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**UNITED STATES DISTRICT COURT
DISTRICT OF OREGON**

THE CHURCH OF THE HOLY LIGHT)
OF THE QUEEN, a/k/a The Santo Daimé)
Church, *et al.*,)
Plaintiffs,)
)
v.)
MICHAEL B. MUKASEY, *et al.*,)
Defendants.)
_____)

CIV. NO. 08-3095-PA

**WITNESS STATEMENT OF
SRIHARI R. TELLA, Ph.D.**

WITNESS STATEMENT OF SRIHARI R. TELLA, Ph.D.

I. Introduction

1. I am an employee of the United States Department of Justice, Drug Enforcement Administration (DEA). I have been employed by DEA as a Pharmacologist since April 2002.

II. Qualifications and Experience

2. I received an undergraduate degree in Pharmacy from Andhra University, Waltair, India and then obtained a M.Sc. in Drug Assay and a Ph.D. in pharmacology from All-India Institute of Medical Sciences, New Delhi, India.

3. I received postdoctoral training in biochemical neuropharmacology from the Department of Physiology, University of Saskatchewan, Saskatoon, Canada, and in drug abuse pharmacology from the National Institute on Drug Abuse, Addiction Research Center in Baltimore, Maryland.

4. Following my postdoctoral training, I became an Assistant Professor on the faculty of the Department of Pharmacology, Georgetown University School of Medicine, Washington, District of Columbia. I was subsequently promoted to Associate Professor. I worked at Georgetown University for approximately 11 years. During my tenure at Georgetown University, I conducted physiological, behavioral and neuropharmacological experimental research funded by the National Institutes of Health (NIH). My research was mainly in the field of drug abuse with a primary focus on cocaine pharmacology and development of treatment drugs for cocaine addiction. I published my research findings as peer reviewed scientific papers in reputable medical journals. I am currently a regular member of the College on Problems of Drug Dependence and attend its Annual meetings regularly.

5. I joined the Drug and Chemical and Evaluation Section (ODE) of the Office of Diversion Control (OD), Drug Enforcement Administration in April 2002 as a Pharmacologist. One of my primary responsibilities as a Pharmacologist at the ODE is to review drugs and other substances for possible control under the Controlled Substances Act (CSA). Since joining ODE, I have reviewed a number of drugs and other substances and prepared scheduling review documents for control of drugs and other substances under the CSA.

6. Since 2002, I have reviewed for possible control under the CSA a number of tryptamine-based substances that are chemically and pharmacologically related to DMT. This resulted in the listing of two tryptamines – alpha-methyltryptamine (AMT), and 5-methoxy-N,N-diisopropyltryptamine (5-MeO-DIPT) – as schedule I controlled substances under the CSA. *See* 69 Fed. Reg. 58050.

7. I also prepared scheduling review documents for a number of other tryptamine-based substances, including:

- a. 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT) (“Foxy”);
- b. 5-methoxy-N,N-diethyltryptamine (5-MeO-DET);
- c. 5-methoxy-alpha-methyltryptamine (5-MeO-AMT);
- d. 5-methoxy-N-methyl, N-isopropyltryptamine (5-MeO-MIPT);
- e. N,N-diisopropyltryptamine (DIPT); and
- f. 4-hydroxy-N,N-diisopropyltryptamine (4-OH-DIPT).

The scheduling review document for 5-MeO-DMT has been sent to the Department of Health and Human Services (“DHHS”) with a request for scientific and medical evaluation and a scheduling recommendation. Other scheduling documents are expected to be sent in the near future to DHHS for its evaluation and a scheduling recommendation. Through these responsibilities, I have acquired significant scientific expertise in the tryptamine class of substances.

8. Since April 2002, as a part of the process of reviewing the above-mentioned tryptamines and a number of drugs or other substances, I have conducted scientific literature searches and reviewed, analyzed and interpreted the data from a number of national and other databases regarding the medical use, drug distribution, drug diversion, drug abuse, mortality, and toxic exposure involving these substances. Some of these databases are: National Survey on Drug Use and Health (NSDUH); Monitoring the Future (MTF); Drug Abuse Warning Network (DAWN); National Forensic Laboratory Information System (NFLIS); System to Retrieve Information from Drug Evidence (STRIDE); National Poison Data System (NPDS); Florida Department of Law Enforcement Medical Examiners (FDLE); and Automation of Reports and Consolidated Orders System (ARCOS). Through this research and analysis, I have acquired significant expertise in procedural and other aspects of the drug review process.

III. Issues to be addressed

9. My testimony addresses the following issues:

- a. The administrative process involved in listing a drug or other substance for control under the CSA;
- b. The criteria for listing a substance as a schedule I controlled substance under the CSA;
- c. The regulation of DMT and any material containing DMT as schedule I controlled substances under the CSA;

- d. The pharmacology of DMT and related tryptamines; and
- e. The potential for toxic effects and pharmacological drug interactions following human consumption of ayahuasca (including Daime) tea.

IV. Summary of Conclusions

10. With regard to the questions presented by plaintiffs' Daime tea consumption, it is my professional scientific opinion that:

- a. Current evidence indicates that schedule I controls, as set forth in the Controlled Substances Act and its implementing regulations, should continue to be enforced for any material, compound, mixture, or preparation which contains DMT, because DMT has a high potential for abuse, no accepted medical use and a lack of accepted safety for use under medical supervision.
- b. The great variation in the concentration of DMT in different batches of the Daime tea, as indicated by the analysis of different Daime tea samples seized by law enforcement officials from Plaintiffs, indicates that the tea has a potential to produce adverse health effects in individuals following its consumption.
- c. Some participants of Santo Daime Church works are on therapy with different pharmaceuticals at the time of their participation. These pharmacotherapies can potentially interact deleteriously with Daime tea and produce serious adverse health consequences.

V. Analysis

A. The Controlled Substances Act and the Drug Enforcement Administration

11. Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, also known as the Controlled Substances Act (CSA), is the legal foundation for the control of drug and other substances with potential for abuse.

12. The Drug Enforcement Administration (DEA) is the agency within the Department of Justice primarily responsible for the administration and enforcement of the CSA and its implementing regulations.

13. The CSA divides substances with potential for abuse into five schedules. A substance's placement in a particular schedule is based on that substance's accepted medical use, safety, potential for abuse, and/or dependence liability. Substances with no accepted medical use in the United States (e.g., heroin, LSD, marijuana) are placed in schedule I, while substances with accepted medical use are in schedules II through V, schedule II being the most restrictive and schedule V the least restrictive.

14. Under the CSA, a party can file a petition to schedule a given drug or substance, transfer a given controlled drug or other substance from one schedule to another, or decontrol a given controlled drug or other substance.

15. Drug control decisions are based on scientifically sound, legally-defensible and timely data relevant to each substance that is being considered for control under the CSA. Both the law enforcement (DEA) and the Scientific (DHHS) communities are involved in the drug control process.

16. Within DHHS, the Food and Drug Administration (FDA), with input from the National Institute on Drug Abuse (NIDA) is entrusted with conducting a scientific and medical evaluation and rendering a scheduling recommendation for a given drug or other substance under consideration for control under the CSA. *See* Expert Witness Statement of Dr. Jerry Frankenheim, Pharmacologist and Program Director, Functional Neuroscience Research Branch, Division of Basic Neuroscience & Behavioral Research, National Institute on Drug Abuse (NIDA), National Institutes of Health (NIH), DHHS (“Frankenheim Statement”).

17. The CSA mandates that both the Secretary of the DHHS and the Administrator or DEA (by delegation of authority from the Attorney General) consider eight specific factors in reviewing a drug or other substance for possible control under the CSA. These factors are:

- (1) actual or relative abuse potential;
- (2) pharmacological effects;
- (3) scientific knowledge;
- (4) history and current pattern of abuse;
- (5) scope, duration and significance of abuse;
- (6) risk to the public health;
- (7) physical and psychological dependence liability; and
- (8) whether the substance is an immediate precursor of an already-controlled substance.

18. The CSA also mandates that both DEA and DHHS make three specific findings for a given substance. These findings are: (1) abuse potential; (2) accepted medical use and safety; and (3) dependence profile. These findings will determine whether a given drug or other substance should be controlled or not and, if controlled, the schedule in which it should be placed.

19. The Administrator of the DEA, by authority of the Attorney General, has the ultimate authority for deciding whether or not a substance should be controlled under the CSA.

20. The Administrator of the DEA evaluates all available data including the scientific and medical evaluation and scheduling recommendation provided by DHHS, and makes a final decision whether to propose that a drug or substance be controlled and into which schedule it should be placed. *See* Frankenheim Statement. The medical and scientific findings of DHHS are binding on DEA. The recommendation on scheduling is binding only to the extent that if DHHS recommends that a substance not be controlled, DEA may not control that substance.

21. For schedule I substances, the criteria that must be considered are: (1) whether the substance has a high potential for abuse; (2) whether the substance has no currently accepted medical use in treatment in the United States; and (3) whether the substance has a lack of accepted safety for use under medical supervision. When the CSA was enacted, the United States Congress included N,N-dimethyltryptamine (DMT) as a schedule I controlled substance under the CSA.

22. In order to implement the CSA regulations governing scheduling, the DEA has established in-house capacity to monitor and analyze scientific, medical and other information relating to controlled substances and other substances with potential for abuse. A typical DEA drug review process resulting in a drug control action can take years for completion. It involves the collection of data at the national, state, and local levels. If necessary, it may also involve conducting specific studies in collaboration with other federal agencies such as NIDA.

23. Within DEA, the Drug and Chemical Evaluation Section (ODE) in the Office of Diversion Control has been tasked with administrative and scientific aspects of the drug scheduling process. The scientific staff of the ODE is primarily responsible for reviewing the necessary scientific, medical, law enforcement and other relevant information and data relevant to the drug scheduling process.

24. Within ODE, the scientific staff of the Drug and Chemical Control Unit (ODEC) has the primary responsibility for conducting the administrative process involved in the scheduling of drugs with potential for abuse. I am currently the acting Chief of the ODEC unit.

b. Pharmacology of Tryptamines, DMT and Daime Tea (Ayahuasca)

25. According to my review of declarations by Plaintiffs and Plaintiffs' expert witnesses, information on tryptamines from a published book¹¹, and other published sources, I understand that the Daime tea is a beverage that is prepared by boiling in water the mixture of the vine, *Banisteriopsis caapi*, together with the leaves of the plant, *Psychotria viridis*. Outside the Santo Daime tradition, Daime tea is also known by various other names (e.g., ayahuasca, hoasca). *Banisteriopsis caapi* contains β -

carbolines, namely harmine, harmaline and tetrahydroharmine which are inhibitors of monoamine oxidase (MAO) enzyme. DMT, the active pharmacological constituent of *Psychotria viridis*, is a tryptamine and a substrate for the MAO enzyme. When administered orally, DMT is rendered inactive by the MAO enzyme present in the digestive system. However, the β -carbolines in the *Banisteriopsis caapi* present in Daime tea protect DMT from this enzymatic inactivation, rendering it orally active. This synergistic interaction is considered the basis for the psychoactive effects of Daime tea.

26. Ayahuasca, similar to DMT acting alone, dose-dependently produces psychedelic effects in humans. The nature of these effects of ayahuasca resembles those of intravenously administered DMT¹.

27. The pharmacology of DMT is substantially similar to numerous other tryptamines and classical hallucinogens (e.g., LSD and DOM) as explained in detail below. This observation is based on (1) known science regarding these substances; (2) my pharmacological expertise; and (3) the information I have gleaned from my involvement as the principal reviewer in past and currently ongoing DEA reviews of numerous tryptamines that are structurally related to DMT, including, for example, 5-MeO-DMT, AMT, 5-MeO-DIPT (street name: "Foxy"), 5-MeO-AMT, 5-MeO-DET, DIPT, 4-OH-DIPT, and 5-MeO-MIPT.

28. Drugs produce responses by binding (or interacting in the body) to specific macromolecular components called receptors. This drug-receptor binding alters the function of physiological system(s) in the body and manifests as pharmacological response(s). In the body, there are numerous different types of receptors. The type of receptor that is activated determines the nature of the pharmacological response (e.g., stimulation of motor activity, sedation, heart rate elevation, hallucinations, etc.). Hallucinogens, such as LSD and DOM, produce hallucinations by binding to specific receptors called 5-HT_{2A}.

29. DMT and numerous other related tryptamines (such as those listed in paragraph 25, *supra*) have been shown to bind to 5-HT_{2A} receptors, similar to the binding activity of classical hallucinogens such as LSD and DOM.

30. A pharmacological method called "drug discrimination" is widely used in scientific research using experimental animals to determine the pharmacological nature of a given new drug or substance and whether or not a new drug or substance is pharmacologically similar to a known drug of abuse. If the new drug or substance exhibits discriminative stimulus effects in animals similar to a known drug of abuse, it is highly likely that this drug or substance shares similar subjective effects in humans, and would be similarly abused by humans. Thus, there is a strong correspondence between the discriminative stimulus effects of a given drug in animals and its subjective effects in humans.

¹ Riba J, Rodriguez Fornells A, Urbano G, Morte A, Antonijoan R, Montero M, Callaway JC and Barbanoj MJ (2001) Subjective effects and tolerability of the South American psychoactive beverage ayahuasca in health volunteers. 154: 85-95.

31. DMT produces discriminative stimulus effects that are substantially similar to those produced by classical hallucinogens such as DOM and LSD. Thus, it is likely to a reasonable degree of scientific probability that DMT shares similar subjective effects in humans with LSD. Therefore, it is scientifically reasonable to draw conclusions about DMT from the much more extensive historical research done on LSD.

32. Numerous other tryptamines that are related to DMT also produce discriminative stimulus effects similar to those of DOM and LSD.

33. In animals trained to discriminate 5-MeO-DMT (a close congener of DMT) from saline solution (placebo), studies show that these trained animals identify numerous other tryptamines (DMT, AMT, 5-MeO-DET, 5-MeO-DPT, 5-N,N-TMT, 7-N,N-TMT, 4-MeO-DMT, 1-N,N-TMT, 6-MeO-DMT, 7-MeO-DMT, 4-MeS-DMT, and 5-MeS-DMT), and classic hallucinogens such as LSD, DOM, mescaline, psilocyn as mimicking the stimulus effects produced by 5-MeO-DMT. These trained animals thus similarly discriminate between the placebo and the other non-DMT hallucinogen despite being trained only to discriminate 5-MeO-DMT. This demonstrated common pharmacological action between DMT and other related hallucinogens further supports drawing conclusions about DMT from the research conducted on these other substances.

34. DMT and numerous other related tryptamines (5-MeO-DMT, AMT, 5-MeO-DIPT, 5-MeO-AMT, 5-MeO-DET, DIPT, 4-OH-DIPT, 5-MeO-MIPT), similar to classical schedule I hallucinogens (e.g., LSD), produce hallucinogenic effects in humans.

35. Youth and young adults are abusing numerous tryptamines (including 5-MeO-DMT, AMT, 5-MeO-DIPT, 5-MeO-AMT, 5-MeO-DET, DIPT, 4-OH-DIPT, 5-MeO-MIPT) that are pharmacologically and chemically related to DMT, as substitutes for LSD and MDMA (ecstasy). These substances are commonly being purchased over the Internet. As just one example, a 2003 law enforcement investigation of an Internet-based company supplying these tryptamines led to the seizure in September 2003 of a computer disk containing records of over two thousand individuals purchasing a number of tryptamines and phenethylamines. This example, in addition to other examples set forth in the Witness Statement of Denise Curry and accompanying exhibits, indicates the existence of a substantial demand for illicit purchase of tryptamines.

36. These tryptamines (5-MeO-DMT, AMT, 5-MeO-DIPT, 5-MeO-AMT, 5-MeO-DET, DIPT, 4-OH-DIPT, 5-MeO-MIPT) have no accepted medical use and carry substantial public health risks similar to those of other controlled hallucinogenic substances such as DOM and LSD. There have been published reports of adverse health effects, emergency room admissions and deaths associated with the abuse of some of these tryptamines^{2,3,4,5,6,7,8,9}.

² Brush DE, Bird SB and Boyer EW (2004) Monoamine oxidase inhibitor poisoning resulting from Internet misinformation on illicit substances. *Journal of Toxicology and Clinical Toxicology* 42: 191-195.

37. These tryptamines (5-MeO-DMT, AMT, 5-MeO-DIPT, 5-MeO-AMT, 5-MeO-DET, DIPT, 4-OH-DIPT, 5-MeO-MIPT), which are substantially similar to DMT in their pharmacological effects, are newly-controlled or under administrative review for control under the CSA. DEA recently controlled AMT and 5-MeO-DIPT as schedule I substances. Others tryptamines, including 5-MeO-DMT, 5-MeO-AMT, 5-MeO-DET, DIPT, 4-OH-DIPT, and 5-MeO-MIPT, are currently undergoing various stages of DEA's administrative process for control under the CSA.

38. Taken together, current evidence establishes that DMT has high potential for abuse, no currently accepted medical use, and a lack of accepted safety for use under medical supervision; this evidence is consistent with the original placement of DMT as a schedule I substance. Thus the continued enforcement of schedule I controls for any material, compound, mixture, or preparation which contains DMT is necessary to safeguard the public health and safety.

c. Potential for toxic effects and adverse drug interactions with Daime tea

39. In connection with the present case involving Daime tea, I have been asked to review declarations and depositions of Plaintiffs and Plaintiffs' expert witnesses. In addition to these documents (and my existing expertise on the subject of tryptamines), I also reviewed information on tryptamines from a well-known book regarding tryptamines and human tryptamine use¹⁰.

40. Based on the statements of Plaintiffs and their witnesses and depositions of members of the Santo Daime Church, the information contained in the book referenced above, and my knowledge of pharmacological principles, and for the reasons mentioned below, I have concerns about the potential adverse health risks that may result from human consumption of the Daime tea as described by Plaintiffs in their practice in Santo Daime Church works.

³ Sklerov J, Levine B, Moore KA, King T and Fowler D (2005) A fatal intoxication following the ingestion of 5-methoxy-N,N-dimethyltryptamine in an ayahuasca preparation. *Journal of Analytical Toxicology* 29: 838-841; *see also* Affidavit of Theodore M. King, Jr., M.D.

⁴ Meatherall R and Sharma P: Foxy, a designer tryptamine hallucinogen (2003). *Journal of Analytical Toxicology*, 27: 313-317.

⁵ Ikeda A, Sekiguchi K, Fujita K, Yamadera H and Koga Y (2005). 5-methoxy-N,N-diisopropyltryptamine-induced flashbacks. *American Journal of Psychiatry*, 162: 815.

⁶ Itokawa M, Iwata K, Takahashi M, Sugihara GI, Sasaki T, Abe YI, Uno M, Hobo M, Jitoku D, Inoue K, Arai M, Yasuda I and Shintani M (2007). Acute confusional state after designer tryptamine abuse. *Psychiatry Clinical Neuroscience*, 61(2): 196-199.

⁷ Smolinske SC, Rastogi R, Schenkel S: (2004). Foxy Methoxy: A new drug of abuse. *Internet Journal of Medical Toxicology*, 7(1): 3.

⁸ Tanaka E, Kamata T, Katagi M, Tsachihashi H and Honda K (2006). A fatal poisoning with 5-methoxy-N,N-diisopropyltryptamine, foxy. *Forensic Sciences International*, 163: 152-154.

⁹ Wilson JM, McGeorge F, Smolinske S and Meatherall R (2005). A foxy intoxication. *Forensic Sciences International*, 148: 31-36.

¹⁰ "TiHKAL (Tryptamines I Have Known and Loved): The Continuation" by Alexander Shulgin and Ann Shulgin", Transform Press, Berkeley, CA.

41. The Daime tea drums imported from Brazil do not have labeling information about the composition of the pharmacologically active ingredients of the tea and their concentrations. Labeling is the initial and most basic requirement necessary to address the safety of any product containing pharmacologically active substances that is distributed for human consumption. In the absence of the basic knowledge typically contained on a label, it is not possible to adequately safeguard the health and safety of the individuals who consume this tea. These concerns are further heightened by the fact that in depositions, members of the Church (Jonathan Goldman, Alexandra Bliss Yeager, and Dr. Doe) described batch-to-batch variation in the concentration of Daime tea as well as an absence of any monitoring of the DMT concentration in Daime tea (deposition of Alexandra Bliss Yeager)

42. Plaintiffs describe the drums containing the Daime tea that are to be imported from Brazil as typically marked with one to three "X" marks corresponding to relative, but unknown, potencies, and no labeling information about the actual concentrations of pharmacologically active substances in the contents or even what substances are included in the contents. As such, the basic quality control that is needed to safeguard the health of the individuals who consume this tea is entirely lacking.

43. Plaintiffs' expert witnesses, Dr. Nicholas Cozzi and George Gerding, state that drinking Daime tea causes vomiting which, in turn, limits the total amount of tea ingested, thereby making it impossible for an individual to ingest lethal amounts of this tea. I disagree with this statement for several reasons. First, other drugs, including for example, opioid drugs (e.g., morphine), despite their ability to produce vomiting, are known to cause death due to overdose. Thus vomiting is not an effective mechanism to prevent ingestion of a lethal dose. Second, Plaintiffs stated in deposition that vomiting is rare among participants in Santo Daime Church works. One published article reported that the oral ingestion of ayahuasca in amounts equal to a DMT dose of 1 mg/kg produced vomiting in 1 out of 5 human volunteers tested¹¹. Therefore, the statements of Dr. Cozzi and Mr. Gerding are not credible in this regard.

44. Plaintiffs' witnesses stated that the tea is prepared by brewing the *B. caapi* bark and *P. viridis* leaves in boiling water for an indeterminate time in a ritual manner; inherent in this process are significant batch-specific variations in the amounts of pharmacologically active substances for the following reasons: (1) the total duration of the brewing process and the actual amounts of material used are not clearly defined; (2) there is no description of the actual boiling time or the exact temperatures used, and thus the measures used in the brewing process are unlikely to yield tea of uniform standards with consistent chemical composition; (3) In deposition, Plaintiff Goldman and Dr. Doe, a physician involved in screening the participants of the Santo Daime Church services, described batch-to-batch variations in DMT concentrations of Daime tea. In deposition, Plaintiff Goldman also mentioned that the location where the vines are grown also influences the tea strength. Further, the affidavit by Plaintiffs' expert witness, Dr. Cozzi,

¹¹ Riba J, Rodriguez Fornells A, Urbano G, Morte A, Antonijoan R, Montero M, Callaway JC and Barbanoj MJ (2001) Subjective effects and tolerability of the South American psychoactive beverage ayahuasca in health volunteers. 154: 85-95

confirms Goldman's statement. According to Dr. Cozzi's affidavit, the concentrations of DMT in the Daime tea exhibits seized from Plaintiff Goldman in May 1999 varied from 0.27 mg/ml to 0.84 mg/ml, an almost four-fold variation in the DMT concentration of different Daime tea samples analyzed. Although it is not possible to infer the maximal degree of batch-specific or exhibit-specific variations, the possibility exists that the magnitude of this variation can be even larger than documented in the reports described by Dr. Cozzi. Thus, the consumption of Daime tea, due to its variable and undefined composition, has a potential to cause unpredictable and potentially adverse health effects in individuals.

45. In his witness statement, Plaintiff Goldman mentioned that Santo Daime Church works can last from 5 to 12 hours. Further, in the deposition of John Seligman, who screens prospective participants of Santo Daime Church works, Mr. Seligman explains that at each work, Daime tea is typically served every 2 hours with up to approximately 2 ounces (60 ml) per serving and between two and six servings over the course of a single work. Moreover, plaintiffs have offered in evidence a video of Santo Daime services in Brazil where it appears that participants regularly consume doses much larger than one or two ounces per serving. Even accepting Mr. Seligman's description of the volume consumed, a participant can potentially consume up to a total of 360 ml of Daime tea.

46. As mentioned earlier, analysis of Daime tea exhibits seized from Plaintiff Goldman revealed a maximum DMT concentration of 0.84 mg/ml. Thus, there is a potential for ingestion of tea containing a total of about 300 mg DMT which is about 3 to 4.5 times larger than the doses described in one published account¹². According to another published study in humans using oral ingestion of ayahuasca at amounts corresponding to DMT equivalent doses of 0.5, 0.75 and 1 mg/kg body weight, the 1 mg/kg dose produced adverse health effects in one of the six subjects tested, and subsequently led to withdrawal of this subject from the study¹³. Thus the maximum dose of ayahuasca that can be administered without adverse consequences according to this published report was the amount corresponding to DMT equivalent of 0.75 mg/kg. This approximates to a total amount of ayahuasca containing about 50 mg DMT (calculated on the basis of an average human body weight of 70 kg). The ingestion of Daime tea containing 300 mg DMT will be about six times larger than the maximal tolerated doses as reported in the above-referenced publication¹³.

47. In her deposition, Ms. Yeager stated that no one keeps a record of how much Daime tea a person drinks in one session. Additionally, in deposition, Mr. Seligman mentioned that the experience of individuals intensifies with progressive doses of Daime tea. Thus, it appears likely that an individual participating in a Santo Daime Church work will be exposed to doses of DMT which are large enough to put his or her health at risk.

¹² "TiHKAL (Tryptamines I Have Known and Loved): The Conituation" by Alexander Shulgin and Ann Shulgin", Transform Press, Berkeley, CA.

¹³ Riba J, Rodriguez Fornells A, Urbano G, Morte A, Antonijuan R, Montero M, Callaway JC and Barbanoj MJ (2001) Subjective effects and tolerability of the South American psychoactive beverage ahyhuasca in health volunteers. 154: 85-95.

48. Moreover, it has been reported that individuals differ in their ability to metabolise (or eliminate) harmine, one of the pharmacologically active ingredient of ayahuasca tea, following its oral consumption¹⁴. One group of individuals metabolized it fast while the other group metabolized it slowly. These differences among individuals (slow versus fast) in metabolizing harmine creates an even greater risk of toxicity for some individuals who are found to be slow metabolizers of ayahuasca.

49. In his declaration, Plaintiffs' witness George Gerding states that in order to ingest the quantity of DMT necessary for toxicity or overdose, one would have to drink 3 to 4 liters of the Daime tea. I disagree with this statement for the reasons explained above and also for the following reason: A dose of 100 mg DMT is known to produce highly intense psychoactive effects including fear, rapid heart beating, a sense of dread and doom, and a feeling of being destroyed and devastated¹². Based on the earlier mentioned maximal DMT concentration of 0.84 mg/ml in an exhibit seized by DEA agents, a mere 120-milliliter dose (100 mg DMT) of Daime tea with similar DMT concentration is likely to produce highly intense psychoactive effects. Amounts larger than 120 ml (only 2 doses) would progressively increase the chances of toxicity, depending upon the volume consumed.

50. Plaintiffs' witness, Dr. Nicholas Cozzi, explains in his statement that three criteria – medical use, ability to produce physical or psychological dependence, and abuse potential – are used in different combinations to control drugs into five different schedules. I disagree with this statement because it neglects to mention the other criterion namely, the lack of accepted safety for use of the drug or other substance under medical supervision used in placing substances into schedule I.

51. In his statement, Dr. Cozzi concludes Daime tea has little or no abuse potential based on the absence of anecdotal or published reports proving the physical and psychological dependence-producing properties of Daime tea. I disagree with this statement. As an initial matter, the CSA does not require consideration of dependence potential as a criterion for schedule I substance, so the contention is not relevant to the question of whether a substance should be scheduled. In any event, a lack of published evidence of something cannot be taken as conclusive evidence of the converse.

52. In his statement, Dr. Cozzi admits that Daime tea, due to its MAO inhibitory activity, is likely to interact with a number of drugs used in clinical practice. Review of sample exhibits of application forms completed by the individuals who seek to participate in Santo Daime Church works indicate that there are individuals who take drugs likely to interact with MAOIs at the time they seek to participate in the works, despite the possibility for adverse interactions between such drugs and the Daime tea. In his deposition, Plaintiff Goldman acknowledges that people taking drugs with potential for adverse interaction with Daime tea are permitted to participate in Santo Daime Church works. This scenario could potentially produce dangerous adverse drug interactions.

¹⁴ Callaway JC (2005) Fast and slow metabolizers of Hoasca. *Journal of psychoactive drugs*. 37: 157-161.

53. In his statement, Plaintiffs' expert witness, George Gerding, states that the "set and setting" (environment) influence the reaction of an individual to biologically induced experiences. Environment-related conditioned learning mechanisms are known to either inhibit or enhance pharmacological responses to drugs or substances being administered.

- (1) However, while such phenomena has been demonstrated using well-controlled research settings such as those present in a clinical or animal research laboratory, I am not aware of any scientifically designed study demonstrating "set and setting" influence in a church setting. The statement of Gerding does not provide the actual data or a source of such information in support of his statement.
- (2) Further, the sample exhibits of application forms completed by the individuals who seek to participate in Santo Daime Church works indicate that these individuals have different medical and psychiatric problems existing at the time of their participation in the church works which might vitiate any "set and setting" effect.
- (3) In the absence of actual data, it cannot be conclusively said that the Daime tea consumption as currently practiced in Santo Daime Church works leads to either inhibition or enhancement of its pharmacological response. With regard to controlled settings, clinical research laboratory settings can not be equated to a group setting in church works. A controlled setting in a clinical research laboratory or hospital involves well-trained medical staff, medical equipment and supplies, and careful selection of patient study subjects, often excluding individuals with preexisting illnesses carrying the potential to evoke adverse health effects. These controls are in place in clinical research laboratory to minimize any potential untoward effects. The Santo Daime Church works lack such rigorous controls.

54. DMT and any material, preparation, compound or mixture containing DMT, can potentially cause adverse health effects. Published evidence indicates that abuse of tryptamines related to DMT has been associated with serious adverse health effects. Some adverse effects reported include increase in blood pressure and heart rate, acute kidney failure, acute confusional state, flashbacks, hallucinations, and paranoia. On a few occasions, abuse of some tryptamines related to DMT has even been associated with deaths^{15,16}.

VI. Conclusion

55. Based on my review, I conclude, to a reasonable degree of scientific probability, that the use of Daime tea for human consumption by Plaintiffs in their church works

¹⁵ Sklerov J, Levine B, Moore KA, King T and Fowler D (2005) A fatal intoxication following the ingestion of 5-methoxy-N,N-dimethyltryptamine in an ayahuasca preparation. *Journal of Analytical Toxicology* 29: 838-841; see also Affidavit of Theodore M. King, Jr., M.D.

¹⁶ Tanaka E, Kamata T, Katagi M, Tsachihashi H and Honda K (2006). A fatal poisoning with 5-methoxy-N,N-diisopropyltryptamine, foxy. *Forensic Sciences International*, 163: 152-154.

cannot be deemed safe and should not be allowed absent further study and, at the least, rigorous controls and monitoring by DEA.

VII. Prior Expert Testimony


56. I previously testified on one occasion, as a DEA expert witness on December 4, 2008, in Allentown, PA. This is a case against one of the sixteen defendants charged in a conspiracy for distributing thousands of schedule II and III controlled substances stolen from sixty-one pharmacies in the Philadelphia area. I testified as to the federal administrative process involved in controlling these drugs under the Controlled Substances Act. I also testified as to the pharmacological and toxic effects of these drugs.

VIII. Compensation

57. This statement is prepared as a part of my responsibility as a federal employee and thus I received no compensation for its preparation other than my salary.

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

DATED: December 8, 2008


Srihari Tella, Ph.D.

IX. Publications in the Last 10 years

1. Schindler CW, Karcz-Kubicha M, Thorndike EB, Muller CE, Tella SR, Ferre S and Goldberg SR: Role of central and peripheral adenosine receptors in the cardiovascular responses to intraperitoneal injections of adenosine A1 and A2A subtype receptor agonists. *Br. J. Pharmacol.* 144: 642-650, 2005.
2. Vaupel DB, Tella SR, Huso DL, Wagner III VO, Mukhin AG, Chefer SI, Horti AG, London ED, Koren AO and Kimes AS: Pharmacological and toxicological evaluation of 2-fluoro-3-(2(S)-azetidylmethoxy)pyridine (2-F-A-85380), a ligand for imaging cerebral nicotinic acetylcholine receptors with positron emission tomography. *J. Pharmacol. Exp. Ther.* 312: 355-365, 2005.
3. Schindler CW, Karcz-Kubicha M, Thorndike EB, Muller CE, Tella SR, Goldberg SR and Ferre S: Lack of adenosine A and dopamine D2 receptor mediated modulation of the cardiovascular effects of the adenosine A2A receptor agonist CGS 21680. *Eur. J. Pharmacol.* 484: 269-275, 2004.
4. Tosaka T, Casimiro CW, Qi Rong MS, Tella SR, Oh M, Katchman AN, Knollmann BC, Pezzullo JC, Pfeifer K and Ebert SN: Sympathetic Induction of a Long QT Phenotype in Adult *Kcnq1*-Deficient Mice. *J. Pharmacol. Exp. Ther.* 306: 980-987, 2003.
5. Kozikowski AP, Johnson KM, Deschaux O, Bandyopadhyay BC, Aradli GL, Carmona G, Munzor P, Smith MP, Balster RL, Beardsley PM and Tella SR: Mixed Cocaine Agonist/Antagonist Properties of (+)-Methyl 4beta-(4-Chlorophenyl)-1-methylpiperidine-3alpha-carboxylate [(+)-CPCA], a Piperidine-Based Analog of Cocaine. *J. Pharmacol. Exp. Ther.* 305: 143-150, 2003.
6. Vaupel DB, Tella SR, Huso DL, Mukhin AG, Baum I, Wagner III VO, Horti AG, London ED, Koren AO, Kimes AS: Pharmacology, toxicology and radiation dosimetry evaluation of [123I]5-I-A-85380, a radioligand for in vivo imaging of cerebral neuronal nicotinic acetylcholine receptors in humans. *Drug Dev. Res.* 58(2): 149-168, 2003.
7. Sakamuri S, Enyedy IJ, Zaman WA, Tella SR, Kozikowski AP, Flippen-Anderson JL, Farkas T, Johnson KM and Wang S: 2,3-Disubstituted Quinuclidines as a novel class of dopamine transporter inhibitors. *Bioorg. Med. Chem.* 11(6): 1123-1136, 2003.
8. Petukhov PA, Zhang J, Kozikowski AP, Wang CZ, Ye YP, Johnson KM and Tella SR: SAR studies of piperidine-based analogues of cocaine. 4. Effect of N-modification and ester replacement. *J. Med. Chem.* 45(15): 3161-3170, 2002
9. Petukhov PA, Zhang M, Johnson KM, Tella SR and Kozikowski AP: SAR studies of piperidine-based analogues of cocaine. Part 3. Oxadiazoles. *Bioorg. Med. Chem.* 11:2079-2083, 2001.
10. Tamiz AP, Bandyopadhyay BC, Zhang J, Flippen-Anderson JL, Zhang M, Zhang CZ, Johnson KM, Tella SR. and Kozikowski AP: Pharmacological and

- Behavioral analysis of the effects of some bivalent ligand-based monoamine reuptake inhibitors. *J. Med. Chem.* 44: 1615-1622, 2001.
11. Tella SR and Goldberg SR: Subtle differences in the discriminative stimulus effects of cocaine and GBR-12909. *Progress in Neuropsychopharmacology and Biol. Psychiatry* 25:639-656, 2001.
 12. Wang S, Sakamuri S, Enyedy IJ, Kozikowski AP, Deschaux O, Bandyopadhyay BC, Tella SR, Zaman WA and Johnson KM: Discovery of a novel dopamine transporter inhibitor as a potential cocaine antagonist through 3D-database pharmacophore searching: Molecular modeling, structure-activity relationships, and behavior pharmacology studies. *J. Med. Chem.* 43: 351-360, 2000.
 13. Tamiz AP, Zhang J, Flippen-Anderson JL, Zhang M, Johnson KM, Tella SR, Deschaux O and Kozikowski AP: Further SAR studies of piperidine-based analogues of cocaine. 2. Potent dopamine and serotonin reuptake inhibitors. *J. Med. Chem.* 43: 1215-1222, 2000.
 14. Tella SR, Schindler CW and Goldberg SR: Cardiovascular responses to cocaine self-administration: Acute and chronic tolerance. *Eur. J. Pharmacol.* 383: 57-68, 1999.
 15. Tella SR and Goldberg SR: Monoamine transporter and sodium channel mechanisms in rapid pressor response to cocaine. *Pharmacol. Biochem. Behav.* 59 (2): 305-312, 1998.