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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 Daime Church, *et al.*, Plaintiffs, v. MICHAEL B. MUKASEY, *et al.*, Defendants.	CIV. NO. 08-3095-PA **WITNESS STATEMENT OF DONALD R. JASINSKI, M.D.**

WITNESS STATEMENT OF DONALD ROBERT JASINSKI, MD

I. Description of Qualifications

1. I am a medical doctor and professor of Medicine at the Johns Hopkins School of Medicine in Baltimore, Maryland. I am also the Chief of the Center for Chemical Dependence at the Johns Hopkins Bayview Medical Center. Since 1965, I have been actively engaged in research of substance abuse, in treatment of patients who abuse or are dependent on such substances, and in the teaching and training of other health care professionals and scientists in regard to substance abuse and dependence. In general, my professional interests are in the causes, treatment and prevention of drug abuse. A major research activity of mine has been the design and execution of studies in humans to assess the abuse potential of various drugs including amphetamines, opioids, sedative hypnotics, hallucinogens and cannabinoids. These studies are done for two purposes: the first is to assist in the regulatory decision making regarding the need for control; the second is to assist in the development of drugs that have lesser abuse potential to replace drugs of high abuse potential and thereby reducing the public health and social problems that attend the abuse and misuse of drugs.

2. From 1965 to 1985, I was a Commissioned Officer in the United States Public Health Service assigned to the Addiction Research Center, the Federal Government's laboratory on addictions located originally in Lexington, Kentucky, and currently the intramural research program of the National Institute on Drug Abuse. In this capacity, I was responsible for conducting research studies in humans to assess the abuse potential of drugs and substances and to understand the causes and treatment of abuse and addiction.

3. From the mid 1950s until the early 1970s, the Addiction Research Center was a major site conducting studies of hallucinogens in humans under the direction of Harris Isbell, M.D. Dr. Isbell retired from the ARC to the University of Kentucky in 1963 but maintained the research program in hallucinogens as a guest worker. In

1965, I assumed medical responsibility for these experiments and became a scientific collaborator of Dr. Isbell. For a number of years, I also lectured on the human pharmacology of hallucinogens.

II. Compensation to Be Paid for the Study and Testimony

4. I am being compensated at the rate of $450 per hour for my services.

III. Previous Testimony

5. I have not testified in court within the last four years.

IV. Summary of Conclusions

A. ***The oral consumption of Ayahuasca produces hallucinogenic and other pharmacological effects. The chemical component within Ayahuasca which causes these hallucinogenic effects is dimethyltryptamine (DMT).***

B. ***The effects of DMT are similar to those produced by LSD. Scientifically, DMT is properly classified as an LSD-like hallucinogen.***

C. ***DMT is a drug of abuse as demonstrated by a history of its abuse and by experimental studies.***

D. ***The known health risks from DMT arise from its pharmacological effects, which include distorted perception, hallucinations, delusions, anxiety, panic and psychosis. At times these pharmacological effects could lead to behaviors that result in physical harm to the user or to others. DMT also carries a potential for dependence. The health risks of ayahuasca are greater than DMT alone due the additional effects of the monoamine oxidase inhibitor in ayahuasca, harmine. DMT and Ayahuasca have been associated with fatalities.***

E. ***Additional risks from Ayahuasca are unknown since there are no controlled safety studies. Before ayahuasca can be deemed safe for consumption – let alone to carry an accepted therapeutic use in medicine – it must be subject to further study.***

V. Analysis

6. ***Pharmacology of Ayahuasca***. Ayahuasca is an extract into water of two plants. The compound of interest in the extract of the plant *Psychotria viridis* is dimethyltryptamine (DMT). In the plant *Banisteriospsis Caapi*, harmine and its metabolites harmoline and tetrahydroharmine are the compounds of interest [8, 9, 10].

This extract combination (known by a number of names, including Ayahuasca) has been used throughout large regions of South America since antiquity. Descriptions from the early twentieth century of uses among indigenous tribes listed religious ceremonies, festivals and other occasions at home with some habitual use [11].

7. ***Pharmacological classification of DMT***. DMT is an LSD-like hallucinogen. This classification is based upon four lines of evidence. These are: (1) the similarity of effects of DMT to those produced by lysergic acid diethylamide (LSD) [2]; (2) partial cross tolerance to the effects of DMT in subjects tolerant to LSD[3]; (3) chemical similarity of DMT to psilocybin; and (4) documented abuse of DMT by users of other LSD hallucinogens.

8. DMT, mescaline, psilocin and psilocybin are naturally occurring chemicals that have been used since pre-history by native cultures within the Americas. DMT is considered an analogue of other hallucinogens that are similar in chemical structure in the tryptamine class of compounds[4]. Tryptamine is found in plants and animals and is thought to play a role as a neuromodulator or neurotransmitter in the brain. Tryptamine is chemically related to the amino acid tryptophan. Three of these tryptamines have been extracted from various plants since antiquity to be used for their hallucinatory effects. These are DMT (dimethyltryptamine), bufotenin (5-hydroxdimethyltryptamine) and psilocin (4 – hydroxydimethyltryptamine). Also in this class is serotonin (5-hydroxytryptamine). Serotonin is a known neurotransmitter in the brain that is believed to play a role in mental disorders ranging from depression to psychosis.

9. These four along with LSD are usually regarded as LSD-like hallucinogens since all produce effects similar to LSD [4, 5, 6] and all four show some degree of cross tolerance in subjects tolerant to LSD [3, 4, 5] . Other hallucinogens of abuse such as phencyclidine (PCP) and marijuana do not show such tolerance [4, 5].. **For all the foregoing reasons, it is appropriate to characterize DMT as an LSD-like**

hallucinogen and to draw comparative conclusions regarding DMT from known information regarding LSD and other LSD-like hallucinogens.

10. ***Legal classification of DMT.*** As a class, LSD, DMT, psilocybin, psilocin, mescaline, bufotenin, and peyote were placed under drug control as hallucinogens effective May 17, 1966. Control resulted from similar public health and social problems that accompanied wide spread abuse of each of these hallucinogens and knowledge of the similarity of effects. This was initially done under Public Law 89-74 or the Drug Abuse Control Amendments Act of 1965 and then under the Drug Abuse Control Act of 1970. Since these drugs had – and continue to have – no accepted or approved therapeutic use in medicine, the LSD hallucinogens are controlled as Schedule I drugs along with other recognized drugs of abuse that do not have recognized therapeutic use (e.g., heroin and marijuana). As was the case when it was first listed, DMT has no accepted or approved therapeutic use in medicine.

11. ***Use and abuse of DMT and other LSD-like hallucinogens in the United States.*** In western culture, the use, misuse and abuse of this class of drugs dates back to the early twentieth century, initially with mescaline, peyote and psilocybin [4, 5]. This consisted of use of the natural products Mexican Mushrooms (psilocybin) and Peyote (mescaline). There was relatively little interest in or use of these drugs in the United States until the 1950s. The discovery of the hallucinogenic actions of LSD led to study and investigation of LSD-like hallucinogens. Through the 1950s and the 1960s, these drugs were proposed as therapeutic agents to facilitate psychotherapy, to treat criminal behavior and to cure alcoholism [4]. The resemblance of perceptual changes, hallucinations and delusional thinking produced by the LSD-like drugs to similar changes seen in naturally occurring psychotic states led to the extensive study of the LSD hallucinogens as models for psychoses [4, 5]. It was speculated that agents such as DMT could under certain circumstances be produced in the brain to produce psychosis. For this reason, this group of drugs now known a LSD hallucinogens was known originally as

psychotomimetics. They were later referred to as hallucinogens when it became apparent that they were not models for psychosis. The LSD-like hallucinogens used for these studies were chemically synthesized.

12. From this experimentation, the effects of LSD-like hallucinogens became popularized. This resulted in widespread use and abuse that resulted in public health and social problems. Three patterns of use were observed [4]: (1) The first was the psychedelic drug movement. Adherents believed that the use of psychedelic drugs (LSD hallucinogens) opened one's mind and perceptions for obtaining religious, mystical or esthetic experiences. (2) A second pattern was use of hallucinogens as substitutes by narcotic addicts. (3) The third was that of polysubstance users who utilized the LSD hallucinogens as well as opiates, amphetamines, barbiturates and other drugs. This type of use became associated with the counter-culture of the 1960s (the "hippie" movement). Of concern at the time was the wide use among college and high school students. The negative public and congressional attitude was formed not only by the widespread use and abuse of these substances but by the subsequent revelation of CIA experiments with the LSD hallucinogens as mind control agents (MKULTRA). As noted, **DMT is among the LSD-like hallucinogens that have a history of abuse in the United States, which abuse has caused public health and social problems and raised legitimate concerns regarding persisting and/or increasing health and social problems.** I will elaborate on these problems and risks below.

13. ***Effects in humans of DMT consumption***. Because of the similarity of effects and mechanism of action among the various LSD-like hallucinogens, including DMT, the effects of these hallucinogens may be described for the class. These effects are well described from experimental studies [4, 5]. These experimental studies usually involved assessing the various effects in relation to dose. In general there were changes in pattern of effects seen with changes in dose. As with all drugs, there is variability in response such that even the more extreme reactions can occur in sensitive individuals. In low doses usually, these drugs are euphoric in

that mood is elevated, and feelings of well being, good humor and relaxation and wonderment are produced. With larger doses nervousness and anxiety may predominate. Fear, panic and terror may emerge usually with even larger doses. Time sense is impaired. Depersonalization may occur. There are changes in body sensation such as awareness of the heartbeat. There are changes in perception that range from increased intensity of colors, increased hearing, distorted distances and distortions of shapes. Hallucinations of people, things and animals are reported. Delusional thinking may occur. Individuals are more subject to suggestibility. Physically, pupils are dilated. Blood pressure, pulse rate and body temperature are slightly elevated. Nausea and vomiting may occur. Deep tendon reflexes are hyperactive; tremor may occur as well as increased muscle tension, incoordination and ataxia. Based upon experimental studies with LSD, Isbell assigned a clinical grade to the type of effects seen[5]. In general, the increase in grade was seen with increases in dose of the hallucinogen although some sensitive subjects experienced the more serious effects even with lower doses. Grade 1 is anxiety and nervousness without perceptual distortion or hallucinations. Grade 2 is anxiety and nervousness with perceptual distortions but without hallucinations. Grade 3 is anxiety, nervousness, perceptual distortions, and true hallucinations but with insight that the effects are related to the drug is maintained. Grade 4 is similar but without realization that the hallucinations and other effects are due to the drug. This may be accompanied by memory loss. More recent experimental studies with intravenously administered DMT support the conclusion that DMT behaves similarly to its peers in the LSD-like hallucinogen class [13,14,15,16].

14. Tolerance occurs rapidly to both the mental and physiologic effects of LSD and presumably to the other LSD-like hallucinogens [1, 3, 4, 5]. LSD tolerance was demonstrated by repeated administration under controlled experimental conditions. This was done because there was animal toxicity data for LSD which was under development as a pharmaceutical. This allowed chronic experimentation in humans. Such animal toxicity data did not exist for DMT so that there were no chronic administration studies for tolerance in humans [3].

Sensitivity to the effects of LSD is completely regained after three days. Tolerance can be overcome by ingesting massive amounts of drug. Subjects tolerant to LSD show cross tolerance to mescaline, psilocin and psilocybin but only partially to DMT [3]. **In summary, the pharmacological effects of DMT in humans include mental changes that range from euphoria through perceptual distortion to depersonalization, hallucinations and, in the extreme, psychosis.**

15. ***DMT as a drug of abuse***. The mental effects, tolerance and the lack of withdrawal seen with LSD-like hallucinogens from experimental studies are consistent with the effects reported from the abuse of these same drugs [4, 5]. In contrast to alcohol and opiate drugs, physiological dependence does not occur. Physiological dependence is demonstrated by the occurrence of characteristic subjective, behavioral and physiologic changes that occur upon abrupt termination of chronically administered alcohol or opiate drugs. At times, this withdrawal can be associated with drug-seeking to relieve symptoms. This withdrawal effect is viewed as secondary reinforcing effect. A reinforcing effect is that which leads to repeated drug-taking and craving. The primary reinforcing effect of drugs of abuse in humans is not physiological dependence, however. Rather, the primary reinforcing effect is related to a drug's ability to produce mental changes that are pleasurable ("euphoria"). Craving can occur with the use of LSD-like hallucinogens. There is recognized euphoria. **DMT and the LSD-like hallucinogens have pharmacological characteristics seen with drugs such as alcohol and opiates that lead to abuse, regardless of the lack of evidence of physiological dependence.**

16. ***Public health problems from abuse of LSD-like hallucinogens***. The major public health problems that resulted from abuse of LSD-like hallucinogens were drug induced changes in mood, feeling, thinking and perception. There are reports in the medical literature of psychotic reactions requiring hospitalization. Feelings of omnipotence can occur that are accompanied by errors in judgment. Delusional

thinking can be seen. Serious injury or death can result, for example, from situations such as delusions of the ability to fly. "Bad trips" or panic states are common. There are also effects that persist after the drug wears off, including reports of recurring persistent LSD-like symptoms after discontinuation of the drug ("flashbacks") as well as chronic anxiety and depression. In addition, psychotic episodes can persist for weeks after the drug is discontinued. There are also reports of persistent psychotic disorders most likely seen in individuals who had a primary psychosis or who had the tendency. The role of hallucinogens in precipitating or worsening the psychosis is unclear. Deaths have been associated with the use of LSD type hallucinogens and ayahuasca. One type are deaths incidental to the intoxicated state where individuals have been in accidents. Others have been behavioral such as an individuals believing they could fly. Individuals experiencing delusions, panic or psychosis. Deaths have been associated with LSD hallucinogen abuse with the suggestion that the death is drug related. Such has also been reported for ayahuasca [20].

17. The most authoritative documentation of the various type of mental disorders associated with abuse of LSD-like hallucinogens is seen in the recognized medical diagnoses that have become established based on experience with treating the adverse consequences of hallucinogen abuse. These diagnoses include both those related to the abuse or dependence potential, as well as the adverse mental effects of hallucinogen use. The Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) of the American Psychiatric Association is the standard reference used for diagnosis of psychiatric disease [6]. As a result of experiences from abuse, the hallucinogen use disorders and hallucinogen-induced disorders related to LSD-like hallucinogens (including DMT) listed in DSM-IV include the following: (1) Hallucinogen Abuse; (2) Hallucinogen Dependence; (3) Hallucinogen Intoxication; (4) Hallucinogen Persisting Perception Disorder (Flashbacks); (5) Hallucinogen Intoxication Delirium; (6) Hallucinogen-Induced Psychotic Disorder, With Delusions; (7) Hallucinogen-Induced Psychotic Disorder, with Hallucinations; (8) Hallucinogen-Induced Mood Disorder; (9)

Hallucinogen-Induced Anxiety Disorder; and (10) Hallucinogen-Related Disorder Not Otherwise Specified. **These established disorders and diagnoses, in addition to the public health problems and risks briefly summarized above, may be reliably associated with the LSD-like hallucinogens, including DMT.**

18. ***Effects of Ayahuasca***. Reports of the chemical analysis of Ayahuasca indicate varying concentrations of DMT and harmine and its metabolites[8, 9]. Such variability probably relates to the concentrations in the plant materials, the degree of extraction over time and the concentration through reduction of the liquid. In addition, studies indicate that there are fast and slow metabolizers of both DMT and harmine[10]. As a consequence, the effects expected from a given preparation are most likely not constant from time to time. The usual way of compensating for such effect is to titrate to effect – that is, to ingest increasing amounts over time to obtain the desired effect. This is what occurs, for example, with low nicotine cigarettes where the smoker increases the rate and depth of the puff to obtain the same amount of nicotine as that obtained from cigarettes of high nicotine content.

19. The effects of ayahuasca are related to the psychotropic effects of DMT [8, 9]. Harmine is viewed as a monoamine oxidase inhibitor (MAOI) that allows absorption of DMT from the gastrointestinal tract. DMT alone given orally would not be absorbed into the body. DMT would be destroyed by the monoamine oxidase (MAO) in the liver. Extracts containing harmine and harmoline without DMT are also used as hallucinogens. The exact effects of harmine alone are unclear[12] but it appears that extracts of the plants containing harmine have been used alone as a hallucinogen since antiquity[11]. Even today, teas containing harmine and harmoline are associated with hallucinations and serious reactions that could lead to death [19]. MAO is an enzyme that metabolizes certain monoamine compounds. MAO is found (1) in the liver and gastrointestinal tract and (2) in the nerve and support cells of the nervous system. In the liver and gastrointestinal tract, MAO acts to degrade ingested compounds

that contain monoamines. As such, the liver MAO is a protective mechanism. In the central nervous system, MAO functions to degrade naturally occurring monoamines such as dopamine, norepinephrine and serotonin. These monoamines are involved in transmitting impulses from one nerve cell to another. A nervous impulse releases these neurotransmitters from one nerve cell that in turn stimulates the next. After stimulation, the neurotransmitters are taken up by the first nerve cell (reuptake). A portion is degraded by MAO. This allows the next impulse to release neurotransmitters that can act on the nerve. MAOI's act to increase the amounts of these neurotransmitters. Depression is believed to result from low levels of these neurotransmitters. Severe depression is treated with MAOIs that were developed by the pharmaceutical industry. **The mental effects of orally-consumed ayahuasca (containing a mixture of DMT and harmine) are primarily those of the LSD-like hallucinogen DMT.**

20. ***Toxic effects of MAOI.*** As a separate matter – and concern – from the effects of DMT, two major types of toxic effects are observed with MAOI used in medicine. First, if the MAO in the liver is inhibited, monoamines can escape destruction and be absorbed into the body and exert effects as is the case with DMT in ayahuasca. Patients treated with MAOI cannot ingest food stuffs containing the amino acid tyramine. If tyramine is not degraded it exerts and action to elevate blood pressure to extreme levels and can result in death. Patients taking MAOI's are placed on severe dietary restrictions. The second set of toxicities result from the co-administration of numerous drugs that affect the central nervous system with MAOI. Many of these drugs cause increased levels of neurotransmitters in the central nervous system. When co-administered with MAOI, toxic levels of neurotransmitters such as serotonin can result in excessive stimulation of serotonin receptors. The resulting serotonin syndrome consists of changes in motor activity, mental functioning and the autonomic nervous system. At times, life threatening complications can occur. Among the drugs known to produce the serotonin syndrome when co-administered with MAOI's are the LSD-like hallucinogens.

21. The MAOI, harmine, would be expected to have a similar potential for interactions with foodstuffs and drugs. ***The harmine in ayahuasca, as an MAOI, can interact with certain foodstuffs and drugs to produce toxic reactions that can be severe and even fatal.***

22. ***Ayahuasca as a drug of abuse.*** The effects of ayahuasca in humans have been assessed in experimental studies in recent years[17, 18]. One study conducted in Spain provides critical information [7]. This was a double blind study that compared the effects of low and high doses of ayahuasca and placebo in volunteers with histories of use of LSD-like hallucinogens. First, ayahuasca produced perceptual changes as measured by the Hallucinogen Rating Scale and by the MBG scale of the Addiction Research Inventory. In addition, ayahuasca produced responses on Scales that measure such subject responses as "Liking" and "High." Effects as measured by these three scales are viewed as a measure of euphoria or the reinforcing effect of drugs of abuse. The second finding of significance was that there were not significant amounts of harmine in blood, suggesting that harmine itself was metabolized in the liver. The investigators interpreted this finding to indicate that harmine predominately inhibits the MAO in the liver and gastrointestinal track. Inhibition of MAO in the brain by harmine would seem unlikely.

23. The effects of ayahuasca in general appear to be similar to those described for synthetic DMT. The effects of ayahuasca taken orally come on a slower rate and last longer than the effects of DMT injected or smoked.

24. Nausea, bitter taste of ayahuasca, and ayahuasca-induced vomiting have been advocated by Plaintiffs' witnesses as an adverse effect that would limit abuse of ayahuasca (nausea and vomiting is produced by DMT and the other LSD hallucinogens.). This conclusion regarding deterrence is not credible. First, the nausea and vomiting is not a consistent effect, and has been reported to be rare by Plaintiffs. More importantly, with other drugs of abuse such as opiates, alcohol

and tobacco, nausea, vomiting, bitterness, and other unpleasant side effects do not prevent abuse or use. Indeed, experienced users of heroin actually use the degree of nausea and vomiting to gauge the strength of the injected drug.

25. The Internet site Erowid (www.erowid.com) provides information about both licit and illicit psychoactive drugs. The relatively extensive section on ayahuasca includes instructions for preparation, reports of experiences with its use and its legal status. This indicates a degree of knowledge and awareness of ayahuasca as a psychedelic or hallucinogenic substance outside its use in the syncratic churches. **As confirmed by its increasing use by drug users, ayahuasca itself produces effects consistent with the risks and probability of abuse seen with DMT alone.**

26. **Potential adverse effects of ayahuasca.** One set of potential adverse effects of ayahuasca would be those changes in mood, thinking, behavior and perception seen in experimental studies and street abuse of DMT and other LSD-like hallucinogens. In addition, a second potential set of adverse effects relates to interactions with the MAOI harmine. These potential interactions could occur with drugs affecting the central nervous system and foodstuffs containing monoamines. **Ayahuasca, therefore, has the potential of even more significant toxic effects than those presented by DMT alone.**

27. ***Therapeutic use of ayahuasca.*** Ayahuasca, in a manner similar to other LSD hallucinogens, has been reported to have therapeutic benefits – in particular by practitioners of the Santo Daime faith tradition, including Plaintiffs (*see, e.g.*, Statement of Mary Row at 3 (stating that Daime consumption "leads to healing on all levels"). These are based upon anecdotal experiences and not from controlled studies to demonstrate efficacy. Indeed the initial introductions into western medicine in the 1950s were possible therapeutic agents with claims of curing alcoholism and criminal behavior [4]. From the 1950s and 1960s, there are a number of reports as to their possible use, none of which have been demonstrated

in controlled trials. Various claims for therapeutic benefit from LSD-like hallucinogens have included: (1) the agents may assist in the process of self discovery and recall of repressed history; (2) the agents may assist in an abreaction in which reliving a moving experience to relieve pent up emotions; (3) the agents produce a psychedelic experience or mind opening experience that leads to a rapid personality change (this is likened to a religious conversion); (4) the agents produce religiomystical experiences of greater intensity than can be experienced in the drug free state; (5) the agents could aid group psychotherapy to facilitate communication and break down defensive barriers; (6) the agents could relieve anxiety, or depression or even schizophrenia; (7) the drug was administered to alcoholics to facilitate a religious type mind opening experience to change drinking behavior; and (8) the drug was administered to psychopaths (antisocial personality disorders in modern terminology) to change personality. These claims were not based upon significant and rigorous study that met legal , regulatory and accepted scientific criteria for therapeutic efficacy .

28. Even today, there is still advocacy for use of hallucinogens as therapeutic agents as evidenced by purported therapeutic use of MMDA ("Ecstasy"), a hallucinogenic phenethylamine that is a current drug of abuse. **Any therapeutic benefit, either of hallucinogens in general as therapeutic agents, or of ayahuasca/DMT in particular, remains unproven.**

29. ***Safety issues with ayahuasca use and the need for further study***. The potential for mental disturbances from the DMT are clear. The potential for adverse effects from interactions of food stuffs and drugs with the MAOI harmine are clear. The safety of long term use is uncertain, at best. To obtain such data, a controlled study would need to be conducted. This requires administration of a preparation containing known and fixed doses of ayahuasca to one group and placebo to a corresponding group. This is the standard for developing drugs in the pharmaceutical industry. This should be preceded by safety studies in animals. ***Before ayahuasca can be deemed safe for consumption, therefore – let alone to***

carry an accepted therapeutic use in medicine – it must be subject to appropriate study that not only assess therapeutic efficacy but also an assessment of risks and benefits..

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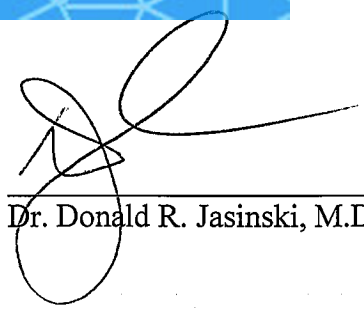
List of all publications written in the past ten years

See attached cv and bibliography.

I declare under penalty of perjury that the foregoing is true and correct.



5 Dec 2008

Dr. Donald R. Jasinski, M.D. Date