

Public Comment Submitted on Behalf of Students for Sensible Drug Policy (SSDP) Regarding the DEA's Proposed Scheduling of Five Tryptamines (Docket No. DEA-2026-1585-0001)

Students for Sensible Drug Policy

Students for Sensible Drug Policy (SSDP) is the largest youth-led grassroots network dedicated to replacing the War on Drugs with policies rooted in evidence, compassion, and human rights — policies that make sense.

Introduction and Guiding Principles

Students for Sensible Drug Policy respectfully urges the Drug Enforcement Administration (DEA) to withdraw the proposed scheduling of 4-Hydroxy-N,N-Diisopropyltryptamine (4-OH-DiPT), 5-Methoxy-alpha-Methyltryptamine (5-MeO-AMT), 5-Methoxy-N-Methyl-N-Isopropyltryptamine (5-MeO-MiPT), 5-Methoxy-N,N-Diethyltryptamine (5-MeO-DET), and N,N-Diisopropyltryptamine (DiPT), which would disrupt crucial scientific research and restrict access to compounds that researchers say warrant further study — not prohibition. Instead, DEA should pursue a science-based regulatory approach that protects public safety while preserving research access.

The proposed Schedule I placement, would produce serious research harms that directly threatens clinical pipelines targeting severe psychiatric conditions and ongoing scientific research. Compounds affected by this proposal are already involved in clinical development programs targeting critical unmet medical needs, including postpartum depression. Imposing additional Schedule I restrictions at this stage risks delaying or derailing the development of potentially lifesaving treatments for patients who urgently need better options.

This proposal also directly conflicts with the objectives of [Executive Order 14401](#), which directs federal agencies to accelerate research, regulatory review, and appropriate patient access to investigational psychedelic treatments for serious mental health conditions. At a time when the Administration has explicitly prioritized advancing these therapies, DEA is proposing new restrictions that could undermine the very research and clinical development the Executive Order seeks to accelerate.

Scientific Background and Pharmacology of the Five Tryptamines

Like most psychedelic drugs, 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT interact with the serotonin 2A receptor. However, sharing a receptor does not mean these substances have identical pharmacological properties, effects, risks, or potential applications. Each compound has a distinct scientific profile, and the available evidence varies considerably among them. Grouping these five substances together for Schedule I placement risks overlooking important differences in their abuse potential, therapeutic applications, and value to scientific research. Each should therefore be evaluated individually, based on compound-specific evidence rather than structural similarities or shared mechanisms of action.

Reunion Neuroscience's lead drug candidate, [luvesilocin \(RE104\)](#), is a patented, shorter-acting prodrug of 4-OH-DiPT that has received [Breakthrough Therapy Designation](#) from the FDA for postpartum depression. This designation recognizes the potential of an investigational treatment to offer substantial improvement over existing therapies for a serious condition. The DEA's proposal to place 4-OH-DiPT and its "salts, isomers, and salts of isomers" in Schedule I could create significant regulatory uncertainty and potentially subject this promising treatment to additional restrictions just as it advances toward Phase 3 clinical trials.

5-MeO-MiPT has already advanced into human clinical research through MindState Design Labs' formulation, MSD-001. A [Phase 1 study](#) involving 47 healthy participants reported that the formulation was well tolerated across the tested dose ranges. These findings demonstrate that 5-MeO-MiPT is already the subject of meaningful clinical investigation and underscore the importance of preserving opportunities for further research into its safety, pharmacology, and potential therapeutic applications.

Unlike many other psychedelics, DiPT is notable for its unusual effects on auditory perception rather than the visual effects more commonly associated with this class of substances. This distinctive pharmacological profile makes it a potentially valuable research tool for understanding how the brain processes sound and may inform future investigations into debilitating auditory conditions such as tinnitus and diplacusis. Restricting access to DiPT could unnecessarily impede research into neurological processes that remain poorly understood.

5-MeO-AMT has a distinctive pharmacological profile, including a relatively long duration of action and reported differences in psychostimulant effects compared with other serotonergic substances. Preliminary animal research has raised questions about its abuse liability that warrant further investigation rather than assumptions based on its structural similarities to other psychedelics. Its characteristics may make it useful for studying the complexities of the serotonin system, which plays an important role in neuropsychiatric and neurological conditions as well as fundamental physiological functions such as sleep and appetite.

Of the five compounds, 5-MeO-DET remains comparatively understudied, with limited available evidence regarding its human effects, patterns of use, safety, and potential applications. However, this lack of evidence should not be used to justify Schedule I placement. Rather, it underscores the need for further scientific investigation. Placing 5-MeO-DET in Schedule I would likely discourage the very research needed to better understand its pharmacology, risks, and potential applications, unnecessarily limiting opportunities for scientific discovery and innovation.

Opposition to Schedule I Designation for 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT

The available scientific evidence does not adequately justify placing these five compounds in Schedule I, particularly given emerging clinical research, limited compound-specific evidence of abuse, and the substantial harms that scheduling would impose on scientific investigation and medical development. Under the Controlled Substances Act, Schedule I classification requires findings of a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. DEA must demonstrate that each compound independently meets these statutory criteria rather than relying on broad assumptions about psychedelics as a class.

Although investigational therapeutic potential does not, by itself, establish a currently accepted medical use under the Controlled Substances Act, ongoing clinical development demonstrates why these substances warrant further scientific investigation rather than additional restrictions. DEA should carefully consider whether the evidence supporting each proposed designation is sufficient to justify the significant consequences for research, medical innovation, and public health.

Beyond obstructing research, Schedule I placement risks further criminalization and the expansion of illicit markets. Prohibition does not eliminate demand for psychoactive substances; instead, it can drive their production and distribution underground, where quality controls, accurate labeling, and reliable safety information are often absent. It can also incentivize the development of novel analogs with poorly understood safety profiles. Rather than protecting public health, these consequences can expose individuals to greater risks while subjecting otherwise law-abiding Americans to criminal penalties.

Furthermore, Schedule I designation imposes substantial legal, financial, and regulatory barriers on scientific research and the development of novel treatments. These restrictions can discourage biotechnology investment, delay or interrupt clinical trials, create institutional obstacles, and jeopardize funding for university and independent laboratories conducting fundamental neuroscience research, including studies of the serotonin 2A receptor. The resulting burdens could slow or prevent critical investigations into these compounds' pharmacology, safety profiles, therapeutic potential, toxicity thresholds, and appropriate regulatory frameworks.

Imposing the nation's most restrictive drug classification before the necessary scientific evidence has been developed risks creating a self-defeating cycle: restricting research because evidence is limited, while simultaneously making it more difficult to generate that evidence. DEA should not allow speculative or inadequately demonstrated risks to justify restrictions that could undermine scientific progress, delay promising treatments, and ultimately compromise the public health objectives that drug scheduling is intended to serve.

A Sensible, Evidence-Based Approach

The United States continues to face serious mental health challenges and persistent barriers to effective care, underscoring the urgent need for new and more effective treatments. At a time when Americans desperately need more options, placing 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT in Schedule I threatens to disrupt promising scientific research and therapeutic development.

For patients facing serious psychiatric conditions, the consequences of restricting this research are not merely theoretical. Delays in scientific investigation and clinical development can mean delays in access to potentially lifesaving treatments. Federal drug policy should facilitate the development of the evidence necessary to protect public health, not create unnecessary obstacles to scientific discovery.

SSDP strongly opposes the proposed scheduling of these five tryptamines and urges DEA to adopt a science-based, public health-centered approach that protects public safety while preserving opportunities for scientific research, medical development, and appropriately regulated access. Specifically, SSDP calls on DEA to:

- **Maintain the current non-scheduled status** of all five compounds while additional evidence is developed regarding their pharmacology, safety, abuse potential, and possible therapeutic applications, allowing research into the serotonin system and its role in psychiatric and neurological conditions to proceed without unnecessary regulatory barriers.
- **Reconsider the existing eight-factor analyses** under Section 201(c) of the Controlled Substances Act (21 U.S.C. § 811(c)), evaluating each compound individually in light of current scientific evidence, its distinct pharmacological characteristics, and the potential consequences of scheduling for research and medical development.
- **Protect lawful scientific research and clinical development** by explicitly assessing the anticipated research harms associated with Schedule I restrictions and making those assessments publicly available to ensure transparency and accountability in the scheduling process.
- **Seek updated scientific and medical input from the Department of Health and Human Services (HHS), including the Food and Drug Administration (FDA)**, to account for recent developments in clinical research, emerging therapeutic applications, and the potential consequences of scheduling before making any final determination.

Rather than imposing additional restrictions on compounds with important scientific and potential medical applications, DEA should prioritize continued research and the development of an evidence-based regulatory framework that protects public health without unnecessarily obstructing scientific progress.

The purpose of drug scheduling should be to protect the public, not to prevent researchers from developing the knowledge and treatments needed to improve public health. SSDP urges DEA to withdraw the proposed Schedule I designations and pursue an approach grounded in science, compassion, and human rights — one that recognizes the risks of prohibition, protects opportunities for medical innovation, and ensures that promising treatments are not placed further out of reach for the people who need them.

Thank you for your consideration.