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Attorneys for Plaintiffs

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF OREGON
(Medford Division)

CHURCH OF THE HOLY LIGHT OF THE QUEEN, a/k/a The Santo Daime Church, an Oregon religious corporation, on its own behalf and on behalf of all of its members, **JONATHAN GOLDMAN**, individually and as

Civil No. 08-cv-03095-PA

REBUTTAL STATEMENT OF JOHN H. HALPERN, M.D.

Spiritual Leader of the "Santo Daime Church," **JACQUELYN PRESTIDGE, MARY ROW, M.D., MIRIAM RAMSEY, ALEXANDRA BLISS YEAGER**, and **SCOTT FERGUSON,** members of the Santo Daime Church

Plaintiffs,

v.

MICHAEL B. MUKASEY, Attorney General of the Unites States; **KAREN J. IMMERGUT,** United States Attorney, District of Oregon; **HENRY M. PAULSON**, Secretary of the U.S. Department of the Treasury,

Defendants.

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This is the second report of John H. Halpern, M.D. For purposes of this report, I have read the reports of Thomas R. Kosten, M.D., Donald R. Jasinski, M.D., George S. Glass, M.D., P.A., Jerry Frankenheim, Ph.D., Loren L. Dawson, Shrihari R. Tella, and Alexander Walker, experts on behalf of the Government. The Government's experts, when their reports are taken in total, create a tremendous amount of misinformation or partial information, some of which overlaps among their reports. My present report contains additional information and context sufficient to make these deficiencies obvious.

Professional Background:

In addition to a description of my professional work and credentials stated in prior report and listed in my Curriculum vitae, I am a physician who is Board Certified in General Psychiatry and who has completed a 3 year fellowship in drug and alcohol abuse research. In the ten years since finishing my residency training in psychiatry, I have treated many hospitalized patients and in outpatient private practice for drug and alcohol abuse and dependence and for those "dually diagnosed" with other psychiatric conditions in addition. I continue to treat such patients and I am sought out to consult on patients where hallucinogen abuse appears part of the presenting problems.

The research of hallucinogen users, including those who do so for religious reasons, is one of keen interest to me, especially as they fall within my stated area of research focus: the use and abuse of hallucinogens. Since psychiatry residency, this research has received the Ethel Dupont Warren Fellowship Award and the Peter Livingston Fellowship Award from Harvard Medical School to support my first year of full-time research as a post-doctoral research fellow of McLean Hospital's Alcohol and Drug Abuse Research Center (ADARC). Two additional years of this fellowship at the ADARC were funded by National Research Service Awards from the National Institutes of Health's National Institute on Drug Abuse (NIDA). My research and career next received 4 years of NIDA support (Mentored Patient Oriented Research Career Development Award), and I currently hold an Original Research Grant (R01) from NIDA on evaluating long-term cognitive consequences from the abuse of the structured amphetamine MDMA (an "empathogen" listed as a hallucinogen). My record of accomplishment has led to my current appointment as Assistant Professor of Psychiatry at Harvard Medical School, and I have been appointed Director

of my own lab, the Laboratory for Integrative Psychiatry, Addictions Division, McLean Hospital.

In addition to publishing studies and reviews related to hallucinogens, I have co-authored 4 medical textbook chapters on hallucinogen abuse.[i,ii,iii,iv,v] As part of my teaching responsibilities to Harvard Medical School and to Harvard residencies in psychiatry, I have co-led a seminar on addiction psychiatry to senior psychiatry residents and I lecture on hallucinogen abuse to psychiatrists completing their fellowship in addiction psychiatry. My NIDA funded study of MDMA and cognitive competence is quite similar in design to my evaluation[vi] (also NIDA funded) of members of the Native American Church (NAC), who consume peyote (containing the hallucinogen mescaline) as their religious sacrament. In the course of my research, I have screened close to 1000 NAC members and carefully interviewed approximately 500 about their drug and alcohol histories, psychiatric and medical histories, and about their use of their peyote sacrament. I have interviewed most of the active membership (approximately 34 of 40) of the Santo Daime group based in Ashland, Oregon.[vii] I have interviewed over 200 MDMA users for the NIDA-funded study, to date.

My expertise therefore does not just derive from my extensive experiences as a psychiatrist treating those individuals seeking medical attention related to their ingestion of hallucinogens – my expertise also derives from a broader evaluation of users than the typical clinician, drug abuse caregiver, theologian, or university-based epidemiologist would encounter. To the best of my knowledge, no other living psychiatrist or other type of physician has completed more psychiatric evaluations and drug use histories of Americans who for religious reasons consume a sacrament that also contains a hallucinogenic drug. My professional work can directly inform on differences between Americans who ingest a religious sacrament that contains a hallucinogen and Americans who recreationally/illicitly ingest hallucinogens outside of a religious context.

Further information on my study of the Native American Church and its relevance for this present case:
I have published in the peer-reviewed literature[viii,ix,x] and given presentations (including as an invited lecturer for two NIDA workshops)[xi,xii] on public drug policy related to

the issue of religious sacraments that contain a hallucinogen.

The key misunderstanding for those unfamiliar with religions like the NAC (and Santo Daime) is the assumption that the ingestion of the sacrament is for inducing a hallucinogen intoxication – that these people seek "getting high" much like a person would in a recreational context. The Hon. Victor J. Clyde of the Chinle Justice Court, Arizona is a Navajo Native American and a lifelong member of the NAC. Judge Clyde once explained that if an NAC member ingested peyote outside of Traditional uses and recognized religious practices, then even that person is violating the Controlled Substances Act because that type of action meets the definition of "drug use" of that Schedule I hallucinogen. Context is key, however, because the purpose of sacramental use goes beyond the narrow definition of a "carrier medium" for dosing a Schedule I hallucinogen. Had the Government's experts taken into account the relevant legal and religious concepts that afford accommodation to the NAC's use of peyote, they would appreciate why I similarly describe the religious sacramental ingestion of Daime as the "non-drug use" of ayahuasca.

A religious sacrament of a legally-valid religion takes on meaning and definition beyond its physical form. By ignoring the concept of "non-drug use" within a bona fide religious context, several of the Government's experts assert that this religious practice should be evaluated by the FDA for safety and for medical utility. The NAC has never been subject to such a requirement for their peyote, nor have Orthodox Jews been forced to prove safety for intoxication with alcohol during the festival of Purim, nor have certain religions that reject childhood vaccination been required to prove lack of vaccination as "safe." The Code of Federal Regulations expressly states at 21 CFR 1307.31 (as of January 5, 2009) that "the listing of peyote as a controlled substance in Schedule I does not apply to the ***nondrug use of peyote*** in bona fide religious ceremonies of the Native American Church, and members of the Native American Church so using peyote are exempt from registration" (bold and italics emphasized). The Church of the Holy Light of the Queen (CHLQ)(Santo Daime) of Ashland Oregon is similarly accepted within their community (at the State level) as employing their Daime sacrament for a nondrug religious purpose: In November, 2000, the State of

Oregon's Board of Pharmacy issued to CHLQ a religious exemption from Oregon narcotics control finding that, "the sacramental use of the Santo Daime tea in the context of a bona fide religious ceremony by practitioners of the Santo Daime religion as described does not constitute abuse of a controlled substance." At no point in my prior report did I intend to imply that religious Daime ingestion erases the presence of a Schedule I hallucinogen, DMT. However, the Government's experts should not ignore in their evaluation the important nondrug function of Daime as the accepted sacrament of followers of Santo Daime.

NAC members consume peyote because it is their sacrament and not because it contains mescaline. NAC members do not consume "San Pedro cactus" (*Echinopsis pachinoi*), a common ornamental cactus,[9] that contains mescaline in sufficient amounts for inducing intoxication. Peyote is collected only in the wild in Texas along the border with Mexico but the San Pedro cactus can be legally purchased from gardening centers. Even so, the NAC needs peyote because that is their sacrament and, similarly, they have no religious use for San Pedro cactus because that is not the NAC's sacrament. The Santo Daime consume ayahuasca ritually prepared as Daime made from the *Banisteriopsis caapi* vine and the leaves of the *Psychotria viridis* plant. There are wild plants growing throughout much of the United States that contain DMT (such as *Desmanthus illinoensis* – "prairie bundleflower")[9] or contain MAOI beta-carbolines (such as Passiflora incarnata – "passion flower"; Peganum harmala – "Syrian rue")[9] and the combination of such plants can be brewed into a tea approximating ayahuasca. Even so, the Santo Daime needs Daime ayahuasca because that is their sacrament, and, similarly, they have no use for other plant sources of DMT or MAOIs because those other plants are not Santo Daime's sacrament.

Sacramental use (whether NAC or Santo Daime) is within a carefully controlled environment in which those in attendance share intent to express their faith through participation. The setting is the religion's place of worship. Believers' mindset, in general, will be respectful to the seriousness of the ceremony and the demands for fulfilling specific rituals, such as prayer and song. In other words, careful attention is paid to "*set and setting*." "Set" refers to the personality, expectations, and preparations of the user, and "setting" refers to the environment and context within which the user will ingest

the hallucinogen. Clinical research with hallucinogens and in evaluation of users in the general population led to the observation that extent of attention to set and setting can positively or negatively impact the hallucinogenic experience (with less attention related to greater risk for a negative experience).[xiii,xiv,xv] Those Government experts reviewing health risks to the consumption of hallucinogens have not provided data that such harms would reasonably be predicted to occur when taken within a religious context by Americans. I am not aware of any data published or unpublished that links psychological harms to sacramental hallucinogen use. In fact, my data on the Native American Church, the only study to date on long-term health consequences for Americans from religious peyote use, failed to capture any such harms but did report better psychological wellness in comparison to healthy, normal controls on most sub-scores of the Rand Mental Health Inventory.[6] This study, completed with NIDA support, had a large population of subjects, had matched comparison groups, and had neuropsychological data collected blind to group assignment. The study completed of American Santo Daime members[7] is similar to earlier work with the NAC, but the results from this Santo Daime paper appear consistent with similar data collected from NAC members. Santo Daime members, just like with NAC members, described in their interviews the central importance of partaking of their sacrament for prayer. None of the Santo Daime members or NAC members I interviewed met criteria for the psychiatric diagnoses of hallucinogen abuse, hallucinogen dependence, hallucinogen persisting perception disorder, hallucinogen intoxication delirium, hallucinogen-induced psychotic disorder with delusions, hallucinogen-induced psychotic disorder with hallucinations, hallucinogen-induced mood disorder, hallucinogen-induced anxiety disorder, or a hallucinogen-related disorder not otherwise specified. In my ongoing NIDA-funded study of Rave (all night dance) attendees who use MDMA, several participants met criteria for a hallucinogen-mediated psychiatric disorder: none of those subjects have a past or present history of involvement in the Santo Daime or NAC or in any religious practice involving hallucinogen consumption. The best evidence to-date is that the religious use of Daime or Peyote does not appear to harm such users and may contribute to overall benefits derived from active participation in an organized religion.

Comparison to the NAC is also relevant because the

Government Experts who predict harms from repeated religious ingestion of hallucinogens must then hold similar concerns regarding the NAC's use of peyote. My NIDA-funded multi-year study of long-term cognitive and emotional health of NAC members versus non-members failed to identify any evidence in support of such predictions of harm.[6] There is no other published data that shows such fears firmly realized, despite hundreds of thousands of members and a ceremony extending back into pre-history. The NAC does not do screening interviews of potential members using standardized written forms: it is only enough that such people feel called to participate. One could assume, much as the Government experts do with ayahuasca, that there may be risky drug-drug complications surrounding peyote ingestion, or that there may be special risks to populations thought vulnerable to adverse effects from the ingestion of hallucinogenic peyote/mescaline (such as individuals prone to psychotic disorders). There are no such focused medical/psychiatric evaluations at all however within the NAC. The NAC cares for its own membership and if there were problems, they would seek out advice or take corrective action. Yet no such problems documented or observed have been realized among Native Americans in the ways that the Government's Experts think reasonable to predict from the Santo Daime expressing their religious faith. Without any such protections or evidence of need for such protections, the NAC is steadily growing in population, is pan-Tribal, and remains the largest single faith of Native peoples of the United States. The only "paperwork" expected of an NAC member is to at some point obtain their "Membership Card" in which the only data collected is their full name, address, telephone number, tribe name, and tribal enrollment number (see attached example of a blank membership form of the Native American Church of North America).

Peyote distribution for the NAC is regulated by the Texas Department of Public Safety and the U.S. Drug Enforcement Administration. Millions of "buttons" of the dried crown (cut top) of the cactus are harvested and sold at reasonable cost (and for less) to the NAC across the United States each year and arrests for diversion are extremely rare, if ever. Accommodation of the NAC's need for their sacrament is evidence that it is possible to design effective oversight. 21 CFR 1307.31 states, "Any person who manufactures peyote for or distributes peyote to the Native American Church, however, is required to obtain

registration annually and to comply with all other requirements of law."

None of the Government's experts have been confronted in clinical research with the delicate issue of exploring the consumption of a hallucinogen-containing religious sacrament by believers. The need for community outreach, building trust, communication, and confidence in the integrity of study administration and reporting – all can take on special cautions and hesitations when the research is of individuals fearing persecution for their religious beliefs. The first two years of my work with the NAC was primarily community outreach and informational, holding meetings across Navajo Nation and with various community, hospital, tribal, and NAC leaders. Research requires much groundwork: they start out slow and with smaller numbers than later studies. Interim and pilot data can and should be published as it will also improve chances for receiving federal support for larger, more ambitious efforts. This is the model of research development employed in my work with Native Americans and it is a similar approach with American Santo Daime. The Government's experts that catalog deficiencies and their suggestions for improvements to my first published study on the Santo Daime are free to attempt replication of this work or to improve upon it but in science they cannot invalidate peer-reviewed results in the absence of conflicting evaluable data. My research group remains committed to expanding our work and accurately publishing our findings. Especially with federal support, a larger study of American Santo Daime members would address a larger range of potential study confounds. This is what we completed in our final published report of the Native American Church.

Comparing ayahuasca and DMT to other hallucinogens is of limited value

Several Government experts attempt to equate Ayahuasca use to DMT use and to LSD. Evidence offered in support is that animal studies have showed partial cross-tolerance to DMT for animals trained for LSD, that the psychoactive effects are "similar," and that hallucinogen abusers have included abuse of DMT along with other hallucinogens. However, conclusions about the pharmacology of ayahuasca and the consequences of such use can only be drawn with reasonable accuracy from actual studies of the pharmacology and consequences of ayahuasca. The use of hallucinogens for

religious and tribal purposes predates the founding of the United States, but there is no historical record of harms consistent with those predicted from evaluations of hallucinogen abusers. Speculation that a drug is similar to a better known and studied drug has many pitfalls and those pitfalls should be clearly described.

Studies that show only partial cross-tolerance between LSD and DMT also report full cross-tolerance among LSD, psilocybin, and mescaline. Another interpretation is then that while there are commonalities among these drugs, they are not identical. Moreover, what is observed to induce full substitution in animals does not equate to proof of hallucinogen activity in humans. 2-Bromo-LSD (BOL) induces cross-tolerance to LSD: when BOL was administered to human subjects over 1 to 2 days, it blocked the psychoactive effects of LSD given next.[xvi] BOL in drug discrimination studies also show full-substitution with LSD.[xvii,xviii] But BOL is not psychoactive in humans.

What about equating ayahuasca with LSD because both LSD and DMT are "psychotomimetic?" The term "psychotomimetic" originates from the early 1950s when scientists were trying to better understand psychotic disorders. The term fell out of favor because, in fact, hallucinogens are not psychotomimetic – the intoxication does not induce "model psychosis." For example, hallucinogens induce visual hallucinations that are quite rare in psychotic disorders. The claim for DMT to be "psychotomimetic" also was related to awareness that DMT is found in trace amounts in the human brain, but DMT level is non-specific to psychosis.[xix] Rather than be a promoter of psychosis, endogenous DMT has been postulated to suppress symptoms of psychosis.[xx]

Conclusions about the pharmacological or psychological effects of ayahuasca cannot be fully extrapolated or determined with scientific accuracy from data on LSD or other hallucinogens. There is no statistical method to extrapolate risk from evaluations of better known hallucinogens to DMT. And so, rather than offer a quantifiable assessment of the risk of DMT and/or ayahuasca, the Government's experts appear to rely on opinion drawn from review of limited research and general concerns for public health. When looking at epidemiological surveys of drug use in the United States, risk to public health from hallucinogens is quite small even though hallucinogens are ingested by a larger population of users

than in the 1960s. The federal government's Substance Abuse and Mental Health Services Administration's (SAMHSA) National Household Survey on Drug Abuse (NHSDUH) estimates (for year 2006) that of Americans aged 12 or older: close to 4 million used hallucinogens that year with 1.1 million trying one for the first time ever, and some 35.3 million Americans have tried one at least once in their lifetime.[xxi] SAMHSA's Drug Abuse Warning Network (DAWN) data estimates (for year 2005) 16,408 emergency room visits for the entire United States involved a hallucinogen (not including PCP: 7,535) with 10,752 for MDMA and less than 1,900 for the classical hallucinogen LSD (out of a total of 1.45 million drug-related visits).[xxii] Scientists applying a nine-category matrix of harm to drugs of abuse ranked LSD lower than alcohol, tobacco, and marijuana.[xxiii]

There are no published studies that compare the pharmacology of ayahuasca to LSD. There is one published study that compares the human pharmacology of DMT to LSD and mescaline.[xxiv] In this study, Dr. Stephen Szara self-administered DMT by intramuscular injection from 10 mg to 150 mg and offered his subjective observations and comparisons to his self-administration of LSD (100 mcg by mouth) and to his self-administration of mescaline (350 mg by mouth). The "most outstanding" difference observed was DMT's quicker rate of onset and very short duration of action. Emotional reactions to DMT and mescaline were described as "euphoric" but "anxious" for LSD. Dr. Szara, it should be noted, eventually became Chief of the Biomedical Research Branch of NIDA.

The pharmacological effects of ayahuasca cannot be extrapolated from data regarding the chemical structure of LSD or other hallucinogens, because, as mentioned above, there are many compounds with similar chemical structure that are not hallucinogenic. Moreover, the chemical structure of hallucinogens cannot predict the pharmacological effects of DMT in combination with the beta-carboline MAOIs that make DMT orally active. Nor can studies of LSD or other hallucinogens' agonism or antagonism at specific neuroreceptors of the brain predict the pharmacological effects of ayahuasca. In fact, the agonism and antagonism of ayahuasca is likely different at some neuroreceptor targets than DMT alone.

Ayahuasca and toxicity

Toxicity refers to the extent of damage to an organism caused by an exposure to a substance is able to damage an exposed organism. A central concept of toxicology is that effects are dose-dependent; water alone in copious amounts can intoxicate and prove lethal (polydipsia), whereas for even a very toxic substance, such as the pufferfish's tetrodotoxin, there is a dose below which there is no detectable toxic effect. Clinical toxicity from ayahuasca has not been quantified to specific dose but the most common adverse reaction is ayahuasca's reliable induction of nausea and associated vomiting. Purging of ayahuasca will obviously lessen the total exposure to the chemicals contained in ayahausca and suggests an upper-limit protective threshold for intentional dosing. Ayahuasca related nausea/vomiting has not been reported as "desirable" but Santo Daime members have stated that it is a marker for "spiritual healing": more nausea/vomiting is not a goal but healing by religious sacrament is. This contrasts markedly from the opiate dependent individual who takes nausea and vomiting as a sign of significant intoxication and validation of opiate strength.

The Government's experts devote much attention to their predicted risk for an MAOI-induced hypertensive crisis, for serotonin syndrome, and for worsening mental illness.

MAOI-induced hypertensive crisis

Monoamine oxidase inhibitors (MAOI) inhibit the monoamine oxidase enzyme, and this, in turn, inhibits the breakdown of monoamine neurotransmitters in the brain and the catabolism of dietary amines. There are two isoforms of monoamine oxidase: MAO-A and MAO-B. MAO-A preferentially deaminates serotonin, melatonin, epinephrine, and norepinephrine. MAO-B preferentially deaminates phenethylamines and other trace amines. MAO-A and MAO-B both deaminate dopamine. MAOIs are irreversible or reversible. Irreversible MAOIs bind permanently to the enzyme, destroying the enzyme's functionality. It will take up to 10 days for the human body to rebuild its supply of MAOI after sufficient exposure and dosing with an irreversible MAOI, such as tranylcypromine. Reversible competitive MAOIs will bind to the MAO enzyme but can be displaced for tyramine (a monoamine derived from the essential amino acid tyrosine); the MAO enzyme was not destroyed. Build up of tyramine can induce a hypertensive crisis because tyramine releases stored monoamines associated with increasing vasoconstriction, heart rate,

and blood pressure: the "tyramine pressor response." In sufficient amount, tyramine alone without any MAOI can still induce this pressor response. MAO-A more than MAO-B is needed to decrease circulating tyramine levels.

Reversible inhibition of MAO-A is termed "RIMA" and it is important to distinguish RIMAs from the irreversible MAOIs, especially in any discussion about risk for tyramine hypertensive crisis (see Appendix 1). Why? Because the risks for hypertensive crisis from a tyramine-rich diet plus ayahuasca as described by the Government's experts are described as if ayahuasca contains irreversible MAOI activity. In fact, the beta-carbolines (harmine, harmaline, 1,2,3,4-tetrahydroharmine) contained in ayahuasca are RIMAs only. Ayahuasca does not irreversibly inhibit MAO. Hypertensive crisis is much less likely with a RIMA[xxv] because, again, tyramine may compete to displace the RIMAs and so a toxic build-up of tyramine is plausible but unlikely except for individuals who might consume a large amount of tyramine-rich foods immediately after ayahuasca consumption. Santo Daime members do not eat right after ingestion of their sacrament: this alone may be why there are no reports in the literature of hospitalization or death from a tyramine hypertensive crisis. RIMAs that are used as medicines do not come with specific dietary restrictions against tyramine.[xxvi] Moreover, if tyramine is absorbed in the presence of a RIMA, MAO-B remains active to degrade tyramine in addition to tyramine having a higher affinity for MAO-A than the RIMA that is competitively blocking MAO-A activity.

MAOIs and serotonin syndrome

Serotonin syndrome may prove lethal and is a well-known complication from the combination of irreversible MAOIs with, for example, SSRI antidepressants. Serotonin syndrome is not drug dose-dependent and sometimes occurs from monotherapy. The half-life of the drugs involved will determine the duration of risk for the development of the syndrome, which is thought to result from overstimulation of CNS serotonin receptors and/or increase synaptic serotonin levels. MAO is an important enzyme pathway for the degradation and control of CNS serotonin levels, but there are several other pathways, as well. Elevated levels of serotonin in the CNS from an SSRI combined with an MAOI blocking serotonin degradation may lead to serotonin syndrome, which is characterized by altered mental status, agitation, myoclonus, hyperreflexia, diaphoresis, tremor,

diahrrhea, and incoordination. If untreated, patients may develop rhabdomyolysis, renal dysfunction, hepatic dysfunction, disseminated intravascular coagulopathy, lactic acidosis, myoglobinuria, or respiratory distress syndrome. Symptoms of serotonin syndrome develop within minutes to hours after exposure to the offending agent(s).[xxvii]

Serotonin syndrome has not been yet been reported from ayahuasca or from ayahuasca taken in combination with drugs known to overstimulate serotonin receptors. The use of ayahuasca by individuals taking an SSRI has been cautioned against because the risk of combination of an SSRI with an irreversible MAOI can prove lethal (even though no irreversible MAOI is contained in ayahuasca). The one peer reviewed paper to focus on ayahuasca and serotonin syndrome, however, is a theoretical report without any clinical evidence of occurrence,[xxviii] though Government expert Dr. Frankenheim cites this paper as confirmation of "acute toxicity." Actual risk of serotonin syndrome from RIMA ingestion is considered decreased in comparison to irreversible MAOIs.[xxix] Government expert Dr. Kosten states, "The serotonergic actions of ayahuasca are substantial and can produce a serotonin syndrome in Church participants." In support of this claim, Dr. Kosten cites a 2005 NEJM article,[xxx] but further review reveals that he misinterprets this paper. Neither the text nor the figures of the NEJM paper mention ayahuasca at all. In fact, the NEJM article relied upon by Kosten attributes serotonin syndrome to drugs used in combination with the synthetic potent serotonin releasing agent and hallucinogen 5-MeO-DMT – which is not found in Daime. I confirmed Dr. Kosten's mistake by consulting the first author of the NEJM paper, who is a research colleague and collaborator of mine.

If beta-carboline RIMAs as contained in ayahuasca could lead to serotonin syndrome and/or a serious tyramine-mediated hypertensive crisis, it would stand to reason that exposure to these RIMA compounds would, independent of ayahuasca exposure, also result in instances of serotonin syndrome and hypertensive crisis. Indeed, all beta carbolines have high affinity toward MAO-A enzyme as RIMAs.[xxxi] But serotonin syndrome and hypertensive crisis are not routinely reported from beta-carboline ingestion, even though beta-carbolines are routinely found in our diets (high concentrations are found in coffee, well cooked meats, and raisins, as examples) and are produced in

tobacco smoke.[xxxii,xxxiii,xxxiv] One research study scanned 16 tobacco smokers versus 15 nonsmokers with positron emission tomography (PET) to evaluate MAO-A inhibition and showed that "tobacco smoke exposure is associated with a marked reduction in brain MAO A, and this reduction is about half of that produced by a brief treatment with tranylcypromine."[xxxv] Tranylcypromine is an irreversible non-selective MAOI antidepressant known to be contraindicated with an SSRI. If people typically are exposed to beta-carbolines, including those contained in ayahuasca, tobacco smoking and those common foods would likely have been identified already as contraindicated to SSRI use. Instead, there is no such evidence of dietary or tobacco contraindications to SSRI use. The scientific foundation for the Government's experts raising extreme concerns about exposure to the beta-carbolines of ayahuasca – appears woefully insufficient to so conclude. The lack of reports on serotonin syndrome or hypertensive crisis mediated by ayahuasca and the relative rarity for these conditions to be otherwise encountered in medicine strongly indicate that these risks are extremely rare, if ever, encountered.

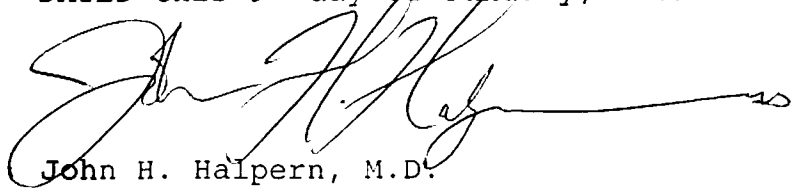
Ayahuasca and worsening mental illness

Government experts theorize multiple psychiatric harms from ayahuasca use but as noted above they fail to cite any research of ayahuasca use supportive of their opinions and they fail to consider evidence that sacramental ayahuasca can and is safely consummed within a religious setting. There are no reports in the literature of ayahuasca causing hallucinogen persisting perception disorder (HPPD), yet the Government's expert do offer this as plausible without offering any quantification on just how common such a disorder would be estimated within the ayahuasca religions. In the general population, HPPD is only very rarely encountered (one group estimated HPPD occurs in 1 in 50,000 LSD users).[xxxvi] Government experts' concerns for other psychiatric complications from ayahuasca appear similarly lacking in substantiating data. Serious side-effects can occur from almost any activity but that does not inform on the likelihood of occurrence. As noted above, out of millions of emergency room visits resulting from drug abuse, hallucinogens are identified only in the tens of thousands despite over 1 million Americans trying a hallucinogen for the first time in their life each year. Rather than avoid psychiatric care, my evaluation of active members of CHLQ identified a majority clearly identifying improved mental and physical health and the two members

with history of bipolar disorder or serious anxiety disorder similarly describe ongoing improvements as well as continue to obtain mental health care from a psychiatrist physician. Skeptics cannot invalidate these findings by opinion but replication or improved methodological studies may find harms where my initial report does not: that is why clear disclaimers of study limitations were presented in the paper's abstract and carefully reviewed in the discussion. Rather than hunt for biases, I would encourage these skeptics to consider the possibility that members of the Santo Daime are much as I observed: healthy and "normal." It is naïve to presume that the practicing clinical psychiatrists who conducted these evaluations of the Santo Daime could be universally gamed into completely baseless findings of wellbeing.

The statements set forth in this document are my own and are based on my education and experience. Pursuant to 28 USC § 1746, I declare under penalty of perjury that the foregoing is true and correct.

DATED this 9th day of January, 2009



John H. Halpern, M.D.

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