending in many important particulars both the Administration and Senate versions and introduced the Sub-committee's "clean" bill as Titles I and II of H.R. 18583. 116 Cong. Rec. H332987 (September

23, 1970). It was the Subcommittee's version of the bill that was ultimately enacted into the Controlled Substances Act of 1970.

Therefore, the testimony before the House Subcommittee on Public Health and Welfare and the report of the House Committee on Interstate and Foreign Commerce on H.R. 18583 are the critical references in determining the intent of Congress in enacting various provisions of the CSA.

a. **House Committee Reports**

With respect to the definition of the term "potential for abuse," the House report provides some guidance on defining that term. Specifically, the House report refers to the definition that existed in regulations promulgated under the sections of the Federal Food, Drug, and Cosmetic Act which were the predecessor statutes to the Controlled Substances Act.

These regulations, as quoted by the House Report, provided as follows: The Director may determine that a substance has potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect if:

> 1. There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community; or
>
> 2. There is significant diversion of the drug or drugs containing such a substance from legitimate drug channels; or
>
> 3. Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such substance; or
>
> 4. The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions

> from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

Report on Comprehensive Drug Abuse Prevention Control Act of 1970 of House Comm. On Interstate and Foreign Commerce, H.R. Rep. No. 91-1444, 91st Cong., 2d Sess. (Part 1) at 4601 (1970).

Most significantly, however, the House report then goes on to make the following critically important observations:

1. The Committee made clear that it "did not intend that potential for abuse be determined on the basis of 'isolated or occasional non-therapeutic purposes.' The Committee felt that there must exist 'a substantial potential for the occurrence of significant diversions from legitimate channels, significant use by individuals contrary to professional advice, or substantial capability of creating hazards to the health of the user or the safety of the community' …." *Id.* at 4602 (emphasis added). The Committee also noted, of course, that it did not intend the agency "to wait until a number of lives have been destroyed or substantial problems have already arisen before designating a drug as subject to controls of the bill." *Id.*

2. The Committee went further in explaining what it meant by declaring that a "substantial potential" had to exist for a significant diversion or significant use. The Committee declared that:

   > the term "substantial" means more than a mere scintilla of isolated abused, but less than a preponderance. Therefore, documentation that say, several hundred thousand dosage units of a drug have been diverted would be 'substantial' evidence of abuse despite the fact that tens of

millions of dosage units of that drug are legitimately used in the same time period.

Id. at 4602.

3. The Committee also observed that "misuse of a drug in suicides and attempted suicides, as well as injuries resulting from unsupervised use, are regarded as indicative of a drug's potential for abuse."

Id. at 4602.

The single most important fact to be noted about these observations by the House Committee is that they apply to the questions of whether any potential for abuse has been established sufficient to warrant controls under the Controlled Substances Act. In other words, the above excerpts from the House Committee Report are seeking to provide guidance on the minimum potential for abuse that must be identified before a substance is included even in the lowest schedule of the Act, i.e, Schedule V. In the excerpts quoted above, the Committee Report was attempting to define the level of abuse that would warrant any control whatsoever of a drug. If a drug did not attain the level of potential of abuse described in the House Report, the drug would then go uncontrolled.

Thus, in order for a drug to be controlled even at the Schedule V level, the Committee intended that there be evidence that at least "several hundred thousand dosage units" of a drug had been diverted, or that there be other evidence establishing "a substantial potential" for either "significant diversion," "significant use by individuals," or "substantial capability of creating hazards to the health of the use or the safety of the community." Only on the basis of this evidence would any control at all—i.e., Schedule V—be warranted.

It follows that, in order to move a substance into Schedule IV, the government would have to show a more substantial level of abuse than described by the Committee as the minimum

necessary for any control at all. In order to move a substance to Schedule III, the Agency would have to show further evidence of an even higher potential for abuse. And finally, in order to move a substance to Schedule I or II—as having a "high" potential for abuse—the government would have to make a showing three orders of magnitude above the level of abuse potential described in the House Committee's report.

Thus, from the legislative history, we do in fact gain an understanding of the continuum of "potential for abuse" reflected in the Schedules established under the CSA. In order to properly classify a substance in one of the five schedules in the CSA according to its relative potential for abuse, there must be evidence of a substance's relative potential for abuse.

3. Proof of Relative Abuse Potential Required Based on Evidence of Actual Experience

The existence of varying degrees of abuse potential required by each of the various Schedules shows that the findings to be made by the Agency must be based on evidence of relative potential for abuse.

Moreover, for drugs that are "on the street," the Agency must prove the relative potential for abuse of individual drugs based on relative levels of actual abuse. This is clear from the testimony provided by Michael Sonnenreich, then deputy chief counsel of DEA's predecessor agency, before the House Subcommittee which drafted the Controlled Substances Act. Under questioning from Representative Paul G. Rogers of Florida, Mr. Sonnenreich specifically testified as follows:

> Mr. Sonnenreich. I would disagree with that, Congressman. No. 1 [the determination about a high potential for abuse] is clearly the street abuse problem or the abuse problem as found by agents of the Bureau of Narcotics and Dangerous Drugs ....

Hearings on Drug Abuse Control Amendments. Before the Subcomm. on Public Health and Welfare of the House Comm. on Interstate and Foreign Commerce, 91st Cong., 2d Sess. 707 (1970) (hereafter "House Hearings"). At 165

Mr. Rogers. Now I would like for you to tell us on your schedules [how] you determine what drugs fall within which schedule . . . Start with schedule I on page 12. It is actual or relative potential for abuse.

Mr. Sonnenreich. High potential for abuse would be considered pretty much as a law enforcement provision. We would have to go out and see what is happening ....

Mr. Rogers. What about the characteristics of the drugs? Would that be a consideration?

Mr. Sonnenreich. Almost all of the drugs you have in the narcotic category of schedule I are known already in terms of their addictive quality and things of this nature, but what we are talking about here is their high potential of abuse.

Mr. Rogers. No, this is already determined because we are classifying these drugs as such. This is for new substances that you may classify.

Mr. Sonnenreich. But there are two criteria: One is potential and one is actual, the high potential for abuse. If it is a new drug and we want to classify it, the first question is does it have any potential for abuse and that is theoretical, that is a scientific determination. Then we have the second part of the determination, is there any actual abuse? If it is a known drug, we have to go out and find out whether or not there is actual abuse and that is a law enforcement determination.

Now if it is a theoretical drug that is not out on the streets, the answer is purely hypothetical and medical. If it is a known drug that is on the street, of course we have to collect the other information and point out diversion.

Mr. Rogers. On Schedule II on page 18, i, a high potential for abuse. We have discussed that.

Mr. Sonnenreich. No, sir, it is different here. Now you are talking about something else. You are talking about a drug that is probably commercially available, a drug that has medical use that is on the street and in this case the criteria and the triggers become far more a law enforcement decision and the legal decision as to whether or not it can go in there because you are dealing with a commercial product to begin with.

> You have to demonstrate diversion, you have to show that it is being prescribed by doctors and being used outside the prescription modality, which is a law enforcement function.
>
> Mr. Rogers. First of all, you have to determine whether the characteristics of the drug have any effect for abuse.
>
> Mr. Sonnenreich. There is always, in every one of these schedules, a pharmacological input, but then when we get into this, we are then talking about getting the information and then we have to get all three factors--actual abuse, the using without a medical prescription and the pharmacological information. Then it must be analyzed to see whether or not, in fact, we have a legally sufficient case to proceed.

House Hearings, at 718-719 (emphasis added).

Petitioners submit that two propositions are evident from this legislative history. First, in order to properly classify a substance in one of the five schedules in the Controlled Substances Act according to its relative potential for abuse, there must be evidence of a substance's relative potential for abuse.

Second, it is clear from the exchange between Mr. Sonnenreich and Rep. Rogers that where there is "a known drug that is out on the street," the determination of "potential for abuse" must be made on a basis that includes comparative information and evidence about what is actually occurring with the drug compared to the abuse of other drugs.

In short, consistent with common sense, as reflected by the above quoted legislative history, it is clear that the intent of the drafters -- both in the Administration and on the Committee -- was that determinations about relative abuse potential were to be made on the basis of comparative evidence about the nature of the actual abuse taking place on the street.

4. Evidence on Potential for Abuse and Proposed Findings of Fact

We now turn to consider the evidence in the record with respect to the nature of the abuse

potential of DOI and DOC. What is critical here is the relative potential for abuse of DOI and DOC, for only a determination about the relative potential abuse can determine whether these substances should be placed in Schedule I.

The Government has the burden of proof in seeking to place DOI and DOC into Schedule I. 21 CFR § 1316.56. Therefore, the initial issue is whether the Government has met its burden of proving that DOI and DOC have a high potential for abuse. Petitioners submit that the evidence demonstrates that both DOI and DOC do not have a high potential for abuse.

A significant portion of the Government's evidence on the issue of potential for abuse is based on (1) the chemical structural relationship between DOI and DOC and other drugs; (2) the pharmacological effects of DOI and DOC and other drugs; and (3) animal drug discrimination studies. As we will discuss below, this evidence does not provide any support for finding that DOI or DOC have a high potential for abuse. Furthermore, the significance of this evidence with respect to a drug's potential for abuse by humans must, of necessity, give way in the case of a drug that is "on the street" to evidence with respect to the actual extent of human abuse.

Because the evidence of the extent of actual abuse of DOI and DOC is by far the most important evidence bearing on the finding of the relative abuse potential of DOI and DOC, we first turn to that evidence. Subsequently, we will consider the evidence in the record on chemistry, pharmacology, and animal data.

(a) Record Concerning Human Use of DOI and DOC

The record contains nine separate categories of evidence bearing on the extent of use of DOI and DOC: (1) National Forensic Laboratory Information System submissions; (2) DEA Microgram Bulletins; (3) Medical Reports; (4) Anecdotal Online Reports; (5) National Drug Early Warning System reporting; (6) High Intensity Drug Trafficking Area reporting; (7) the National

Survey on Drug Use and Health; (8) Dr. Joseph Palamar's survey of New York City nightclub attendees; and (9) Testimony of Expert Witnesses. We will discuss each in turn.

1. National Forensic Laboratory Information System (NFLIS) Submissions

NFLIS is a DEA system that collects data about drugs specific to law enforcement encounters or seizures from state, local, and federal labs. Pg. 86, 19-20. If a substance is confirmed positive, labs can then voluntarily submit information about the encounter, such as the location where it occurred, to NFLIS, where it can then be used by DEA to assess drug trends. Pgs. 86, 24-25; 87, 1-7.

Between 2005 and 2023, there were 40 encounters of DOI, and 790 encounters of DOC reported in NFLIS. Gov't. Ex. 8. During that time, the number of submissions testing positive for DOI remain stable, ranging from 0-12 per year with a peak of 12 detections in 2012. *Id.* There have been 5 detections of DOI since 2014 and no detections of DOI between 2019 and 2022. *Id.*

The number of submissions testing positive for DOC ranged from 1-152 per year with a peak of 152 detections in 2012. *Id.* Between 2012 and 2015, there were 115-152 detections per year followed by a steep decrease through about 2020. In 2020 to 2022, there were a total of 6 submissions testing positive for DOC. *Id.* There were three detections in 2022.

Dr. Palamar, who was admitted as an expert in drug use epidemiology, interpreted this data to mean "that neither of these substances are available or illicitly available to the public." Pg. 1062 lines 4-7. According to Dr. Palamar, drug availability is a good indicator of drug use; for example, when other drugs such as fentanyl become more available, fentanyl overdose deaths increase. Pg. 1063, 11-23.

2. DEA Microgram Bulletin

The Microgram Bulletin was a newsletter that used to be routinely published by the DEA Office of Forensic Sciences but is no longer published and included information related to drug seizures. Pg. 132, 15-19. Based on the evidence in the record, there were approximately 500 issues of the Microgram Bulletin published. Pgs. 442, 15-25; 443, 1-20. There were five submissions of DOI and two submissions of DOC reported in the Microgram Bulletin since 2006. Gov't Ex. 6, pg. 9. It was not established in the record whether these reports were duplicates of the information reported through NFLIS. Dr. Palamar testified that in his work as an epidemiologist, he follows many DEA reports but was unfamiliar with the Microgram Bulletin.

3. Medical Reports

The Government presented evidence of three published medical reports of adverse events associated with DOC. Gov't. Ex. 6, pgs. 9-10. Two of those reports were of individuals receiving medical care after consuming multiple drugs, including DOC. *Id.* One report was of a 37-year-old individual with a history of methamphetamine use who was found dead and whose decomposing body tested positive for DOC and caffeine. *Id.*

The parties have previously stipulated that there is no documentation in medical literature of the human use of DOI. Prehearing Ruling, ALJ Ex. 53, pg. 3.

4. Anecdotal Online Reports

Dr. Carbonaro testified under cross examination that she relied on HHS's evaluation to conclude that people are taking DOI and DOC in "amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community." Pg. 160, 11-16. Dr. Carbonaro testified that the HHS analysis she relied upon was based on anecdotal reports taken from public internet forum posts, namely from the websites Erowid and Reddit. Pgs. 161, 19; 127, 18; Gov't Ex. 7, pg. 9. There is no way to verify the veracity of what is posted on public forums like Erowid

and Reddit, or even whether the posts on those forums are written by humans. Pg. 171, 12-23. Anecdotal reports are the only evidence offered by the Government as proof of human consumption of DOI.

The parties have stipulated to the fact that, "It is impossible to know if the street drugs sold to an individual as DOI or DOC on which anecdotal reports are based are in fact the substances they are marketed as in the absence of chemical analysis or evaluation of biological fluids following ingestion." Prehearing Ruling, ALJ Exhibit 53, pg. 3.

Dr. Harrison Elder was offered and admitted as an expert in the study of respiratory depression and substance use disorders, specifically the use of monoamines, including psychedelics, as modulators of respiratory depression. Pg. 747, 8-14. Dr. Elder testified that he has experience evaluating the quality and legitimacy of scientific research as it pertains to substance abuse. Pgs. 720, 5-25; 1-23. Dr. Elder testified that non-verified online posts about purported drug use are potentially spurious, not considered reputable scientific information, and are not used as evidence in the scientific world. Pgs. 754, 16; 755, 11-14.

Dr. Elder testified that examples of verifiable evidence would be a report from an emergency department, a report from a drug testing center finding DOI in a blood or urine sample, or a survey of psychedelic users, and that no such evidence exists for DOI. Pg. 756, 7-15.

5. National Drug Early Warning System reporting

Dr. Palamar testified under direct examination that he is the Deputy Director of the National Drug Early Warning System (NDEWS) and that in that position he focuses on the epidemiology of drug use, specifically monitoring emerging trends of drug use. Pg. 1060, 6-19. NDEWS is funded by the National Institute on Drug Abuse (NIDA). Pg. 1090, 21-22. One of the main purposes of NDEWS is to monitor the use and trends of various drugs in real time in order to

rapidly alert scientists and the public about emerging drug trends, with a particular focus on novel drugs. Pgs. 1090, 23-25; 1091, 1-10; 1093 6-10.

The data collected by NDEWS has not resulted in any warnings being issued for DOI. Pg. 1092, 12-15. According to NDEWS survey data, between 2022 and 2023, 0.02 percent of over 6,000 survey respondents reported past year use of DOC. Pg. 1092, 19-25.

6. High Intensity Drug Trafficking Area reporting

Dr. Palamar testified that he also analyzes data from nationwide law enforcement High Intensity Drug Traffic Areas (HIDTA) to monitor emerging drug use. Pg. 1064, 5-19. SSDP/Ramos Exhibit 85, pg. 2. Dr. Palamar testified that based on his analysis of HIDTA data, between 2017 and 2022 across all 50 states, only 3 seizures tested positive for DOC and there were no recorded seizures of DOI within that time frame. Pgs. 1064, 22-25; 1065, 1-5. Dr. Palamar testified that in the 3 seizures of DOC, occurring in 2017, 2020, and 2021, the respective dosing units were 55, 34, and 8. Pg. 1065, 3-4. Based on HIDTA seizure data, DOI and DOC are almost nonexistent compared to other drugs, such as cocaine or methamphetamine or fentanyl, for which HIDTA reports tens of thousands of seizures. Pg. 1067, 6-11.

7. The National Survey on Drug Use and Health

Dr. Palamar testified that he analyzed DOI and DOC use reported in the National Survey on Drug Use and Health (NSDUH), the leading national drug survey in the United States which has been conducted annually since the 1970s. Pgs. 1067, 17-25; 1068, 1-7. SSDP/Ramos Ex. 85, pg. 3. The NSDUH surveys over 50,000 per year and tracks lifetime drug use, meaning how many times people have ever used a particular drug over the course of their entire life. Pgs. 1067, 6-11; 1074, 23-25; 1075, 1-10.

NSDUH has never included survey questions specifically about DOI and DOC use because they are so uncommon, but respondents can report them through type-in responses. Pgs. 1073, 12-25; 1074, 1-9. NSDUH received a total of nine mentions of lifetime use of DOI and 32 mentions of DOC use between 2005 and 2022. Pg. 1076, 6-9. SSDP/Ramos Ex. 85, pg. 3.

Dr. Palamar's analysis of this data concludes that DOI and DOC are extremely rare, especially in more recent years, and very few people have been using these compounds. Pg. 1077, 2-8. Based on independent analysis conducted by Dr. Palamar of type-in NSDHU survey responses, DOI and DOC are much less prevalent than other phenethylamines, specifically the 2C category, including 2C-B. Pg. 1078, 5-14.

8. Dr. Joseph Palamar's Survey of New York City Nightclub Attendees

Dr. Palamar also conducts his own NIH-funded research monitoring drug use in the New York City nightclub scene. Pgs. 1079, 19-22; 1080, 1-8. SSDP/Ramos Ex. 85, pg. 4.

In Dr. Palamar's research, neither DOI nor DOC have ever been detected in hair testing. 1082, 1-3. In Dr. Palamar's research, the unweighted prevalence of reported DOC use between 2016 and 2022 ranged from 0 percent to 0.4 percent, meaning "essentially nobody reported using [DOC] within that time frame." Pg. 1082, 6-15. SSDP/Ramos Ex. 85, pg. 4. Dr. Palamar no longer surveys for DOI use because it when it was surveyed in the past there were zero responses for DOI. Pgs. 1084, 21-25; 1085, 1-4. Dr. Palamar's research found that within the New York City nightclub scene, which has an exponentially higher prevalence of drug use than the general population, the amount of people who indicated they were willing to use DOC if offered was less than one percent. Pgs. 1085, 5-8; 1090, 2-14.

Dr. Palamar testified that he has no personal stake in the outcome of these proceedings and does not care whether DOI and DOC are placed in Schedule I. 1108, 4-12.

9. **Testimony by Expert Witnesses**

One subject produced total unanimity among every expert witness that addressed the issue. Both Dr. Carbonaro and witnesses for Petitioners agreed that individuals did not use DOI and DOC intensively. Dr. Carbonaro testified on direct examination, "I mean, yeah, **because most people only take it once.** There are reasons why somebody may not become dependent. Like, something happening, like, a long duration of action may reduce its dependence. There are many factors going into it. But because **it's usually only taken once**, there is generally no withdrawal." Pg. 140, 15-21.

Dr. Mario de la Fuente Revenga testified, "If this drug that has been known for decades, available from regular chemical suppliers for decades, and it didn't quite find its niche in the community, one might wonder why is that, given that it's clearly a psychedelic, clearly a 2a agonist, but there's a natural selection process. The drugs that become popular become popular because they have distinct property around them." Pg. 1163, 6-19. Also, from Dr. De la Fuente, "But ultimately, there is no demand. The drugs don't get an imprint in the society. And I think that's what happened with DOI. In as much as I know about this drug, I can see why the inherent properties of DOI make them an amazing research tool but not a drug that anyone would like to mess with." Pgs. 1175, 17-25; 1176, 1-4.

Dr. Harrison Elder testified that in his surveillance work around online drug sales, he "never once came across a vendor offering DOI in that time (2019-2023)" Pg. 759, 5-8 and that DOx compounds "exceedingly rare" due to their "duration of their onset, their duration of effects, their general unpleasantness…they just don't seem to be very popular with the vendors." Pg. 761, 7-13.

Dr. Cameron testified that "DOI actually has an ability to be anti-addictive...so it can actually reverse drug seeking of other drugs." Pg. 850, 21-23. She then testified that "DOI would be at the bottom [ranking of addiction]...Something like opioids would be way at the top, with meth and probably alcohol somewhere in there" Pg. 858, 5-8, and "The consensus is that there is low abuse potential [of DOI]." Pg. 885, 8-9.

(b) No Proof of High Potential for Abuse

All the evidence is consistent. First, every piece of officially compiled data reflects a low absolute level of DOI and DOC usage. Second, every piece of officially compiled data reflects a steady level of low usage—with no trend toward any increase over the last decade. Third, all evidence comparing actual DOI and DOC usage reflects their usage being many times less prevalent than other psychedelics. Fourth, every witness including the DEA witness who addressed the issue held the view that DOI and DOC were not used in high amounts or with high frequency.

In sum, the extremely low amount of actual DOI and DOC usage compels a finding that it does not have a high potential for abuse.

During cross-examination, Dr. Carbonaro occasionally sought to explain why individual pieces of data showing a level of DOI and DOC usage should not be taken at face value. Petitioners respectfully submit that the consistently low numbers reflected across the entire spectrum of evidence in the record—including every official compilation of date measuring drug use and abuse in the U.S.—cannot be explained away.

Moreover, it is important to recognize that DOI and DOC during this period was not a controlled substance. If individuals wanted to produce it or buy it, there was no risk of arrest or criminal deterrent to doing so. Despite this, the incidence of use of DOI and DOC remained miniscule. Under these circumstances, Petitioners respectfully submit that that evidence cannot

support a finding that DOI or DOC have a "high" potential for abuse. On the basis of its potential for abuse, the evidence requires that DOI and DOC should be found to have less than a high potential for abuse and should not be placed in Schedule I.

5. Evidence on Chemical Structure, Pharmacology, and Animal Data

One overriding point should be made regarding the data discussed in the Government's evidence presented: None of the data in any of their exhibits or testimony provides any basis whatsoever to come to a conclusion about DOI and DOC's relative potential for abuse. Petitioners do not dispute the fact that DOI and DOC are chemically similar to other psychedelics like DOM in that it has an affinity for the 5-HT2 serotonin receptors. Gov't. Ex. 7, pg. 5. Dr. Elder testified that despite this similar mechanism of action, **"**DOI is quite different from those classical psychedelics in the sense that it has no affinity for 1A as LSD and psilocybin and MDMA do, very little affinity for dopamine or other monoaminergic – so it's very selective for this one receptor. It's very different from other psychedelic drugs which tend to be promiscuous." Pg. 772, 5-16. Due to these differences, "It would be likely that the effects would differ from those more promiscuous serotonergic agonists in their subjective character and pharmacological effects." Pgs. 773, 23-25; 774, 1-2.

The Government leans heavily on the fact that DOI and DOC can substitute for other psychedelics in drug discrimination studies to support their argument. However, drug discrimination alone is not a measure of abuse potential in a drug. Drug discrimination is a pharmacological tool used to determine how similar two drugs are. Pg. 861, 19-25. Dr. Carbonaro's testimony about using drug discrimination to assess abuse liability in humans is based on speculation: "we can use it to suggest that because we know those drugs are used for their

hallucinogenic effects, it would likely show cause that these drugs can also be used." Pg. 128, 12-15.

Dr. Jaster testified that drug discrimination alone is no longer considered a useful measure for determining abuse liability because it is impossible to assess the subjective experience of mice and rats. Pg. 482, 9-12. According to Dr. Jaster, the best method for assessing abuse liability would be a combination of drug discrimination and some type of self-administration study. Dr. Cameron agreed that drug discrimination is not used to study abuse potential. Pg. 859, 17. According to her testimony, NIDA considers the gold standard for studying addiction to be self-administration. Pg. 862, 21-25. Dr. De la Fuente also testified that drug discrimination can be used to establish some similarity between substances, but that it cannot be used to determine abuse liability. Pg. 1176, 15-19. The Government seems to be clinging to drug discrimination in this case because, as Dr. Carbonaro testified, "it's pretty well known that drugs that work for the serotonin 2A receptor don't produce self-administration. It's been published and cited many times." Pg. 192, 11-17.

6. Evidence on Harms to Research

It was the consensus among Petitioner's expert witnesses that placing DOI and DOC in Schedule I would cause significant negative impacts to not only their own research, but to the research of any scientists using these substances. Dr. Carbonaro testified that the time to acquire a Schedule I license is on average three months. Pg. 247, 8-16. Dr. David Nichols, a renowned researcher who has spent 55 years studying psychedelics, refuted this claim, stating that if someone has an idea about studying the Serotonin 2A receptor, and you want to get a tool to study it, the only way to do it, if it's controlled, is to go to the DEA, apply for a license, and wait a year -- if you're lucky -- to get your license to do it." Pg. 989, 1-7. He continues by stating that unless a

researcher is dedicated to studying psychedelics, they will give up, and switch to another research topic where they can make progress without barriers, Pg. 989, 8-10.

The fact that it takes on average a full year to obtain a DEA Schedule I license was corroborated by many other Petitioner witness. Regarding the timeline for Schedule I approvals, Dr. Ramos testified that [...Schedule I] could take up to a year, yes, or more...because there's several levels of administrative hurdles." (pg. 666, 9-15). Dr. Elder testified that "the scheduling status of a drug absolutely has bearing on which drugs you choose and have access to for your research, just due to the onerous regulatory, financial, availability issues, there are many different hurdles to go through when you work with Schedule I drugs." Pg. 779, 7-13. Dr. Elder then elaborates on instances where researchers opt to study other compounds because of difficulties and hurdles associated with Schedule I status. Pg. 780, 8-25; 781, 1-25; 782, 1-5. Regarding the long timeline to approval, Dr. Cameron testified, "I haven't seen [a Schedule I approval] done in less than a year, ever." Pg. 877, 18-19; Dr. Cameron testified explicitly about obtaining a Schedule I registration and why she has not seen it done in less than a year. Pg. 888, 4-25; 889, 1-8. Dr. Jason Youngkin testified that he requires DOI to compare against the properties of new, uncharacterized psychedelic compounds, Pg. 930, 23-25; 931, 1-25. Regarding his understanding of the timeline, "I estimate at least a year to get a DEA license to be able to have DOI again, plus all the other various psychedelics that are scheduled currently. So it would be a minimum of a year delay to just get started." Pg. 932, 2-6.

Outside of the testimony of Petitioners, it is widely recognized that Schedule I status for a drug impedes research. The House Appropriations Committee requested NIDA to provide a brief report on the barriers to research that result from the classification of drugs and compounds as Schedule I substances no later than 120 days after enactment.", (Consolidated Appropriations Act

H.R.1158, page 64). Dr. Francis Collins, former director of the National Institutes of Health, issued this report titled "Barriers to Research with Schedule I Substances". In the Executive Summary, Dr. Collins states, "...and the barriers that have been reported by National Institute on Drug Abuse (NIDA)-funded researchers, which may delay or discourage research on such substances." Page 1. Dr. Collins later states, "Researchers have reported that obtaining a new registration can take more than a year, that modifying a registration can also be time consuming, and that differing interpretations of the Schedule I registration requirements among local DEA field offices, research institutions, as well as distinct federal and state registration requirements, greatly complicate the process. These challenges can impede critical research on Schedule I substances and deter or prevent scientists from pursuing such work."

SSDP/Ramos, in its motion in limine, references the April 16, 2018 letter from Brett P. Giroir, Assistance Secretary for Health. ALJ Ex. 63, Ex. 1. Dr. Giroir recommended rescinding the recommendation that mitragynine and 7-hydroxymitragynine be placed in Schedule I. He wrote, "This decision is based on many factors, in part on new data, and in part on the relative lack of evidence, combined with an unknown and potentially substantial risk to public health if these chemicals were scheduled at this time. Further research, which I am proposing be undertaken, should provide additional data to better inform subsequent scheduling decision." *Id.* Dr. Giroir acknowledges there is a risk to public health by placing these two compounds in Schedule I and that further study is needed. Dr. Giroir writes, "I am also concerned about the impact of scheduling kratom on our ability to conduct research", page 8.

V. CONCLUSIONS OF LAW

A. Research Harm Should Be Considered Within the Eight Factor Analysis, Specifically Under Factor Six, Because It Creates a Risk To Public Health.

Throughout this hearing, we have heard researchers from many distinct fields testify that DOI and DOC are vital to their research. Lindsay Cameron testified that DOI possesses anti-addictive properties and may provide insight into therapeutics for substance use disorders (pg. 848, 1-20); she also mentioned that DOI has anxiolytic properties, potentially paving the way for new treatments for anxiety (pg. 848, 1-20). Dr. Raul Ramos testified that DOI is essential for his and others' studies of pain processing in the central nervous system and could provide insights into therapies for acute and chronic pain (pg. 570, 13-22; pg. 608, 19-25). Dr. Alaina Jaster testified that DOI administration led to reduced preference for opioids in animals (pg. 467, 3-18). Dr. David Nichols testified that DOI shows incredibly potent anti-inflammatory effects (pg. 976, 1-13).

Fentanyl addiction. Pain. Inflammation. Anxiety. These are among the most pressing issues affecting our society today and are hugely detrimental to our collective public health. Factor 6 of the CSA directs us to consider "What, if any, risk there is to the public health" in the proposed rulemaking to control a substance under the CSA. Heretofore, this has been taken to mean the negative impact that a drug may have on public health and the evidence presented has often been negative in nature. But what of the positive impact? DOI and DOC, but DOI in particular, hold tremendous promise to unlock solutions to some of the largest public health threats facing our nation and our world. Their role is not as therapies themselves, but as research tools to help scientists understand the mechanisms of the body and brain behind the devastating illnesses of addiction, pain, inflammation etc.

So, in considering Factor 6 in the decision whether to control a substance in the CSA, a cost-benefit analysis must be done. What, if any, risks does a drug *currently* pose to public health? What, if any, harms would the *scheduling* of a drug pose to public health? And how do these harms compare; is one significantly greater than the other? In the case of DOI and DOC, the answer is

clear. There are almost no harms at the present moment; there is sparse, if any, documentation of human use of these compounds and even less evidence that there are even harms associated with their use. The only reasonable answer as to what their harms are to public health, at the present moment, would be "none" or "almost none". What, on the other hand, are the risks to public health of *scheduling* these drugs? The answer is overwhelming; throughout the course of the proceedings, many scientists from the world's top institutions working on addressing some of the world's biggest problems have testified that these drugs are vital to their and others' research and that their placement into Schedule I would be disastrous for public health.

We heard from early-career scientists like Joseph Hennessey, and Jason Younkin, whose entire scientific career may be altered as the result of this hearing. And we heard from scientists at the very pinnacle of their fields like David Nichols at UNC-Chapel Hill and Lindsay Cameron at Stanford, who testified that these drugs hold the key to unlocking tremendously important mysteries of the brain and body. We heard from scientists in diverse fields like pain, mental health, inflammation, and many more, all decrying this proposed rulemaking as unnecessary, not evidence-based, and unimaginably damaging to research and public health.

So, when considering "What, if any, risk there is to the public health", there is only one risk: the risk of what will be lost if these compounds are scheduled. The risk that careers will be altered, that therapies will go undiscovered, that scientific knowledge will not be gained, and with it the solutions to myriad diseases and maladies affecting every aspect of our society. For the above stated reasons, the harm to research that would occur by placing DOI and DOC in Schedule I should be considered within Factor 6 of the CSA's Eight Factor Analysis.

In determining the weight to be given to an issue in an administrative agency's interpretation of a proposed rule, courts rely on principles rooted in administrative law. The weight

of such a judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control. *Skidmore v. Swift Co*, 323 U.S. 134, (1944) Under Skidmore, the weight that should be afforded is predicated on the thoroughness of the agency's reasoning, consistency of the agency's interpretation over time, the agency's expertise and specialized knowledge and the validity of the interpretation in the broader statutory and regulatory context. *Id.*

In the interpretation of statutes, the function of the courts is easily stated. It is to construe the language so as to give effect to the intent of Congress. *U.S. v. Amer. Trucking Ass'ns,* 310 U.S. 534, 542-43 (1940) There is no invariable rule for the discovery of that intention. *Id.* There is, of course, no more persuasive evidence of the purpose of a statute than the words by which the legislature undertook to give expression to its wishes. *Id.* Often these words are sufficient in and of themselves to determine the purpose of the legislation. *Id.* In such cases, we have followed their plain meaning, but when that meaning has led to absurd or futile results, however Courts have looked beyond the words to the purpose of the act. *Id.* Frequently, however, even when the plain meaning did not produce absurd results but merely an unreasonable one "plainly at variance with the policy of the legislation as a whole," Courts have followed that purpose rather than the literal words. *Id.* The interpretation of the meaning of statutes, as applied to justiciable controversies, is exclusively a judicial function. *Id.* This duty requires one body of public servants, the judges, to construe the meaning of what another body, the legislators, has said. *Id.*

The agency or proponent of the rule has the burden of proof, and such rules must be issued “on consideration of the whole record … and supported by … substantial evidence.” 5 U.S.C. § 556(d). As a general matter, there is a “strong presumption that Congress intends judicial review

of administrative action." *Bowen v. Mich. Acad. of Family Phys*. 476 U.S. 667, 670 (1986); The APA provides that courts may hold unlawful and set aside agency actions under a number of circumstances including if the actions are unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute. 5 U.S.C. §§ 701-706. The contours of "arbitrary and capricious" review were articulated in the Supreme Court's decision of *Motor Vehicle Manufacturers Association v. State Farm Auto Mutual Insurance Co.* 463 U.S. 29, 42-44 (1983). In State Farm, the Court explained that "a court is not to substitute its judgment for that of the agency" but rather, a court should only invalidate agency determinations that fail to "examine the relevant data and articulate a satisfactory explanation for [the] action including a 'rational connection between the facts found and the choice made.'" *Id.* at 43 (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)). When reviewing that determination, courts must "consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Id.* (quoting *Burlington Truck Lines*, 371 U.S. at 168).

In general, the Court will find an agency decision is arbitrary and capricious: if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise. Fundamentally, the arbitrary and capricious standard requires that an agency demonstrate that it engaged in reasoned decision-making by providing an adequate explanation for its decision. *State Farm*, 463 U.S. at 52; *Petroleum Commc'ns, Inc. v. FCC*, 22 F.3d 1164, 1172 (D.C. Cir. 1994). The agency must be able to provide the "essential facts upon which the administrative decision was based" and explain what justifies the determination with

actual evidence beyond a "conclusory statement." *United States v. Dierckman*, 201 F.3d 915, 926 (7th Cir. 2000) (quoting Bagdonas v. Dep't of the Treasury, 93 F.3d 422, 426 (7th Cir. 1996)); *Allied-Signal, Inc. v. Nuclear Reg. Comm'n*, 988 F.2d 146, 152 (D.C. Cir. 1993). An agency decision that is the product of "illogical" or inconsistent reasoning; that fails to consider an important factor relevant to its action, such as the policy effects of its decision or vital aspects of the problem in the issue before it; *Ctr. for Biological Diversity v. U.S. Bureau of Land Mgmt*., 698 F.3d 1101, 1124 (9th Cir. 2012) or that fails to consider "less restrictive, yet easily administered" regulatory alternatives, *Cin. Bell Tel. Co. v. FCC,* 69 F.3d 752, 761 (6th Cir. 1995). will similarly fail the arbitrary and capricious test. *Id*.

A reviewing court may still accord the agency construction of a statute significant weight pursuant to reasoning established in *Skidmore v. Swift Co*, 323 U.S. 134, (1944). The weight of such a judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control. *Id.*

In the interpretation of statutes, the function of the courts is easily stated. It is to construe the language so as to give effect to the intent of Congress. *U.S. v. Amer. Trucking Ass'ns,* 310 U.S. 534, 542-43 (1940) There is no invariable rule for the discovery of that intention. *Id.* There is, of course, no more persuasive evidence of the purpose of a statute than the words by which the legislature undertook to give expression to its wishes. *Id.* Often these words are sufficient in and of themselves to determine the purpose of the legislation. *Id.* In such cases, we have followed their plain meaning, but when that meaning has led to absurd or futile results, however Courts have looked beyond the words to the purpose of the act. *Id.* Frequently, however, even when the plain meaning did not produce absurd results but merely an unreasonable one "plainly at variance with

the policy of the legislation as a whole" Courts have followed that purpose, rather than the literal words. Id When aid to the construction of the meaning of words, as used in the statute, is available, there certainly can be no "rule of law" that forbids its use, however clear the words may appear on "superficial examination." *Id.* at 544.

Modern jurisprudence based upon the aforementioned case law supports a broad notion that courts should endeavor to avoid absurd results and should effectuate the intent of Congress. The intent of the CSA was not to cause harm to public health but rather to protect public health. When research has the potential to reduce harm to public health, the best reading of the CSA is one that preserves that research. If not even a scintilla of harm has been demonstrated regarding a substance, and severe impact was to occur through curtailing access to that substance, possibly ending research that could lead to novel treatments addressing some of the most pressing health issues facing the nation, the best reading of the CSA as well as any reasonable reading of the statute mandates affording great weight to the impact of research harm. Case law supports the judiciary's role in guiding the law's application to prevent aberrant results, and Loper Bright would seem to mandate this, barring a clear mandate in the statute to the contrary. For these reasons, we request that this Tribunal, at a minimum, afford research harm the same importance as any other factor under consideration in scheduling.

B. Loper Bright and the End of Chevron Deference

In 1984, the Supreme Court decided the foundational administrative law case Chevron U.S.A., Inc. v. Natural Resources Defense Council. *See Chevron U.S.A., Inc. v. Nat. Res. Def. Council*, 467 U.S. 837 (1984). Under the Chevron Doctrine, where a statute was "silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Id*. at 843. When Congress is silent

on an issue, it has implicitly delegated to an agency the responsibility to interpret the law by regulation. *See id*. at 843-44. Such agency interpretations were given controlling weight unless they were “arbitrary, capricious, or manifestly contrary to the statute." *Id*. at 844.

The basic requirement of the Chevron doctrine was a "two-step" approach to judicial review of agency interpretations of their authorizing statute requiring reviewing courts to ask two questions. *Id.* at 842-43. First, using the "traditional tools of statutory construction," has us first assess "whether Congress has directly spoken to the precise question at issue." *Id.* at 842. If congressional intent was “clear”, the court was required to enforce that answer, regardless of the agency's views. *Id.* If not, then the court would ask whether the agency's interpretation was one that a reasonable interpreter might adopt. *Id.* at 843-44. If reasonable, the court would uphold the agency interpretation as permissible, even if it was not the one the court regards as the best interpretation. *Id*. at 843 n.11. Under the Chevron doctrine, courts were required to defer to "permissible" agency interpretations of the statutes those agencies administer-even when a reviewing court interpreted the statute differently. *Id.* at 843.

The Supreme Court overruled the Chevron doctrine with its decision in *Loper Bright*. *See Loper Bright Enterprises v. Raimondo*, 144 S. Ct. 2244 (2024). The Court held that the Administrative Procedure Act requires courts to exercise their independent judgment in deciding whether an agency has acted within its statutory authority, and courts may not defer to an agency interpretation of the law simply because a statute is ambiguous. Id. Congress in 1946 enacted the APA "as a check upon administrators whose zeal might otherwise have carried them to excesses not contemplated in legislation creating their offices." *Id.* at 13 (Quoting Morton Salt, 338 U.S., at 644). The APA establishes procedures for agency actions and outlines the fundamental framework for judicial review of those actions. *Id.* It also codifies a principle that has been a cornerstone of

judicial practice since *Marbury v. Madison*: courts resolve legal questions by exercising their own independent judgment. *Id.* at 14

The APA requires courts, not agencies, to decide "all relevant questions of law" arising on review of agency action, including those involving ambiguous laws. *Id.* It prescribes no deferential standard for courts to answer those legal questions despite mandating deferential judicial review of agency policymaking and factfinding. *Id.* The Court stated, "And by directing courts to "interpret constitutional and statutory provisions" without differentiating between the two, §706, it makes clear that agency interpretations of statutes—like agency interpretations of the Constitution—are not entitled to deference." *Id.* at 14-15. Under §706(2)(A) of the APA, agency action is to be set aside if "arbitrary, capricious, [or] an abuse of discretion". *Id.* at 14. Under §706(2)(E), agency factfinding in formal proceedings is to be set aside if "unsupported by substantial evidence." *Id.* at 14. Under the APA, it thus "remains the responsibility of the court to decide whether the law means what the agency says." *Id.* at 15 (Quoting *Perez v. Mortgage Bankers Assn.*, 575 U. S. 92, 109 (2015) (Scalia, J., concurring in judgment)).

The Court held: "When the best reading of a statute is that it delegates discretionary authority to an agency, the role of the reviewing court under the APA is, as always, to independently interpret the statute and effectuate the will of Congress subject to constitutional limits. The court fulfills that role by recognizing constitutional delegations, "fix[ing] the boundaries of [the] delegated authority," H. Monaghan, Marbury and the Administrative State, 83 Colum. L. Rev. 1, 27 (1983), and ensuring the agency has engaged in "'reasoned decisionmaking' " within those boundaries, Michigan, 576 U. S., at 750 (quoting *Allentown Mack Sales & Service, Inc. v. NLRB*, 522 U. S. 359, 374 (1998)); see also *Motor Vehicle Mfrs. Assn. of United States, Inc. v. State Farm*

Mut. Automobile Ins. Co., 463 U. S. 29 (1983). By doing so, a court upholds the traditional conception of the judicial function that the APA adopts." *Id.* at 17-18.

Chevron defied the command of the APA that it was "the reviewing court"—not the agency whose action it reviews—is to "decide all relevant questions of law" and "interpret . . . statutory provisions." §706 (emphasis added). It requires a court to ignore, not follow, "the reading the court would have reached" had it exercised its independent judgment as required by the APA. Chevron demanded that courts mechanically afford binding deference to agency interpretations, including those that have been inconsistent over time. *Id.* at 21; *See* 467 U. S., at 863. Chevron itself noted that ambiguities may result from Congress's inability to squarely answer the question at hand or from a failure to even "consider the question" with the requisite precision. *Id.* at 22 (Quoting 467 U. S., at 865). In neither case does an ambiguity necessarily reflect a congressional intent that an agency, instead of a court, resolve the resulting interpretive question, and many or perhaps most statutory ambiguities may be unintentional. *Id.*

When faced with a statutory ambiguity, the ambiguity is not a delegation, and a court is not somehow relieved of its obligation to independently interpret the statute. *Id.* Courts cannot throw up their hands because "Congress's instructions have" supposedly "run out," leaving a statutory "gap." *Id.* Courts instead understand that such statutes, no matter how impenetrable, do— in fact, must—have a single, best meaning. *Id.* Instead of declaring a particular party's reading "permissible" in such a case, courts use every tool at their disposal to determine the best reading of the statute and resolve the ambiguity. *Id.* at 23.

In any agency case, as in any other, there is always a "best" interpretation of a statute — "the reading the court would have reached" using its independent judgment if no agency

interpretation were involved. *Id.* at 23 (Quoting *Chevron,* 467 U.S. at 843 n.11.). In Loper Bright, the Court stated:

"It, therefore, makes no sense to speak of a 'permissible" interpretation that is not the one the court, after applying all relevant interpretive tools, concludes is best. In the business of statutory interpretation, *if it is not the best, it is not permissible*. [emphasis added] Perhaps most fundamentally, Chevron's presumption is misguided because agencies have no special competence in resolving statutory ambiguities. Courts do. The Framers, as noted, anticipated that courts would often confront statutory ambiguities and expected that courts would resolve them by exercising independent legal judgment. And even Chevron itself reaffirmed that "[t]he judiciary is the final authority on issues of statutory construction" and recognized that "in the absence of an administrative interpretation," it is "necessary" for a court to "impose its own construction on the statute." *Id.*, at 843, and n. 9. Chevron gravely erred, though, in concluding that the inquiry is fundamentally different just because an administrative interpretation is in play. The very point of the traditional tools of statutory construction—the tools courts use every day— is to resolve statutory ambiguities. That is no less true when the ambiguity is about the scope of an agency's own power—perhaps the occasion on which abdication in favor of the agency is least appropriate." *Id.* at 23.

The Loper Bright Court disavowed the claim that deference must be given to the agency's judgment when technical matters are involved. *Id.* at 24. When an ambiguity implicates a technical matter, it does not follow that Congress has taken the power to authoritatively interpret the statute from the courts and give it to the agency but rather, Congress expects courts to handle technical statutory questions. *Id.* "[M]any statutory cases" call upon "courts [to] interpret the mass of technical detail that is the ordinary diet of the law," *Egelhoff v. Egelhoff*, 532 U. S. 141, 161 (2001)

(Breyer, J., dissenting), and courts did so without issue in agency cases before Chevron, see post, at 30 (GORSUCH, J., concurring).” *Id*. The Court held that a better presumption is that Congress expects courts to do their ordinary job of interpreting statutes with due respect for the views of the Executive Branch. *Id.* at 25.

The Court refuted notions that statutory interpretation of ambiguous statutory provisions amounts to policy making and is better suited to political actors and not judges. *Id.* at 26. Resolving statutory ambiguities is fundamentally a matter of legal interpretation, not policymaking. Regardless of the context, courts interpret statutes using the traditional tools of statutory construction and not by relying on personal policy preferences, even when a court has an "agency to fall back on." *Id*. (Quoting *Kisor v. Wilkie*, 588 U. S. at 575 (opinion of the Court)). As they did without an issue before Chevron, Congress expects courts to handle technical statutory questions, and delegating ultimate interpretive authority to agencies is unnecessary to ensure that the resolution of statutory ambiguities is well informed by subject matter expertise. *Id.* at 25.

The Court opined that Chevron has proved to be fundamentally misguided and, for its entire existence, has been a “rule in search of a justification” if it was ever coherent enough to be called a rule at all. *Id. at 29-30* (Quoting *Knick*, 588 U. S., at 204). A statute's basic nature and meaning does not change when an agency is involved, and it does not change because the agency has offered its interpretation through the sort of procedures necessary to obtain deference or because the other preconditions for Chevron happen to be satisfied. *Id.* at 31. A statute still has a best meaning, necessarily discernible by a court deploying its full interpretive toolkit. *Id.* at 31. Four decades after its inception, Chevron had become an impediment rather than an aid in accomplishing the basic judicial task of “say[ing] what the law is.” *Id.* at 32 (Quoting *Marbury*, 1 Cranch, at 177).

Under Chevron, statutory ambiguity became a license that authorized agencies to change positions as much as they liked and to change course even when Congress had given them no power to do so. *Id.* at 33. Chevron fostered unwarranted instability in the law and left an "eternal fog of uncertainty." *Id.* Chevron was a judicial invention that required judges to disregard their statutory duties. *Id.* at 34. In his concurring opinion, Justice Thomas opined that although the Framers drafted a Constitution that divides the legislative, executive, and judicial powers between three branches of Government, Chevron's deference compromised this separation of powers by curbing the judicial power afforded to courts and simultaneously expanded agencies' executive power beyond constitutional limits. *See Loper Bright*, 603 U. S. ____ (2024) (opinion of THOMAS, J.). By tying a judge's hands, Chevron prevented the Judiciary from serving as a constitutional check on the Executive and allowed "the Executive . . . to dictate the outcome of cases through erroneous interpretations." Id. (quoting *Baldwin*, 589 U. S., at ___ (opinion of THOMAS, J.)). Chevron's deference also permitted the Executive Branch to exercise judicial power by allowing agencies to interpret laws so long as they were ambiguous, transferring the Judiciary's interpretive judgment to the agency. *Id.,* at 4. Chevron was a fundamental disruption of the separation of powers, improperly stripping courts of judicial power and simultaneously increasing executive agencies' power. *Id.* For these reasons, the Court held:

> Chevron is overruled. Courts must exercise their independent judgment in deciding whether an agency has acted within its statutory authority, as the APA requires. Careful attention to the judgment of the Executive Branch may help inform that inquiry. And when a particular statute delegates authority to an agency consistent with constitutional limits, courts must respect the delegation, while ensuring that the agency acts within it. But courts need not and under the APA may not defer to an agency interpretation of the law simply because a statute is ambiguous.

Chief Justice Roberts characterized Chevron as a doctrine about interpretive method. *Loper Bright,* 603 U. S. ____ (2024) at 34. A later court might cite the use of the disapproved method as evidence that the precedent was wrong, but mere error does not deprive statutory interpretation decisions of strong stare decisis effect. *Id.* "Mere reliance on Chevron cannot constitute a "'special justification'" for overruling such a holding. Halliburton Co. v. Erica P. John Fund, Inc., 573 U. S. 258, 266 (quoting Dickerson v. United States, 530 U. S. 428, 443). Pp. 29–35." *Id.* However, in his concurring opinion, Justice Gorsuch wrote, "Proper respect for precedent helps "keep the scale of justice even and steady," by reinforcing decisional rules consistent with the law upon which all can rely. 1 Blackstone 69. But that respect does not require, nor does it readily tolerate, a steadfast refusal to correct mistakes." *Id.* at 31(opinion of GORSUCH, N.). Justice William O. Douglas observed how a new colleague might be inclined initially to "revere" every word written in an opinion issued before he arrived but, over time, Justice Douglas reflected, his new colleague would "remembe[r] . . . that it is the Constitution which he swore to support and defend, not the gloss which his predecessors may have put on it." *Id.* at 32 (Quoting W. Douglas, Stare Decisis, 49 Colum. L. Rev. 735, 736 (1949).). Justice Douglas explained, this process of reexamination, Justice is a "necessary consequence of our system" in which each judge takes an oath—both "personal" and binding—to discern the law's meaning for himself and apply it faithfully in the cases that come before him. *Id.*

Administrative Law Judges and Judicial Review

There can be "little doubt that the role of the modern hearing examiner or administrative law judge within this framework is 'functionally comparable' to that of a judge." *Butz v. Economou*, 438 U.S. 478, 513 (1978). "His powers are often, if not generally, comparable to those of a trial judge: He may issue subpoenas, rule on proffers of evidence, regulate the course of the

hearing, and make or recommend decisions." *Id. See also* § 556(c). The agency adjudication process must be structured to assure that the hearing examiner or ALJ exercises independent judgment on the evidence before him, free from pressure by the parties or officials within the agency. *Id.* Courts face a difficult challenge to determine, cx post, whether the agency was fair and reasonable in its fact-finding. There is no clear alternative to reliance on the record development provided by an independent ALJ system, which requires an independent exercise of judgment by the ALJ.

Judicial review is tied to examining the administrative record for evidence that an agency has failed to provide a fair review and analysis of relevant facts to reach its desired goals impermissibly. It is crucial that ALJs have independence from the agencies within which they work so as to generate an unbiased and fair initial administrative record. Courts and ALJs are thus engaged in a form of cooperative review, constraining agency fact-finding from both the top and the bottom. Absent an independent ALJ, the agency would be free to develop the administrative record to prevent the appearance of red flags, essentially nullifying effective judicial review.

The Impact of *Loper Bright*

Chevron's deference insulated the DEA from meaningful judicial review, allowing the agency to interpret ambiguous statutory language in a manner that expanded its authority, particularly in the classification of controlled substances. *Loper Bright* provides a critical opportunity to curtail administrative overreach and restore the balance of power between agencies, Congress, and the judiciary. Returning authority to the judiciary will allow for the system of checks and balances to ensure the separation of powers is honored, leading to greater accountability and adherence to statutory authority. In doing so, this Tribunal can ensure that the DEA's drug scheduling decisions reflect modern science, public health priorities, and the true legislative intent

of Congress regarding the CSA. This shift is legally necessary and essential for fostering public trust and advancing fair and evidence-based drug policies.

A particularly relevant case to this scheduling action is that of *Grinspoon v. Drug Enforcement Admin*., 828 F.2d 881 (1987). In *Grinspoon*, Dr. Lester Grinspoon, a psychiatrist and faculty member of the Harvard Medical School, challenged the Drug Enforcement Administration's (DEA) decision to classify MDMA as a Schedule I controlled substance under the Controlled Substances Act (CSA). *Id.* The case involved a challenge to the Drug Enforcement Administration's interpretation of the Controlled Substances Act's criteria for scheduling MDMA and requested the Court vacate the Administrator's decision to add MDMA to Schedule I. *Id.* Grinspoon argued the Administrator applied the wrong legal standards for "currently accepted medical use in treatment in the United States" and for "accepted safety for use ... under medical supervision" in 21 U.S.C. Sec. 812 (b) (1). Id Grinspoon questioned whether the lack of FDA approval can fulfill the statutory requirements for no currently accepted medical use and lack of safety for use under medical supervision. The other three reasons contained in Dr. Grinspoon's petition challenged the scheduling determination as arbitrary and capricious because (a) the Administrator's determination that MDMA had a "high" potential for abuse was flawed by his failure to articulate a legal standard and his reliance on insufficient record evidence; (b) the Administrator failed to give adequate weight to the evidence showing that placing MDMA into Schedule I would create a barrier to medical research on the drug; and (c) the rule is based upon incomplete and arbitrary recommendations from the Secretary of Health and Human Services. The court examined whether the Drug Enforcement Administration's determination that MDMA has a high potential for abuse was supported by substantial evidence, including structural similarities to other Schedule I or II substances and instances of actual abuse. Grinspoon challenged the Drug

Enforcement Administration's reliance on recommendations from the Department of Health and Human Services, arguing procedural inadequacies in the evaluation process and the sufficiency of evidence reviewed.

The Court held that Dr. Grinspoon's first claim regarding the DEA's requirement of FDA approval had considerable merit and remanded the scheduling determination for reconsideration by the Administrator. *Id.* at 883. The Court then reviewed Grinspoon's remaining three claims. *Id.* The Court held the DEA's interpretation of the CSA must be viewed in light of the guidelines set forth in Chevron. Id at 884. The Court employed the two-step Chevron analysis, focusing first on whether Congress had directly spoken to the precise question at issue. *Id.* The Court held, "It is undisputed that Congress has not directly spoken to the question at issue here, namely, the proper means of interpreting the second and third criteria of section 812(b)(1)." *Id.* at 885. Based solely on the language of the CSA and the FDCA, the Court found the lack of FDA interstate marketing approval for the statutory requirements sufficient to establish a substance lacked both an "accepted medical use" and "accepted safety for use ... under medical supervision" and was inconsistent with the intent of Congress in enacting the CSA. *Id.* at 888.

The Court then considered Grinspoon's arguments objecting to the DEA's understanding of "high potential for abuse." *Id.* at 893. Although the Court held that the CSA provides no definition of the phrase "high potential for abuse," the statute's legislative history provided guidance in this regard. The report of the House Committee on Interstate and Foreign Commerce accompanying the bill that eventually became the CSA set forth four alternative legal standards for determining when a substance possesses a "potential for abuse," which would become known as the "four-prong test." *Id.* The Court referenced the Hearings on Drug Abuse Control Amendments Before the Subcommittee on Public Health and Welfare of the House

Committee on Interstate and Foreign Commerce, 91st Cong., 2d Sess. 696 (1970). *Id.* The House Committee Report stated the Committee Report states that "potential for abuse" exists only when there is "a substantial potential for the occurrence of significant diversions from legitimate channels, significant use by individuals contrary to professional advice, or substantial capability of creating hazards to the health of the user or the safety of the community." *House Committee Report* at 4602. The Court held that the Administrator's construction of subsections (B) and (C) of 21 U.S.C. Sec. 812(b)(1) was contrary to congressional intent. The Court stated that Our review of the litigants' sources convinces us that Congress neither expressed nor implied an affirmative intent regarding how the second and third Schedule I criteria should be interpreted. Nevertheless, these same sources--the language and structure of the CSA and FDCA, the legislative history of the CSA, and the subsequent handiwork of Congress in the area of controlled substance regulation--lead the Court to conclude that the Administrator's construction of subsections (B) and (C) of 21 U.S.C. Sec. 812(b)(1) is contrary to Congressional intent. *Id.* at 886. The Court also clarified the Administrator's lack of authority to define general statutory terms:

> Contrary to the assertions of the Administrator, this is not a situation in which Congress has expressly vested the Administrator with authority to define general statutory criteria by issuing regulations. Were this such a case, such regulations would be controlling unless they were "arbitrary, capricious, or manifestly contrary to the statute." Chevron, 467 U.S. at 843-44, 104 S.Ct. at 2782. Here, the CSA expressly delegates to the Attorney General only the authority to make "the findings prescribed by subsection (b) of section 812 of this title for the schedule in which [a] drug is to be placed." 21 U.S.C. Sec. 811(a)(1)(B) (emphasis supplied). This explicit delegation of authority to apply prescribed statutory criteria is not equivalent to an explicit delegation of authority to define those criteria. *Id.* at N. 5.

The Supreme Court's decision in Loper Bright fundamentally altered the landscape of administrative law by overruling the Chevron doctrine, which had been a cornerstone for judicial deference to agency interpretations of ambiguous statutes. Rather than deferring to the DEA's

interpretation of the CSA under the prior reasonableness standard, now under Loper Bright, judges must find the "best reading of the statute." Loper Bright at 25. When the best reading of a statute is that it delegates discretionary authority to an agency, the role of the reviewing court under the APA is, as always, to independently interpret the statute and effectuate the will of Congress subject to constitutional limits. *Id.* When the Grinspoon court found no explicit congressional intent regarding the potential for abuse, it deferred to the DEA. Yet, Loper Bright dismantles this rationale, requiring courts to resolve ambiguities through traditional tools of statutory interpretation rather than deferring to the agency. The statutory language of the CSA does not explicitly tether "accepted medical use" to FDA approval. Under Loper Bright, a court would likely find that the DEA's interpretation exceeds its statutory authority, given the absence of a clear congressional mandate. Furthermore, evaluating the holding in Grinspoon under the requirement for the "best reading of the statute" rather than the very low bar of "reasonableness" renders the precedent set in Grinspoon relying on Chevron deference untenable as good law. Loper Bright restores the principle that courts, not agencies, have the final authority to interpret ambiguous statutes.

While Loper Bright does not automatically invalidate cases decided under Chevron, its rejection of Chevron deference necessitates re-evaluating cases like Grinspoon. The rationale underlying Grinspoon—the permissibility of the DEA's interpretation in the face of statutory ambiguity—is incompatible with Loper Bright's requirement for courts to make independent legal determinations. Furthermore, the policy concerns cited in Grinspoon regarding barriers to research on MDMA underscore the dangers of excessive deference and align with Loper Bright's criticism of agency overreach.

C. International Treaty Obligations Regarding DOC

In considering potential obligations, we propose that neither the Single Convention nor the CSA requires DEA to place DOC in Schedule I or Schedule II. Both the Single Convention and the CSA allow DEA to satisfy the United States' international obligations by supplementing scheduling decisions with regulatory action, at least in circumstances where there is a modest gap between the Convention's requirements and the specific controls that follow from a drug's placement on a particular schedule. *Questions Related to the Potential Rescheduling of Marijuana,* 48 Op. O.L.C. __ (Apr. 11, 2024) As a result, we propose that DEA may satisfy the United States' Single Convention obligations by placing DOC in Schedule III through V while imposing additional controls pursuant to the CSA's regulatory authorities. *Id.* at 28.

The CSA provides broad regulatory authority and further suggests that DEA need not rely on scheduling decisions alone to comply with the Single Convention. *Id.* at 29. The CSA authorizes the Attorney General (and thus DEA) both to "promulgate rules and regulations . . . relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances," 21 U.S.C. § 821, and to "promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions," 21 U.S.C. § 871(b). *Id.* Courts recognize that broad, discretionary language such as this conveys "extensive" regulatory authority, Volpe, 486 F.2d at 761; see also, e.g., Friends of Animals v. Bernhardt, 961 F.3d 1197, 1209 (D.C. Cir. 2020)—and, here, the language by its plain terms would seem to encompass regulatory actions that DEA may take to satisfy Single Convention obligations not met by a drug's schedule alone. *Id.*

Based upon the Memorandum Opinion For The Attorney General, the DEA is not required to place DOC under Schedule I to comply with international treaty obligations. *Id.* To prevent research harm and as we believe that the DEA has failed to meet their evidentiary burden

requisite for classification under Schedule I, we believe a more appropriate resolution would be not to schedule DOC and institute additional control measures.

VI. CONCLUSION

For the reasons set out above, Petitioners SSDP and Dr. Raul Ramos respectfully submit that DOI and DOC should not be placed in Schedule I under the Controlled Substances Act. Keeping DOI and DOC unscheduled is the only scheduling decision consistent with the criteria set out in the Controlled Substances Act based on the evidence presented. Further, it will allow needed research into DOI and DOC's therapeutic potentials to continue instead of obstructing it. The damage that would be done by placing these substances into Schedule I vastly outweighs any negligible benefit that may come from such action.

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Respectfully submitted,

Brett Phelps, Esq.
PHELPS LAW OFFICE
P.O. Box 1777
Las Vegas, NM 87701
(505) 425-5129
(505) 454-8936 FAX
brett@brettphelpslaw.com
Attorney for Science Policy Council, Students for Sensible Drug Policy

/s/ Robert T, Rush
Signature

Robert T. Rush, Esq.
LAW OFFICE OF ROBERT T. RUSH
600 17th Street
Suite 2800 South
Denver, CO 80202
(201)759-1493
rrush@rrushlaw.com
Attorney for Dr. Raoul M. Ramos

CERTIFICATE OF SERVICE

This is to certify that the undersigned, on January 6, 2025, 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) Paul A. Dean, Esq., Counsel for the Government, via email at Paul.A.Dean@usdoj.gov and to the DEA Government Mailbox at dea.registration.litigation@dea.gov; (5) David Heldreth, CEO of Panacea Plant Sciences, via email at davidh@panaceaplantsciences.net; (6) Brett J. Phelps, Esq., Counsel for Science Policy Council, Students for Sensible Drug Policy, via email at brett@brettphelpslaw.com; and (7) Robert T. Rush, Esq., Counsel for Ramos, via email at rrush@rrushlaw.com.

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Brett Phelps, Esq.
PHELPS LAW OFFICE
P.O. Box 1777
Las Vegas, NM 87701
(505) 425-5129
(505) 454-8936 FAX
brett@brettphelpslaw.com
Attorney for SSDP