IN THE UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

IN THE MATTER OF	§	
	§	
	§	Docket No. 22-15
Scheduling 4-OH-DiPT, 5-MeO-AMT,	§	
5-MeO-MiPT, 5-MeO-DET, and DiPT	§	
	§	

DECLARATION OF ADMIRAL BRETT GIROIR

1. My name is Brett Giroir, M.D. I am a pediatric critical care specialist and a former four-star admiral in the U.S. Public Health Service Commissioned Corps. I previously served as the 16th Assistant Secretary for Health during the Trump administration from February 15, 2018, to January 19, 2021. I also served as the Acting Commissioner of Food and Drugs in November and December 2019 and was a Board Member of the World Health Organization. I submit this affidavit in the form of a declaration pursuant to 21 C.F.R. § 1316.57 and 28 U.S.C. § 1746 to be considered in light of the lack of opportunity for cross-examination.

2. I have reviewed the 2012 evaluations from HHS (**GX 6-10**) as well as DEA's Eight Factor Analysis dated August 2021 (**GX 11**). I have also reviewed the DEA NFLIS Drug Data for 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT (queried August 17, 2021) (**GX 12**).

3. Since the original 2012 evaluations by CDER, our medical and scientific understanding of hallucinogenic and dissociative compounds has progressed considerably, evidenced by the testimony to be offered by the subject matter experts in this case, such as Dr. Averill, as well as the literature cited by the parties, such as **M&TX 10**, a 2016 article discussing the use of hallucinogens to treat addictions. These classes of substances, which include compounds like ketamine and psilocybin, are showing us how to combine drugs that induce neuroplasticity

with specific behavioral interventions to produce lasting changes in ways currently available therapies cannot match. Make no mistake, although research remains in progress, these compounds could represent a major breakthrough for treating severe and frequently terminal mental illnesses like refractory depression and post-traumatic stress.

4. In light of this research—much of which has developed over the past decade—there is a compelling need for a new medical and scientific evaluation by CDER and the Assistant Secretary of Health that is not a decade old and reflects the current state scientific knowledge regarding the compounds at issue.

5. For that reason alone, the case for revisiting the medical and scientific findings in this case before moving forward with a Schedule I placement is much more compelling than the case of kratom.[1] Many of the statements I made in the letter with respect to kratom apply with equal or greater force to the compounds at issue in these proceedings. In the case of kratom, I concluded that new data, a lack of evidence, and an unknown and potentially substantial risk to public health justified halting or postponing the scheduling of kratom until further research could provide additional scientific and medical data to better inform the decision. The same could be said here. In addition, I note that DEA reports use of these unscheduled substances to be far less than kratom. I have seen no evidence that would suggest any of the compounds at issue in this case currently present a hazard to the public or a public health risk.

6. The issue of scheduling the substances at issue in these proceedings was not an issue discussed with me or my office during my tenure. I also emphasize that I am not a subject expert in clinical psychology, chemistry, or neuroscience, although I have spent considerable time

[1] I certify that **M&TX 21** is a true and correct copy of a letter I sent to the Acting DEA Administrator rescinding the HHS recommendation

reviewing the scientific data in the field. Therefore, I express no opinion as to whether the substances at issue in these hearings are or will prove to be medically and scientifically useful. I absolutely express my opinion as a physician-scientist that these substances need to be available for controlled scientific studies to demonstrate their potential.

7. To the extent any of these substances may have a potential medical or scientific usefulness—and the science is currently showing that many psychedelic or hallucinogenic compounds do—it is my opinion that placement of these substances in Schedule I, which may prove to be medically useful after more research and appear to have no track record of significant abuse, will unnecessarily restrict and impede research and innovation into compounds that may benefit the public health.

Pursuant to 28 U.S.C. § 1746, I certify under penalty of perjury that the foregoing is true and correct.

Executed on 7/7/22

Admiral Brett Giroir, MD