UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

In the Matter of **Scheduling 2,5-Dimethoxy-4-chloroamphetamine and 2,5-Dimethoxy-4-iodoamphetamine**	**Docket No. 24-24** ADMINISTRATIVE LAW JUDGE PAUL E. SOEFFING

Response in Opposition to Government's Motion in Limine

Petitioners Science Policy Council, Students for a Sensible Drug Policy ("SSDP") and Dr. Raoul M. Ramos (collectively, "Petitioners") by and through their attorneys, hereby file their Opposition to Government's Motion in Limine. For the reasons discussed herein, the Government's Motion must be denied.

Overview

The Government moves to exclude various witnesses, witness testimony, and exhibits proposed on the grounds purporting much of the testimony and exhibits are incompetent, irrelevant, immaterial, and/or unduly repetitious despite the less rigid evidentiary rules that exist for administrative hearings where courts have repeatedly established that the Administrative Law Judge (ALJ) has great deference in deciding what evidence may be permitted. The Government moves to severely restrict virtually all the Petitioners' witnesses based on a pedantic analysis of the summaries of testimony offered in the Petitioners' Prehearing Statement that mischaracterizes their proposed testimony and attempts to preclude testimony that may be regarded as expert opinion testimony in addition to excluding non-opinion evidence. The Government further

incorrectly claims that evidence of "research harm" is irrelevant. Finally, the Government attempts to exclude the testimony entirely of Dr. David Nichols, Dr. David Nutt, and Dr. Jason Younkin despite decades of experience and being leading figures in psychopharmacology, pharmaceutical science, and medicinal chemistry.

Issues Regarding Labeling and Disclosure of Exhibits

The Government raises the issue in their Motion in Limine that the proposed exhibits disclosed by Petitioners were not properly paginated or marked for exhibit purposes. The final versions submitted to the Administrative Law Judge via hardcopy and via the Box.com submission folder (labeled Scheduling DOI-DOC Docket No. 24-24) are indeed properly paginated and marked for exhibit purposes. All of these exhibits and page number totals are properly disclosed in the Table of Contents submitted along with the marked exhibits. Unfortunately, DOJ's document submission system does not allow Petitioners access to modify previous submissions so the earlier disclosed documents do not have full pagination or exhibit identification. However, the Government has access to the properly paginated and identified Table of Contents and Proposed Exhibits in the final submission folder. Therefore, Petitioners' proposed exhibits are in compliance with the Court's prehearing ruling.

The Government notes in their Motion in Limine that Petitioners have not disclosed what was originally marked in the the Joint Prehearing Statement as Exhbits 7, 34, 44, 47, and 72. Petitioners stipulate that Exhibits 7, 34, 44, 47, and 72 were not properly disclosed and Petitioners do not intend to introduce them as exhibits at the hearing.

The Government also argues that proposed exhibits 2, 6, 14-15, 23, 27, 29-31, 37, 43, 56, 58-60, and 85 are not referenced or mentioned in the prehearing statement, and that proposed exhibit 10 is not mentioned by authoer or number. Proposed Exhibit 2 is referenced in Tanner

Anderson's proposed testminony and was timely disclosed to the Government on September 11, 2024. In regards to proposed Exhibit 10, this is indeed the article referenced in Dr. Mario de la Fuente Revanga's summary of proposed testimony and referred to in the Government's Motion in Limine. The information included in Exhibit 85 is specifically identified in Dr. Joseph Palamar's proposed summary of testimony and therefore is properly disclosed and admissible. For these reasons, Petitioners argue that proposed Exhibits 2, 10, and 85 should not be excluded from admission at the hearing. While proposed Exhibit 37 is not mentioned specifically, Dr. Alaina Jaster's proposed testimony does raise the issue of current criticisms of drug discrimination research and therefore Exhibit 37 is relevant and should not be excluded.

In regards to the remaining Exhibits mentioned by the Government in the Motion in Limine, specifically Exhibits 6, 14-15, 23, 27, 29-31, 43, 56, and 58-60, Petitioners stipulate that these exhibits were not properly identified in Petitioners' Prehearing Statements and therefore should not be admitted.

Admissibility of Evidence in Administrative Proceedings

Evidence is admissible if it is "competent, relevant, material, and not unduly repetitious." *See* 21 C.F.R. § 1316.59. Federal administrative proceedings have long been exempt from most of the formal rules of evidence that govern trials before juries. As early as 1904, the Supreme Court declared that the inquiries of the Interstate Commerce Commission should not be hampered by the "narrow rules [of proof] which prevail in trials at common law." *ICC v. Baird,* 194 U.S. 25, 44 (1904). Rather than shackle agencies with rigid adherence to such rules, courts have encouraged administrative decision-makers to consider "all evidence which can conceivably throw any light" upon the issue at hand. *Samuel H. Moss, Inc. v. FTC*, 148 F.2d 378, 380 (2d Cir. 1945) "In a bench trial, 'it is virtually impossible for a trial judge to commit reversible error by receiving incompetent

evidence, whether objected to or not.'" *Builders Steel Co. v. Comm'r*, 179 F.2d 377, 379 (8th Cir. 1950) Applying this principal to administrative agencies, courts have "strongly advise[d] administrative law judges: if in doubt, let it in." *Multi-Med. Convalescent & Nursing Ctr. of Towson v. NLRB*, 550 F.2d 974, 978 (4th Cir. 1977)

The Court in *Klinestiver* held, "Accordingly, we hold that nothing in 21 C.F.R. § 1316.59(a) requires DEA to limit admissible testimony to that which would be acceptable in a jury trial or under the Federal Rules of Evidence." *Klinestiver v. Drug Enforcement Administration*, 606 F.2d 1128 (D.C. Cir. 1979) Under the more stringent Federal Rules of Evidence, "[e]vidence is relevant if . . . it has any tendency to make a fact more or less probable than it would be without the evidence[] and . . . the fact is of consequence in determining the action." *See* Fed. R. Evid. 401. The Tenth Circuit has observed that this "standard is not stringent; it is aimed at each 'brick' of evidence potentially making a wall and not every witness 'mak[ing] a home run.'" *United States v. Yazzie*, 188 F.3d 1178, 1189 (10th Cir.1999) The "relevancy requirement under the federal rules" is "minimal [in] nature." *United States v. Murzyn*, 631 F.2d 525, 529 (7th Cir. 1980) Furthermore, "it is universally recognized that evidence, to be relevant to an inquiry, need not conclusively prove the ultimate fact in issue, but only have 'any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.'" *New Jersey v. T.L.O.*, 469 U.S. 325, 345 (1985).

Research Harm Is Relevant in Scheduling Determinations

In deciding whether to initiate proceedings for control or removal of a drug or other substance, in addition to the recommendation and the report of the Secretary of Health and Human Services, the Attorney General must consider these facts and "all other relevant data that constitute substantial evidence of potential for abuse such as to warrant control or substantial evidence that

the drug or other substance should be removed entirely from the schedules." *See* 21 C.F.R. § 811(b). In making any finding under 21 C.F.R. § 811(a) or 21 C.F.R. § 812(b), the Attorney General shall consider the eight-factors under 21 C.F.R. § 811(c).

The Government, in its own motion to exclude evidence of research harm as irrelevant, acknowledges, "comments regarding barriers or hinderances to research may be considered by the Administrator" yet then paradoxically argues "such evidence is not relevant to addressing the factors listed above and resolving the ultimate issues posed by 21 U.S.C. §§ 811 & 812(b)(1)." The Government cites *Grinspoon* in support of its position that harm to research is irrelevant, yet *Grinspoon* states the Administrator said explicitly that he "read with interest the comments from various parties in the record concerning the effect placement of MDMA into Schedule I would have on legitimate research into the substance." *Grinspoon v. Drug Enforcement Administration*, 828, F.2d 881, 896 (1st Cir. 1987) The Government claims in their motion that the Administrator considered harm to research in her analysis, and historically, the Administrator considered the harm to research scheduling may pose, yet antithetically, the Government claims harm to research is irrelevant. If harm to research is irrelevant, why did this Administrator consider harm to research in her analysis and past administrators acknowledge considering harm to research? The weight that the Administrator may assign to a particular factor is not the same question as to its relevancy.

The Adminstrator has been applying an interpretation presented *Grinspoon* that is not the best interpretation of 21 U.S.C. §§ 811 & 812. The Administrator in *Grinspoon* contended that congressional intent favoring his interpretation of the CSA can be gleaned from the language of the statute, its legislative history, and the language and history of subsequent legislative enactments designed to enhance the regulatory system established by the CSA in 1970. In the alternative, he argues that if the intent of Congress is ambiguous, then his construction of the statute is permissible

in view of the statutory scheme." *Id at 885*. In the notes of the opinion, the Court in *Grinspoon* commented, "this is not a situation in which Congress has expressly vested the Administrator with authority to define general statutory criteria by issuing regulations." *Id at 898.* The *Grinspoon* court then stated, "Our review of the sources identified by the litigants 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 us 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 885.* The Court in *Grinspoon* held "Our review of the legislative sources below also convinces us that the Administrator's interpretation is unreasonable and would be invalid even under the second prong of the *Chevron* test. *Id* at 898. The *Grinspoon* found the Administrator's interpretation of 812(b)(1) arbitrary and capricious regarding currently accepted medical use. *Id.*

The *Grinspoon* Court, citing *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 , 104 S.Ct. 2778 ,81 L.Ed.2d 694 (1984), stated: The nature of our review further constrains us from requiring the Administrator to adopt Dr. *Grinspoon*'s proposed construction of section 812(b)(1). Although we find that the Administrator's present interpretation of the second and third Schedule I criteria contravenes congressional intent, we are unable to ascertain with any certainty what Congress intended to be the proper interpretation of subsections (B) and (C). In other words, while we are satisfied that Congress intended to preclude reliance on the absence of FDA approval in assessing whether a substance has an "accepted medical use" and "accepted safety for use ... under medical supervision," we have found nothing to indicate how Congress affirmatively intended these two ambiguous statutory phrases to be construed and applied. It

appears to us that Congress has implicitly delegated to the Administrator the authority to interpret these portions of the CSA, and we must therefore refrain from imposing our own statutory interpretation upon the agency." *Id* at 892. The precedent that the Government relies on held that the Administrator's interpretation of 21 U.S.C. Sec. 812 contravened congressional intent but the Court was prevented from interjecting their interpretation because they were prevented by *Chevron*. *Id.*

In *Loper Bright Enters. v. Raimondo,* No. 22-4751, 2024 WL 3208360 (U.S. June 28, 2024) ("Loper Bright"), *the Supreme Court formally overruled Chevron*: "Courts must exercise their independent judgment in deciding whether an agency has acted within its statutory authority." *Id.* at 22. The Court's reasoning focused on the APA, which instructs "'the reviewing court' to 'decide all relevant questions of law' and 'interpret . . . statutory provisions.'" *Id.* at 16 (quoting 5 U.S.C. § 706). This requirement "cannot be squared with" *Chevron*'s directive to accept any "permissible" construction of an ambiguous statutory provision. *Id.* at 14, 18. Even when a "statute [is] ambiguous, there is a best reading all the same," and the reviewing court is required to adopt the one that "after applying all relevant interpretive tools, [it] concludes is best." *Id.* at 16. The Administrator's interpretation is far from the best interpretation of the 21 C.F.R. §§ 811 and 812 and is in contravention of congressional intent as stated in *Grinspoon*, the precedent the stand upon. For these reasons, in light of the overruling of *Chevron*, the Tribunal should not accept any of the Government's arguments predicated on *Grinspoon*.

Under 21 C.F.R. § 811(b), "the Secretary shall consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection (c) and any scientific or medical considerations involved in paragraphs (1), (4), and (5) of such subsection. … The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical

matters…" On April 16, 2018, Brett P. Giroir, M.D., Assistant Secretary for Health of the Department of Health and Human Services, issued a recommendation rescinding a prior recommendation from October 17, 2017, that the substances mitragynine and 7 hydroxymitragynine, two of the constituents of the plant Mitragyna speciosa (M. speciosa), commonly referred to as kratom, be permanently placed in Schedule I. *See* Exhibit I at 1. Dr. Giroir states, "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 any subsequent scheduling decision." *Id.* "I now conclude that while mitragynine and 7-hydroxymitragynine have many properties of an opioid, scheduling these chemicals at this time in light of the underdeveloped state of the science would be premature. For example, one recently published peer reviewed animal study indicated that mitragynine does not have abuse potential and actually reduced morphine intake. As such, these new data suggest that mitragynine does not satisfy the first of the three statutory requisites for Schedule I, irrespective of broader considerations of public health. While a single study is rarely dispositive, it strongly suggests that further evaluation is warranted." *Id.*

The Assistant Secretary stated in his HHS scheduling recommendation, "Furthermore, there is a significant risk of immediate adverse public health consequences for potentially millions of users if kratom or its components are included in Schedule l, such as: …The stifling effect of classification in Schedule I on critical research needed on the complex and potentially useful chemistry of components of kratom." *Id*. at 3-4. In Footnote 1, the Assistant Secretary commented, "I am also concerned about the impact of scheduling kratom on our ability to conduct research,

especially survey research and our currently inability to routinely test for kratom in those brought into an emergency room as a result of a possible overdose." *Id* at 4.

The Department of Health and Human Services has statutorily been given the authority to evaluate the risk to public health. *See* 21 C.F.R. § 811(c)(6). The Assistant Secretary considered the potential risk that adding a substance to Schedule I may have to public health by impacting and curtailing research. The Department of Health and Human Services found the impact on research to be not only relevant but also a significant determining factor in the decision not to add Kratom to Schedule I. The Department of Health and Human Services is an integral part of the decision-making process regarding whether to schedule a substance and "recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters…" See 21 C.F.R. § 811(b). In evaluating the risk to public health under subsection (c)(6) of section 811, HHS has found that research harm is a relevant factor in determining whether to add a substance to Schedule I; therefore, evidence of research harm is relevant. *Id.*

The Government Is Attempting to Exclude Expert Opinion Testimony Improperly

The ALJ's Order states, "The parties are herein noticed that, pursuant to 21 C.F.R. § 1316.59(b), '[o]pinion testimony shall be admitted when the presiding officer is satisfied that the witness is properly qualified.' A witness can be qualified as an expert based upon the witness' skill, training, knowledge, education, or experience. United Prescription Servs., Inc., 72 Fed. Reg. 50,397, 50,405 (2007)." *See* Second Order for Pre-hearing Statements (2nd Ord. PHS) at p. 4. The Petitioners filed their Supplemental Joint Prehearing Statement on September 12, 2024, indicating that all of the Petitioners' witnesses will be testifying as experts. The Government has not objected to the Petitioners' Witnesses testifying as experts. The Government has objected throughout their motion regarding many of the Petitioners' Witnesses that the testimony to be offered is speculative

or conclusory and should be excluded. The Government further argues, "David Heldreth's testimony must be excluded in its entirety. Mr. Heldreth is not offered as an expert and presents no expertise that would assist the Tribunal. … Any statements he may offer regarding abuse, misuse, or diversion are strictly speculative." The Government is attempting to preclude the testimony of the Petitioners' witnesses based on the same argument it makes to exclude Mr. Heldreth, even though they have not objected as to their offering testimony as experts.

Under the more stringent Federal Rules of Evidence, opinion testimony by an expert is permitted to assist the trier of fact in understanding the evidence or in determining a fact in issue. *See* Fed. R. Evid. 702. The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. *See* Fed. R. Evid. 703. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence for the opinion to be admitted. *Id*.

Determinations as to whether a witness meets the qualifications as an expert are made by the Tribunal. The Petitioners' witnesses' skills, training, knowledge, education, and experience qualify them as experts. Regardless, the Government has failed to object to the Petitioners' witnesses testifying as experts, and their objections must fail because, as experts, the Tribunal may consider testimony based on experts' opinions.

Summaries of Testimony Are Sufficient to Avoid Surprise

The Government moves to exclude witness testimony and exhibits alleging the Petitioners have failed to provide adequate disclosures in their pre-hearing statements, complying with the (the ALJ's Order that Petitioners provide witness summaries that "state what the testimony will be, rather than merely list[ing] the areas to be covered." See Second Order for Pre-hearing

Statements (2nd Ord. PHS) at p. 3. "The court must then decide whether plaintiffs' disclosures adequately comply with Rule..." *Hayes v. Am. Credit Acceptance, LLC, Case* No. 13-2413-RDR (D. Kan. Aug 12, 2014) As the Federal Rules of Evidence do not strictly apply in administrative hearings, and the Tribunal has considerable discretion in the admission of evidence, we look to the Federal Rules of Evidence to be illustrative of the underlying principles regarding the sufficiency of a detail requisite in a summary of testimony. The disclosure requirements for non-retained experts are governed by Rule 26(a)(2)(C) for guidance, A party must make three disclosures if they intend to present evidence through a non-retained expert: (1) the expert's identity; (2) "the subject matter on which the witness is expected to present evidence"; and (3) "a summary of the facts and opinions to which the witness is expected to testify." Fed.R.Civ.P. 26(a)(2)(A) & 26(a)(2)(C)(i)-(ii); *Vanderberg v. Petco Animal Supplies Stores, Inc*., 906 F.3d 698, 702 (8th Cir. 2018). Scant case law exists outlining what constitutes a sufficient disclosure under Rule 26(a)(2)(C). *See Hayes v. Am. Credit Acceptance, LLC,* Case No. 13-2413-RDR (D. Kan. Aug 12, 2014). "At a minimum, the disclosure should obviate the danger of unfair surprise regarding the factual and opinion testimony…" *Id.*

The disclosing party should provide "a brief account that states the main points" of the entirety of the anticipated testimony. *Id at 6*. This does not mean that the disclosures must outline each and every fact to which the non-retained expert will testify or outline the anticipated opinions in great detail. *Id.* Imposing these types of requirements would make the Rule 26(a)(2)(C) disclosures more onerous than Rule 26(a)(2)(B)'s requirement of a formal expert report. …"

Id.

The purpose of Rule 26(a) is "generally [] to 'allow both sides to prepare their cases adequately and efficiently and to prevent the tactic of surprise from affecting the outcome of the

case.'" *Fielden v. CSX Transp., Inc.,* 482 F.3d 866, 871 (6th Cir. 2007) (quoting *Sherrod v. Lingle*, 223 F.3d 605, 613 (7th Cir. 2000)). Rule 26(a)(2) aims to prevent surprise both as to the existence of an expert as well as "to the scope of the [expert's] testimony." *Id.*

"The determination of whether a Rule 26(a) violation is justified or harmless is entrusted to the broad discretion of the district court." " *Hayes v. Am. Credit Acceptance, LLC*, Case No. 13-2413-RDR (D. Kan. Aug 12, 2014) at 7, (Quoting *Sibley*, No. 08-2063-KHV, 2013 WL 1819773, at 7)... While a court "need not make explicit findings concerning the existence of a substantial justification or the harmlessness of a failure to disclose," the court should be guided by the following factors: 1) the prejudice or surprise to the party against whom the testimony is offered, 2) the ability to cure any prejudice, 3) the potential for trial disruption if the testimony is allowed, and 4) the erring party's bad faith or willfulness. *Id.* The primary goal of sanctions is to deter misconduct. "*Burton v. R.J. Reynolds Tobacco Co*., 203 F.R.D. 636, 640 (D. Kan. 2001 "In ruling on a motion to exclude expert testimony under Rule 37(c)(1), the court should bear in mind that it is a 'drastic sanction.'" *Hayes v. Am. Credit Acceptance, LLC,* Case No. 13-2413-RDR (D. Kan. Aug 12, 2014) (citing *Myers v. Mid-West Nat. Life Ins. C*o., No. 04-cv-00396-LTB-KLM, 2008 WL 2396763, at *2 (D. Colo. June 9, 2008)).

The Prehearing Statement, in conjunction with the Supplemental Prehearing Statement of the Petitioners, is sufficient to provide notice to the Government and prevent surprise. The Summary of Testimony of the Petitioners contains sufficient detail to allow the Government to prepare adequately and efficiently and to prevent the tactic of surprise from affecting the outcome of the hearing. There is no indication of a willful failure or bad faith on the part of the Petitioners if this Tribunal were to find the details that could have been more expansive to justify the draconian sanction of excluding the testimony. Although the Petitioners strongly argue the summaries are

sufficient and the Government's motion should fail, if the Tribunal were to find that greater detail is required, the interest of justice would be served by allowing the Petitioners the opportunity to file amended summaries, as it would not materially prejudice the Government.

Dr. Nichols, Dr. Nutt, and Dr. Younkin Will Present Relevant Testimony

The Government strangely seeks to exclude Dr. David Nutt, the leading psychopharmacologist in the world as ranked in 2024 by Scholar GP, from providing testimony to the Tribunal. *See* https://scholargps.com/scholars/73699337611906/david-j-nutt. Dr. Nutt Dr. Nutt for over twenty-five years, acted as the editor of the Journal of Psychopharmacology, one of the top journals in the world on the effects of drugs and the brain, and now edits the journal Drug Science Policy and Law. Dr. Nutt has spoken at the UN Office of Drugs and Crime, the Houses of Parliament (UK), the European Commission, and in the Dutch and New Zealand legislatures. Dr. Nutt has conducted scientific research on the brain actions in humans of a wide range of legal and illegal drugs over the past decade and has studied the impact of psychedelic drugs on the human brain using both psychological and neuroimaging measures. Dr. Nutt has sufficient expertise to examine multiple factors under 21 C.F.R. § 811(c).

Dr. David Nichols was a Purdue University School of Pharmacy Professor for thirty-eight years and is currently an Adjunct Professor of Chemical Biology and Medicinal Chemistry in the School of Pharmacy at the University of North Carolina, Chapel Hill. His laboratory developed the original chemical synthesis for DOI. Dr. Nichols has a degree of expertise regarding the medicinal chemistry of drugs, including DOI that is nearly unrivaled. Dr. Nichols has sufficient expertise to examine multiple factors under 21 C.F.R. § 811(c).

Dr. Jason Younkin is a postdoctoral trainee at Virginia Commonwealth University (VCU) and an adjunct faculty member at Virginia State University. Dr. Younkin's research involves

psychedelic drugs and the use of DOI. He can speak to the impact that adding DOI would have on research conducted by young researchers and at small historically black colleges and universities. Eliminating or severely curtailing research is a risk to public health. Dr. Younkin has sufficient expertise to examine multiple factors under 21 C.F.R. § 811(c).

Conclusion

WHEREFORE, PREMISES CONSIDERED, the Petitioners respectfully pray the Tribunal denies the Government's Motion in Limine. The Petitioners further pray for any and all other relief this Tribunal deems fit in law or in equity.

Date: October 3, 2024

Respectfully submitted,
/s/ Robert T, Rush
Signature

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Exhibit 1

Letter from Dr. Brett Giroir, Assistant Secretary of Health, Dept. of Health & Human Services, dated August 16, 2018

AUG 16 2018

The Honorable Uttam Dhillon
Acting Administrator
Drug Enforcement Administration
U.S. Department of Justice
8701 Morrissette Drive
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Dear Mr. Dhillon:

Pursuant to the Controlled Substances Act (CSA), 21 U.S.C. § 811, I am rescinding our prior recommendation dated October 17, 2017, that the substances mitragynine and 7-hydroxymitragynine be permanently controlled in Schedule I of the CSA. HHS is instead recommending that mitragynine and 7-hydroxymitragynine not be controlled at this time, either temporarily or permanently, until scientific research can sufficiently support such an action. Mitragynine and 7-OH-mitragynine are two of the constituents of the plant *Mitragyna speciosa* (*M. speciosa*), commonly referred to as *kratom*. 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 any subsequent scheduling decision.

Procedural History

On August 31, 2016, the Drug Enforcement Administration (DEA) issued a Notice of Intent to temporarily schedule the chemicals mitragynine and 7-hydroxymitragynine into Schedule I pursuant to the temporary scheduling provisions of the CSA, 21 U.S.C. § 811(h). *See,* 81 Fed. Reg. 59,929 (Aug. 31, 2016). In response to the Notice of Intent, the DEA received numerous comments from the public on mitragynine and 7-hydroxymitragynine, including comments offering their opinions regarding the pharmacological effects of these substances. To allow consideration of these comments, as well as others received on or before December 1, 2016, the DEA issued a Withdrawal of Notice of Intent and Solicitation of Comments on October 31, 2016.

On October 17, 2017, the then-Acting Assistant Secretary for Health of HHS wrote to then-Acting Administrator of the DEA to indicate that HHS was recommending that the substances mitragynine and 7-OH-mitragynine be permanently controlled in Schedule I of the Controlled

Substances Act. Recently, I became aware of DEA's intent to schedule mitragynine and 7-OH-mitragynine - into Schedule I.

Analysis

The Controlled Substances Act ("CSA") provides in pertinent part that the Attorney General may by rule add to Schedule I any drug or other substance if the Attorney General makes the findings prescribed by subsection (b) of section 812 of the CSA for Schedule I. *See,* 21 U.S.C. § 811(a). Such findings are:

1. The drug or other substance has a high potential for abuse.
2. The drug or other substance has no currently accepted medical use in treatment in the United States.
3. There is a lack of accepted safety or use of the drug or other substance under medical supervision.

The CSA requires that "[i]n making any finding under subsection (a) of this section or under subsection (b) of section 812 of this title, the Attorney General shall consider the following factors with respect to each drug or other substance proposed to be controlled or removed from the schedules:

(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 drug or other 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 the public health.
(7) Its psychic or physiological dependence liability.
(8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter."

21 U.S.C. § 811(c).

Before scheduling a substance, though, the Attorney General must "request from the Secretary (of HHS) a scientific and medical evaluation, and his recommendation, as to whether such drug or other substance should be so controlled or removed as a controlled substance." *Id.* at § 811(b). The Secretary's evaluation should be based on factors (2), (3), (6), (7), and (8), noted above, and the scientific and medical considerations involved in factors (1), (4), and (5). Moreover, the "recommendation of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance." *Id.*

The Secretary has delegated to the Assistant Secretary for Health, in consultation with the National Institute on Drug Abuse and the Food and Drug Administration, the responsibility to make a recommendation under the CSA to the Attorney General. On October 17, 2017, my

predecessor, the Acting Assistant Secretary for Health, forwarded to you his recommendation that mitragynine and 7-hydroxymitragynine be permanently controlled in Schedule I of the CSA. The recommendation included a scientific and medical evaluation prepared by the FDA of the eight factors determinative of control under the CSA. The FDA evaluation also recommended in favor of the three findings that are required for DEA to place a substance in Schedule I.

I have reviewed the Acting Assistant Secretary's earlier recommendation as well as previous and new scientific data. In light of this review, combined with concerns for unintended public health consequences, I now conclude that while mitragynine and 7-hydroxymitragynine have many properties of an opioid, scheduling these chemicals at this time in light of the underdeveloped state of the science would be premature. For example, one recently published peer reviewed animal study indicated that mitragynine does not have abuse potential and actually reduced morphine intake. As such, these new data suggest that mitragynine does not satisfy the first of the three statutory requisites for Schedule I, irrespective of broader considerations of public health. While a single study is rarely dispositive, it strongly suggests that further evaluation is warranted.

Although there remains cause for concern for 7-hydroxymitragynine and potentially mitragynine, the level of scientific data and analysis presented by the FDA and available in the literature do not meet the criteria for inclusion of *kratom* or its chemical components in Schedule I of the CSA at this time. There is still debate among reputable scientists over whether *kratom* by itself is associated with fatal overdoses. Further analysis and public input regarding *kratom* and its chemical components are needed before any scheduling should be undertaken. It is important that we have additional information to justify scheduling, such as:[1]

- A scientific assessment of how many Americans utilize *kratom*, and an understanding of the geographic and demographic distribution of these users (Factors 4, 5);
- A scientific assessment of the actual scale and degree of dependence and/or addiction of Americans utilizing *kratom* (Factors 1, 5, 7);
- A scientific determination based on data whether *kratom* actually serves as a gateway drug that promotes further use of more dangerous opioids (Factors 1, 4, 5);
- A valid prediction of how many *kratom* users will suffer adverse consequences if *kratom* is no longer available, including:
    - Intractable pain, psychological distress, risk for suicide;
    - Transition to proven deadly opioids such as prescription opioids, heroin, or fentanyl; and
    - Transition to other potent or harmful drugs (Factor 6);
- A scientifically valid assessment of causality in the current few deaths in which *kratom* was co-utilized with known lethal drugs such as fentanyl (Factors 1, 2, 3, 5 & 6).

Furthermore, there is a significant risk of immediate adverse public health consequences for potentially millions of users if *kratom* or its components are included in Schedule I, such as:

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[1] I am also concerned about the impact of scheduling *kratom* on our ability to conduct research, especially survey research and our currently inability to routinely test for *kratom* in those brought into an emergency room as a result of a possible overdose.

- Suffering with intractable pain;
- *Kratom* users switching to highly lethal opioids, including potent and deadly prescription opioids, heroin, and/or fentanyl, risking thousands of deaths from overdoses and infectious diseases associated with IV drug use;
- Inhibition of patients discussing *kratom* use with their primary care physicians leading to more harm, and enhancement of stigma thereby decreasing desire for treatment, because of individual users now being guilty of a crime by virtue of their possession or use of *kratom*
- The stifling effect of classification in Schedule I on critical research needed on the complex and potentially useful chemistry of components of *kratom*.

Therefore, I conclude at the current time, available evidence does not support mitragynine and 7-hydroxymitragynine being controlled in Schedule I of the Controlled Substances Act. This assessment supersedes the previous recommendation letter from Acting Assistant Secretary Wright dated October 17, 2017. In the meantime, it is recognized that *kratom* may potentially have harmful effects, especially in specific circumstances and/or when used with potent prescription or illicit drugs.

Finally, it is entirely possible that new data and evidence could support scheduling of chemicals in *kratom* at some future time. *Kratom* may have harmful effects, particularly when used with other drugs. As such, I encourage continued enforcement by the FDA against unproven claims by *kratom* manufacturers. I also support enhanced public awareness that *kratom* contains molecules that may potentially be dangerous. I also plan to work expeditiously with colleagues throughout the U.S. government to seek transparent public and scientific input, and to collect data on the critical public health considerations outlined above.

Should you have any questions regarding this recommendation, please contact my office at (202) 690-7694.

Sincerely yours,

Brett P. Giroir, M.D.
ADM, U.S. Public Health Service
Assistant Secretary for Health
Senior Advisor for Opioid Policy

CERTIFICATE OF SERVICE

I hereby certify that on this 3rd day of October 2024, a copy of the foregoing Opposition to Government's Motion in Limine was sent via email to the DEA Office of Administrative Law Judges at ECF-DEA@dea.gov and via email to:

(1) Government Mailbox at dea.registration.litigation@usdoj.gov,
(2) Francis W. Mann, DEA at Francis.W.Mann@dea.gov,
(3) Kayla L. Kreinheder, DEA at Kayla.L.Kreinheder@dea.gov,
(4) Alexis B. Attanasio, DEA at Alexis.B.Attanasio@dea.gov,
(5) Paul A. Dean, DEA at Paul.A.Dean@dea.gov,
(6) David Heldreth, CEO of Panacea Plant Sciences, via email at davidh@panaceaplantsciences.net, and
(7) Brett Phelps, Esq., Attorney for Science Policy Council, Students for Sensible Drug Policy, via email at brett@brettphelpslaw.com.

Date: October 3, 2024

/s/ Brett J. Phelps
Signature