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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

**DEFENDANTS'
MOTION IN LIMINE
TO EXCLUDE TESTIMONY OF
HALPERN, GURULE, MACRAE,
GERDING, WINKELMAN,
AND COZZI**

Pursuant to Federal Rules of Evidence 401, 402, and 702, Defendants respectfully request that the Court enter an order to exclude the testimony of Plaintiffs' expert witnesses provided in the witness statements filed on December 1, 2008. The portions of testimony Defendants request the Court exclude and the grounds for doing so are set forth in the attached memorandum.

Dated: December 18, 2008

Respectfully submitted,

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**DEFENDANTS' MEMORANDUM
IN SUPPORT OF THEIR
MOTION IN LIMINE
TO EXCLUDE TESTIMONY OF
HALPERN, GURULÉ, MACRAE,
GERDING, WINKELMAN,
AND COZZI**

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<i>Morton v. Mancari</i> , 417 U.S. 535 (1974)	12-13
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<i>Obrey v. Johnson</i> , 400 F.3d 691 (9th Cir. 2005)	8, 10
<i>S.E.C. v. Capital Consultants, LLC</i> ,	

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United States v. Chang,
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United States v. Cordoba,
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United States v. Hermanek,
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OTHER AUTHORITIES

American Society for Pharmacology and Experimental Therapeutics,
“About Pharmacology,” available at
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Occupational Outlook Handbook, 2008-09 Edition, Pharmacists, available at
<http://www.bls.gov/oco/pdf/ocos079.pdf> 20

INTRODUCTION

The expert witness statements submitted by Plaintiffs suffer from a wide range of fatal flaws that require exclusion of all or significant parts of each expert's testimony. Plaintiffs statements veer dramatically from their respective areas of expertise and offer a broad range of opinions that are neither drawn from their specialized knowledge nor obtained through any discernible scientific method. *See* Fed. R. Evid. 701-02. Moreover, much of the testimony is irrelevant and inapplicable to factual issues before this Court. *See* Fed. R. Evid. 401, 402.

The Amended Expert Witness Statements of Dr. John Halpern, Mr. Jimmy Gurulé, Dr. Edward MacRae, and Mr. George Gerding should be excluded in their entirety. Dr. Halpern is a psychiatrist who, along with the Plaintiffs, conceived of and led a study concerning the safety of ayahuasca use. This study suffers from severe methodological deficiencies that render it completely unreliable and potentially misleading. As a result of these methodological defects, Dr. Halpern's study and accompanying testimony should not be admitted into evidence.

Mr. Gurulé, as a former federal and state prosecutor, is presented as an expert in drug trafficking, but his testimony is written as if he were tasked with rendering a legal opinion in this matter. He does not draw upon specialized knowledge to assist the Court in reaching findings of fact, but instead does nothing more than offer his personal legal opinion about how this Court should apply the Religious Freedom Restoration Act ("RFRA") to the facts of this case. Mr. Gurulé's witness statement is a classic example of improper legal opinion testimony, which is clearly prohibited under established law.

Dr. MacRae's testimony also should be excluded. Plaintiffs present Dr. MacRae as an expert in Brazilian history and law and seek to introduce his testimony about how the Brazilian

government regulates ayahuasca. Dr. MacRae's knowledge of Brazilian history and law, while substantial, is plainly irrelevant to this case and thus fails the relevance prong of Rule 702. Brazilian law has no factual bearing on whether RFRA entitles the Plaintiffs to an exemption from the Controlled Substances Act ("CSA").

Finally, Mr. Gerding's testimony should also be excluded in its entirety. Plaintiffs present Mr. Gerding as an expert on the health and safety of ayahuasca use, as well as an expert on public policy concerns surrounding the Plaintiffs' use of ayahuasca. Mr. Gerding is asked to make these statements based on his experience as a pharmacist and a former member of the Oregon Pharmacy Board. Mr. Gerding's education and experience do not qualify him to offer the opinion testimony contained in his witness statement. Furthermore, the decisions of the Oregon Pharmacy Board have no bearing on the central question in this case, which is whether the Plaintiffs should be granted an exemption from the CSA. Mr. Gerding strays from his limited area of specialized knowledge and offers testimony that is not "based upon sufficient facts or data." *See* Fed. R. Evid. 702. As a result, Mr. Gerding's testimony should be excluded in its entirety.

Plaintiffs' remaining experts, Dr. Michael Winkelman and Dr. Nicholas Cozzi, may be qualified to offer opinions on certain issues in which they have expertise. Their testimony, however, strays substantially from these distinct areas of expertise. Dr. Winkelman, as an anthropologist, may be qualified to discuss the anthropological history of the Santo Daime Church, but the Federal Rules of Evidence do not permit him to opine about pharmacology, toxicology, or diversion control. Similarly, Dr. Cozzi may have specialized knowledge of

pharmacology and toxicology, but he is not qualified to veer from his area of study to offer his personal opinions about drug control policy.

LEGAL STANDARDS

The testimony and opinions of an expert witness must satisfy the requirements of Rule 702, which governs the admissibility of expert testimony. Rule 702 provides:

If scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. Rule 702 “assigns to the district court the role of gatekeeper and charges the court with assuring that expert testimony . . . is relevant to the task at hand.” *United States v. Hermanek*, 289 F.3d 1076, 1093 (9th Cir. 2002) (citing *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993)) (internal quotations omitted).

A court must also ensure that an expert has laid the proper foundation on which to offer his testimony. When “[f]aced with a proffer of expert scientific testimony . . . the trial judge must determine at the outset, pursuant to [Federal] Rule [of Evidence] 104(a), whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue.” *Daubert*, 509 U.S. at 592. This inquiry is a flexible one, but trial courts should focus “solely on principles and methodology, not on the conclusions that they generate.” *Id.* at 595.

The Supreme Court has explained that conclusions and methodology are not entirely distinct from one another, and that a “court may conclude that there is simply too great an

analytical gap between the data [or information considered] and the opinion proffered.” *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). The Court has made clear that this gatekeeping function of the district court extends beyond scientific testimony to “testimony based on ‘technical’ and ‘other specialized’ knowledge.” *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999).

Thus, courts conduct a two-part analysis. First, courts must determine “whether the experts’ testimony reflects ‘scientific knowledge,’ whether their findings are ‘derived by the scientific method,’ and whether their work product amounts to ‘good science.’” *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1315 (9th Cir. 1995) (“*Daubert I*”) (quoting *Daubert*, 509 U.S. at 590, 599). Second, a court must “ensure that the proposed expert testimony is ‘relevant to the task at hand.’” *Daubert II*, 43 F.3d at 1315 (quoting *Daubert*, 509 U.S. at 580). In other words, evidence must be reliable and relevant.

A. Testimony Must Be Based on Reliable Methodology.

The test for reliability “is not the correctness of the expert’s conclusions but the soundness of his methodology.” *Daubert II*, 43 F.3d at 1318 (9th Cir. 1995). The Supreme Court has enumerated a few factors to guide a court’s evaluation of whether an expert’s methodology is sufficiently scientific: “whether the theory or technique employed by the expert is generally accepted in the scientific community; whether it’s been subjected to peer review and publication; whether it can be and has been tested; and whether the known or potential rate of error is acceptable.” *Id.* at 1316. In addition, “in order to qualify as ‘scientific knowledge,’ an inference or assertion must be derived by the scientific method.” *Id.* at 1316 (quoting *Daubert*, 509 U.S. at 590). After determining that testimony is reliable, the court must then move to a

determination of relevance. *See Daubert*, 509 U.S. at 591 (“Expert testimony which does not relate to any issue in the case is not relevant, and ergo, non-helpful.”)

B. Testimony Must Be Relevant to the Case at Hand.

The second prong of the court’s inquiry addresses relevancy and often implicates the questions set forth in Rules 401 and 402. *See Hemmings v. Tidyman’s Inc.*, 285 F.3d 1174, 1184 (9th Cir. 2002) (“Whether testimony is helpful within the meaning of Rule 702 is in essence a relevancy inquiry.”). “‘Relevant evidence’ means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.” Fed. R. Evid. 401; *Baker v. Delta Airlines, Inc.*, 6 F.3d 632, 641 (9th Cir. 1993). All relevant evidence is generally admissible. Fed. R. Evid. 402. “The particular facts of the case determine the relevancy of a piece of evidence.” *United States v. Vallejo*, 237 F.3d 1008, 1015 (9th Cir. 2001). The determination of relevancy is the sole province of the court, “[a] district court has broad discretion to determine whether evidence is relevant.” *United States v. Lopez*, 803 F.2d 969, 972 (9th Cir. 1986).

ARGUMENT

I. DR. HALPERN’S TESTIMONY AND STUDY SHOULD BE EXCLUDED IN THEIR ENTIRETY.

Dr. Halpern seeks to support Plaintiffs’ claim that regular ayahuasca consumption involves no medical or psychiatric risk.¹ His testimony flows from his personal belief that

¹ Following the lead of Plaintiffs’ experts, Defendants will refer to the mixture of the *Banisteriopsis caapi* vine with the leaves of the *Psychotria viridis* as “ayahuasca.” *See* Amended Expert Witness Statement of Dr. John Halpern at 3, 9; Amended Expert Witness Statement of Mr. Jimmy Gurulé at 6, 7, and 9; Amended Expert Witness Statement of Mr. George Gerding at 3, 4, and 11; Amended Expert Witness Statement of Dr. Nicholas Cozzi at 2.

certain hallucinogenic drug use should be considered “non-drug use,” *see* Amended Expert Witness Statement of Dr. Halpern at 6, and from a methodologically-flawed study conceived by the Plaintiffs themselves. Def. Ex. 1103. This study, which was the result of interviews with a carefully-selected subset of members of the Plaintiff Church, runs far afoul of Rule 702’s standard for admissibility. Because Dr. Halpern’s study is based on flawed principles and unscientific methodology, any testimony regarding that study should be excluded.

Dr. Halpern attempts to bolster the conclusions in his study by referencing an earlier study performed by Dr. Charles Grob on ayahuasca use in Brazil. This study (the “Grob Study”) shares many of the methodological flaws of Dr. Halpern’s study, and therefore, cannot serve as the basis for any expert testimony.

A. Dr. Halpern’s Testimony Does Not Satisfy the *Daubert* Standard for Methodology.

Dr. Halpern’s study does not satisfy the standard set forth in *Daubert* because his study is based on results gained from unscientific methods. “The subject of an expert’s testimony must be ‘scientific . . . knowledge.’ The adjective ‘scientific’ implies a grounding in the methods and procedures of science.” *Daubert*, 509 U.S. at 589-90. If the methods underlying the testimony of an expert are not sound, the results obtained through that method should be excluded. *See Daubert II*, 43 F.3d at 1318.

Even though Dr. Halpern may be an expert in psychiatry, his methodology must be scrutinized. *See id.* at 1315-16 (“[S]omething doesn’t become scientific knowledge just because it’s uttered by a scientist; nor can an expert’s self-serving assertion that his conclusions were ‘derived by the scientific method’ be deemed conclusive.”).

Dr. Halpern's expert witness statement (and accompanying study) are undermined by at least six methodological defects that require its exclusion. *See* Expert Witness Report by Alexander Walker at 9 (Doc. # 70); Expert Witness Report by Lorne Dawson (Doc. # 71).

First, Dr. Halpern relies on non-comparable comparators. He takes his small study group, composed entirely of self-selected church members, and compares it to statistics gathered from the United States as a whole, which has a very different make-up than a small selection of church members. Even Halpern himself acknowledges this lack of a comparable control group to be a "study limitation." Halpern Study at SR20. As both Dr. Halpern and Dr. Walker acknowledge, it is invalid to compare national norms against the church members because the two groups are too demographically different to reasonably compare. *Id.*; Walker Report at 7. The two groups' social and psychological dissimilarities preclude drawing any reasonable conclusion from their comparison.

Second, Dr. Halpern excluded those subjects who were most likely to manifest an ill effect. In his study, Dr. Halpern interviewed only current church members, which left him with a skewed study group. As he explains, "the entire current membership of the Santo Daime Church in Oregon . . . were informed about this study." Halpern Article at SR17. Dr. Halpern fails to note, however, that anyone who suffered from brain cancer, had a head injury, or took antidepressants, anti-psychotics, opiates, mood stabilizers, benzodiazepine, or anti-seizure medication was intentionally excluded from the study. *See* Def. Ex. 1241. It is important to note that while people taking these medications were not allowed to participate in the study, the use of such drugs did not prohibit these people from drinking ayahuasca within works of the Plaintiff Church. *See* Dep. of John Seligman at 114, Def. Ex. 1035. In limiting the study participants in

this way, Dr. Halpern effectively ensured that those who had negative experiences with ayahuasca were not captured by the study. With such a select group, it is perhaps not surprising that the Halpern Study offers the following conclusion: “[w]hat [the Church] preach[es] is that taking the sacrament and following the doctrine will promote psychological and physical health in a holistic manner for Church members. I have not found any evidence to question this expression of their faith but have found evidence in support.” Halpern Statement at 8. This exclusion of members who might have experienced negative outcomes means that the study group is not a fair representation of people who used ayahuasca, and therefore, cannot be viewed as “the product of reliable principles and methods.” Fed. R. Evid. 702; *see also Daubert*, 509 U.S. at 589-90; *Obrey v. Johnson*, 400 F.3d 691, 695 (9th Cir. 2005) (holding that “[c]onsiderations such as small sample size may, of course, detract from the value of such evidence”).

Third, Dr. Halpern further limited his study group by interviewing only regular attendees of the church. “[T]wo were relatively new members reporting little participation in Church services . . . and, as such, were excluded.” Halpern Study at SR17. Repeat consumers of ayahuasca are presumably more likely to report beneficial experiences from participation in the Plaintiff Church. Therefore, limiting study participation to those who regularly attend the church over an extended period of time exacerbates the problem of unrepresentative results. *See United States v. Cordoba*, 194 F.3d 1053, 1060 (9th Cir. 1999) (noting that since “the surveys only sampled a small segment of the relevant . . . community,” the study did not meet the requirements for general acceptance and was therefore unreliable). In addition to the

representation problem, those people who are most involved with the church likely would have the greatest institutional support from the church and therefore would report the most benefits.

Fourth, the relationship between the interviewees and Dr. Halpern leads to unreliable results because the study was not blind, a quality considered vital to scientific studies. The Church commissioned Dr. Halpern to perform this study with the expectation that the study results would prove their claims of the health and safety of ayahuasca use. As Jonathan Goldman wrote in an email soliciting participants.

On our path towards gaining the legalized right to practice our religion without threat of government interference, there are some questions that we ourselves must answer to the satisfaction of the courts or other agencies who will decide if we receive their protection to do so. One of the major ones is concerning the effects on the health of those who drink our sacrament in its ritual context. We have to show, in a way and a form that meet strict scientific and established legal standards, the truth of those effects.

Def. Ex. 1236. The Plaintiffs specifically reached out to Dr. Halpern to lead this study because of his support for ayahuasca, *see dep.* of Jonathan Goldman at 137-39, Def. Ex. 1001, and church members were encouraged to participate with the apparent aim of substantiating the church's claims of safety. *See Halpern Study* at SR 17 (noting that members "were encouraged by the church leadership to participate"). This type of methodology, characterized by Dr. Walker as "unblinded interviews of religious adherents by public advocates for their cause," cannot meet the standard for objective scientific evaluation, and thus, cannot satisfy the standard set forth in *Daubert* and its progeny. Walker Report at 8; *see also Hermanek*, 289 F.3d at 1093-94 (noting that "[i]t is well settled that bare qualifications alone cannot establish the admissibility of scientific expert testimony") (citing *Daubert II*, 43 F.3d at 1315). Dr. Halpern acknowledges

this particular limitation, noting that “[f]urther research is warranted with blinded raters.”

Halpern Study at SR15.

Fifth, Dr. Halpern’s study failed to include any scientifically-reliable historical comparisons of the subjects’ well-being and health. Halpern Statement at . Subjects were asked about their psychological and physical health prior to ayahuasca use, but they reported these recollections after using ayahuasca. *Id.* The questions, therefore, were filtered through the experiences of a subject who presumably did not suffer any deleterious effects from ayahuasca use, which “makes it uncertain that the group differences from ‘national norms’ seen in the ayahuasca users actually represent any change from their pre-use status.” Walker Report at 10. This filter of ayahuasca use renders the subjects’ historical data inaccurate and unusable for creating a scientific baseline for the study.

Finally, the small size of the study casts doubt on the application of the findings to a larger population and “[leads] to unreliable group estimates.” *Id.*; *see also Obrey*, 400 F.3d at 695 (holding that “[c]onsiderations such as small sample size may, of course, detract from the value of such evidence”). Any one of these methodological defects would cast doubt on the reliability of Dr. Halpern’s findings. When taken together, these myriad defects cut so deeply into Dr. Halpern’s conclusions as to render them unsound and misleading.

In addition to the methodological defects inherent in his own study, Dr. Halpern also relies heavily on a study of ayahuasca use led by Dr. Charles Grob. Def. Ex. 1093. Dr. Grob’s study centered on the use of hoasca (an alternate name for ayahuasca) by the Brazilian religious group Uniao Do Vegetal (“UDV”). As Dr. Lorne Dawson explains in his witness statement, “the methodological problems” in Dr. Grob’s study “raise serious doubts about the reliability of the

conclusions.” Report of Dr. Dawson at 2. The methodological problems identified by Dr. Dawson include the small size and homogeneity of the sample population; the fact that the sample group had only long-term, committed church members, all of whom were aware of the importance of the study; the fact that a number of the study participants had direct or indirect ties to the leadership of the movement; and the fact that the study was too short. *Id.* at 2-4. These methodological shortcomings, the same problems plaguing Dr. Halpern’s study, raise so many questions about the validity of the results as to place the study far below the benchmark for admission set by Rule 702. *See Daubert II*, 43 F.3d at 1315-16 (holding that “something doesn’t become ‘scientific knowledge’ just because it’s uttered by a scientist”).

In sum, neither Dr. Halpern’s study nor Dr. Grob’s is grounded in the objective scientific principles that determine an expert’s credibility under Rule 702. Without meeting this standard, set forth by the Supreme Court to ensure the validity of expert testimony, the results of these studies are far too speculative to be admissible.

B. Dr. Halpern’s Testimony About Drug Policy Should Be Excluded.

In addition to the fatal methodological flaws in his study, Dr. Halpern offers personal opinions about subjects outside his area of expertise. Dr. Halpern is a psychiatrist, not an expert in illegal drugs. It is inappropriate for a psychiatrist to opine on whether a drug should or should not be illegal, or whether a particular use of a drug is licit or illicit. Although trained experts commonly extrapolate from existing data, “[n]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.” *Gen. Elec.*, 522 U.S. at 137. Dr. Halpern’s research on the health risks of ayahuasca use provides no foundation for his discussion about how the law should

be applied to an individual or group's use of that substance. Testimony about drug policy is plainly outside of Dr. Halpern's area of expertise and is thus inadmissible under Rule 702.

C. Dr. Halpern's Testimony About Peyote Should be Excluded.

In Dr. Halpern's view, Plaintiffs should be permitted to consume ayahuasca because the Native American Church ("NAC") is permitted to use peyote. He sets forth his argument that "consumption of Daime as a sacrament is literally then the non-drug use" by arguing the following:

there is very clear precedent in the United States for permitting the sacramental ingestion of Daime, all the while acknowledging that it also contains a small amount of a chemical listed as a Schedule I substance in circumstances outside of an approved religious setting. Specifically, I refer to the protection of the sacramental use of the peyote cactus (*Laphophora williamsii*) by American citizens who belong to the Native American Church.

Halpern Statement at 6-7. Dr. Halpern's discussion of peyote should be entirely excluded as irrelevant under Rules 401 and 402.

First, Plaintiffs do not allege any equal protection violation or raise any other claim that would make relevant a discussion of the NAC. Second, the NAC has a statutory and regulatory exemption from the CSA for the ceremonial use of peyote. *See* 42 U.S.C. § 1996a; 21 C.F.R. § 1307.31. As such, the DEA is not charged with policing the NAC's use of peyote to the same extent that it regulates other permissible uses of controlled substances. The NAC's exemption was enacted by Congress to reflect the federal government's historically unique relationship with Native Americans. This relationship is firmly rooted in constitutional jurisprudence and is based on a political distinction, not a religious one.

Even if the peyote exemption were not established by Congress, the NAC is different from the Plaintiff Church in so many ways as to render any analogy useless. Native Americans

hold a distinct place in American society. In *Morton v. Mancari*, 417 U.S. 535, 555 (1974), the Supreme Court ruled that Native American tribes enjoy a special legal status, and that “[a]s long as the special treatment [of Native Americans] can be tied rationally to the fulfillment of Congress’ unique obligation towards the Indians, such legislative judgments will not be disturbed.” As a demographic group, Native Americans enjoy a unique sovereign status, including the right to form their own government, enforce laws (both civil and criminal), tax, establish requirements for membership, license and regulate activities, zone, and exclude persons from tribal territories. Plaintiffs have none of these sovereign rights, placing them in a political and – more importantly here – legal category separate and distinct from that of Native Americans. The NAC and its peyote exemption are simply *sui generis*. Any discussion of the NAC or analogies between the NAC and the Plaintiff Church are thus irrelevant to this case and should be excluded.

II. MR. GURULÉ’S TESTIMONY SHOULD BE EXCLUDED IN ITS ENTIRETY BECAUSE IT CONSISTS SOLELY OF IMPROPER LEGAL CONCLUSIONS.

Mr. Jimmy Gurulé is a former federal and state prosecutor and now a law professor at Notre Dame University. He studies criminal law, drug law enforcement, and federal drug policy. Amended Expert Witness Statement of Mr. Gurulé at 3. Plaintiffs present Mr. Gurulé as an expert on illegal narcotics trafficking, but his statement consists entirely of improper legal conclusions and should be excluded.

Mr. Gurulé’s entire statement is structured as if it were his obligation – rather than the Court’s – to conduct the RFRA analysis and render a legal opinion about whether there is a substantial burden on Plaintiffs’ religious exercise (*id.* at 6-7), a compelling governmental interest in burdening Plaintiffs’ exercise (*id.* at 7-13), or a less restrictive means to meet that

compelling governmental interest (*id.* at 13-15). Testimony on matters solely within the province of the court, including conclusions of law, is clearly impermissible. *See, e.g., Aguilar v. Int'l. Longshoremen's Union Local No. 10*, 966 F.2d 443, 447 (9th Cir. 1992) (noting that “matters of law” are “inappropriate subjects for expert testimony”). The exclusion of improper legal testimony is well established. As the Ninth Circuit explicitly stated in *Crow Tribe of Indians v. Racicot*, “[e]xpert testimony is not proper for issues of law. Experts interpret and analyze factual evidence. They do not testify about the law.” 87 F.3d 1039, 1045 (9th Cir. 1996) (citations and quotations omitted).

In his statement, Mr. Gurulé does not interpret and analyze factual data about trafficking in hallucinogenic drugs. Instead, Mr. Gurulé engages in RFRA analysis even though “an expert witness cannot give an opinion as to [his] *legal conclusion*, i.e., an opinion on an ultimate issue of law.” *Nationwide Transp. Fin. v. Cass Information Sys., Inc.*, 523 F.3d 1051, 1058 (9th Cir. 2008) (emphasis in original) (internal citations and quotations omitted) (quoting *Hangarter v. Provident Life & Accident Ins. Co.*, 373 F.3d 998, 1016 (9th Cir. 2004)).

After setting forth his legal qualifications, Mr. Gurulé submits that “the federal government has no compelling interests that are endangered by the importation of the sacred Daime tea by the members of Santo Daime Church and ingestion as a sacrament in religious ceremonies.” Gurulé Statement at 5. Whether or not the government has any compelling interests is a determination for the Court to make. Moreover, after analyzing RFRA and purporting to apply that analysis to Plaintiffs’ case, Mr. Gurulé reaches the plainly inadmissible conclusion that the Government has “failed to demonstrate a compelling interest for prohibiting and criminalizing the use of Daime tea for religious purposes.” *Id.* at 14-15.

Mr. Gurulé also asserts that “the Santo Daime church is a legitimate, bona fide religion centered in Brazil,” a legal conclusion that falls squarely within the province of the Court. *Id.* at 6. Mr. Gurulé continues, stating that “there is insufficient evidence that [ayahuasca] poses a danger to the public health.” *Id.* at 10. These statements are legally inadmissible. *See, e.g., S.E.C. v. Capital Consultants, LLC*, 397 F.3d 733, 749 (9th Cir. 2005) (holding that “[e]xperts may interpret and analyze factual evidence but may not testify about the law.”). Under *Capital Consultants*, all of Mr. Gurulé’s statements are impermissible legal testimony and properly excluded from admission.

III. DR. MACRAE’S TESTIMONY SHOULD BE EXCLUDED IN ITS ENTIRETY.

Dr. Edward MacRae has served in various positions in the Brazilian government, including as a member of the Brazilian National Antidrug Council (“CONAD”) and CONAD’s Technical-Scientific Advisory Chamber. Amended Expert Witness Statement of Dr. MacRae at 3. His experience in these positions, as well as his educational and professional experience in anthropology, may make him qualified to speak on a number of issues relating to Brazilian policy, the social history of Brazil, and the use of ayahuasca by the Santo Daime Church in Brazil. Despite these qualifications, Dr. MacRae’s testimony fails the second prong of the test: relevancy. Since his testimony is irrelevant, it should be excluded under Rule 402. Fed. R. Evid. 402 (“Evidence which is not relevant is not admissible.”).

In addition, in much of his statement, Dr. MacRae offers testimony regarding diversion control and the Plaintiffs’ use of ayahuasca, neither of which falls in his area of expertise and should be excluded.

A. Dr. MacRae’s Testimony on Brazilian Policy is Irrelevant.

Dr. MacRae relies on his experiences and background with the Brazilian government and testifies to the social history of ayahuasca use in Brazil and the religious development of Santo Daime (MacRae Statement at 4-6). He also discusses the Brazilian government's response to the spread of the church, explaining that the government created groups to study the religious practices of the Santo Daime. *Id.* at 10. Although these statements may lie within the scope of his knowledge, Dr. MacRae's testimony on Brazil is irrelevant to this case and should be excluded.

Evidence is considered to be relevant if it has "any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Fed. R. Evid. 401. When testimony has merely "slight" relevance to the issue in the case, the trial court has discretion to exclude the evidence. *See United States v. Scholl*, 166 F.3d 964, 971 (9th Cir. 1999) (holding that since the proffered testimony was both misleading and confusing, "the district court had discretion under Rules 402 and 403 to limit [the expert's] testimony . . . and to exclude that portion of his proffered opinion which had slight (if any) relevance, and was both speculative and misleading").

Dr. MacRae claims no familiarity with the Controlled Substances Act. He claims no expertise in, and fails to address, any matters related to drug policy in the United States. His experience as an anthropologist on advisory councils in a separate nation, with unique laws, social structure, society, and sociological concerns, can provide no meaningful insight into the policy interests at play under the CSA and RFRA in the United States. He is in no position, therefore, to reach his sweeping conclusion that "from a drug policy perspective, there are no government policy objectives that are violated by the sacramental use of Daime." MacRae

Statement at 14-15 (emphasis added). At best, his testimony offers indirect and unsupported testimony regarding health and safety questions arising from ayahuasca use in Brazil. However, as Dr. Dawson explained, conclusions about Plaintiffs' ayahuasca use cannot be drawn from information regarding Brazilian ayahuasca use. *See* Dawson Statement at 19-29 (regarding the inability to draw conclusions regarding Brazilian ayahuasca use to the practices of Plaintiffs in Oregon). For all these reasons, his testimony offers no assistance to the trier of fact and speaks to no relevant aspect of the case. Therefore, Dr. MacRae's testimony on Brazil should be excluded.

B. Dr. MacRae's Testimony on Drug Categorization, Diversion Control and Pharmacology Lack Foundation.

Even if Dr. MacRae's testimony regarding Brazilian drug policy had any bearing on this action, much of his testimony should nonetheless be excluded. Most glaringly, Dr. MacRae frequently opines about subjects in which he has no expertise, such as drug categorization, diversion control, and pharmacology. For example, Dr. MacRae asserts that "there is no evidence that [ayahuasca use] leads to any ill results, as attested by recent medical studies of long time users." *Id.* at 6. This assertion about health effects falls well outside of his expertise. *See United States v. Chang*, 207 F.3d 1169, 1172 (9th Cir. 2000) (holding that "[t]o qualify as an expert, a witness must have 'knowledge, skill, experience, training, or education' relevant to such evidence or fact in issue") (quoting Fed. R. Evid. 702).

Similarly, Dr. MacRae presents his conclusions concerning the possibility of recreational use of ayahuasca by announcing, without support, that "the brew is not taken extraritually." MacRae Statement at 6. He also states, "I am satisfied that the brew is controlled in a way that renders the likelihood of it being distributed to the illicit market virtually impossible." *Id.* at 12.

Dr. MacRae is apparently unaware that Plaintiff Goldman was arrested after the seizure of hundreds of gallons of ayahuasca in his home (in addition to other illicit hallucinogenic substances), far more than might be needed to supply the modest needs of his small Oregonian congregation. Nor does he discuss the liberal admission practices of the Plaintiffs, which facilitate the frequent use of ayahuasca by non-member “visitors.” Absent a more complete understanding of Plaintiffs’ practices, Dr. MacRae has no basis to assert that the “traditional” drug effects sought out by recreational users “are in no way applicable to the religious drinking of ayahuasca or Daime.” *Id.* at 12. Nor can Dr. MacRae reasonably characterize the use of Daime as “non drug” use to which the “taboos that accompany the typical drug user, do not, in this case, pertain in any manner.” *Id.* at 8. Dr. MacRae has no apparent experience in enforcement, and certainly none with enforcement of U.S. drug laws, and is thus unqualified to opine regarding the risk of diversion in the United States.

Dr. MacRae’s statements regarding the health effects of ayahuasca use, including his observation that ayahuasca use may serve as some sort of replacement therapy for other addictions, are likewise inadmissible. Apart from being unproven at any level, much less in any clinical study cited by MacRae (*see* Report of Donald Jasinski at 12-14, Doc. 73 (observing that “[a]ny therapeutic benefit, either of hallucinogens in general as therapeutic agents, or of ayahuasca/DMT in particular, remains unproven”)), these statements fall far outside Dr. MacRae’s purported areas of expertise. Dr. MacRae is not a pharmacologist, a physician, a medical researcher, or a toxicologist. He is an anthropologist. He is unqualified to opine on any purported therapeutic benefits of ayahuasca use; consequently his testimony in this regard (as in all others) should be excluded.

IV. MR. GERDING'S TESTIMONY SHOULD BE EXCLUDED IN ITS ENTIRETY BECAUSE IT IS UNRELIABLE AND IRRELEVANT.

A. Mr. Gerding's Testimony Is Unreliable.

George Gerding's testimony on "law enforcement . . . concerns" and "public policy considerations" associated with sacramental ayahuasca use, as well as his "[r]eview of the Santo Daimé Religion" and "illicit drug trafficking in the United States" should be excluded because Mr. Gerding is not qualified in the relevant fields. Amended Expert Witness Statement of George Gerding at ¶¶ 2-3, 11, IVa. Mr. Gerding has a Bachelor's of Science degree in pharmacy, and his professional experience is limited to the field of pharmacy. *See* Gerding CV, Doc. #57. Although Mr. Gerding states that he has "done post-graduate work" at several universities and "professional centers," he has not earned an advanced degree and does not elaborate on the nature and extent of this other course work. Gerding Statement at ¶ 1. Specifically, nothing in Mr. Gerding's curriculum vitae indicates any education, experience, or expertise in the areas of "law enforcement," "public policy," "religion," or "illicit drug trafficking." *See* Gerding CV. Thus, to the extent Mr. Gerding's testimony veers away from the limited field of pharmacy, it must be excluded. *See Chang*, 207 F.3d at 1172 (holding that "[t]o qualify as an expert, a witness must have 'knowledge, skill, experience, training, or education' relevant to such evidence or fact in issue") (quoting Fed. R. Evid. 702).

Moreover, Mr. Gerding's testimony about the pharmacology, toxicity, and abuse potential of ayahuasca falls outside the bounds of the field of pharmacy and what one might reasonably expect a pharmacist to know.² Yet, he provides no foundation for knowledge or

² While pharmacology is often confused with pharmacy, the two are "separate discipline[s]." *See* American Society for Pharmacology and Experimental Therapeutics, "About

expertise in areas that are, at best, tangential to his demonstrated experience and education. *See* Gerding CV. Specifically, Mr. Gerding cites no basis for his knowledge of the concentration of the ayahuasca the Plaintiffs use, nor does he state he has ever performed any test on the ayahuasca to determine its chemical composition or the concentration of its psychoactive components. *See* Gerding Statement at ¶¶ 6-7, 12-13 (stating that “[t]here are two major active ingredients in ayahuasca, or the tea called Daime, Dimethyltryptamine [*sic*] (DMT) and Harmine”). Moreover, knowledge of exotic plants with no established medical use and no demonstrated safety in the United States is well outside the expected knowledge and experience of the typical pharmacist. *See id.* at ¶¶ 12-13 (stating that “[t]he Harmine is in the bark and stems of a vine, *Banisteriopsis caapi* and while not a controlled substance, may have some pharmacological activity”). Because Mr. Gerding describes no special training or education in botany, plant pharmacology, or another relevant field, his testimony as to the effects of ayahuasca must be excluded. *See id.* at ¶¶ 14, 18-19, 21, 23-24, 30, 35 (e.g., stating that “[i]n order to ingest the quantity of DMT for toxicity or overdose, one would have to drink 3 to 4 liters of the tea”).

Pharmacology,” available at http://www.aspet.org/public/pharmacology/about_pharmacology.html (last accessed Dec. 16, 2008) (hereinafter “ASPET”). Pharmacology is “the study of the effects of chemical agents of therapeutic value or with the potential toxicity on biological systems.” *Id.* In contrast, pharmacy is “the profession responsible for the preparation, dispensing, and appropriate use of medication.” *Id.* According to the Bureau of Labor Statistics, “[p]harmacists distribute prescription drugs to individuals. . . . Compounding—the actual mixing of ingredients to form medications—is a small part of a pharmacist’s practice, because most medicines are produced by pharmaceutical companies in a standard dosage and drug delivery form.” Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook, 2008-09 Edition*, Pharmacists, available at <http://www.bls.gov/oco/pdf/ocos079.pdf> (last visited Dec. 17, 2008).

Similarly, Mr. Gerding neither describes nor demonstrates any knowledge of DMT, one of the two psychoactive components of ayahuasca. *See id.* at ¶¶ 17, 23-24, 36 (e.g., stating that “the process of extracting the very minute quantities of DMT from the Daime tea would be technically difficult and would require a great deal of tea to obtain an amount that would be sufficient for purposes of even entering the illicit drug market”). DMT has no medical use in the United States and is rarely studied in humans even in controlled research settings. It is improbable that a pharmacist would have any experience prescribing or observing DMT in humans. Mr. Gerding cites no education, training, or experience handling DMT or related substances in his practice. Thus, Mr. Gerding can demonstrate no “special knowledge, skill, experience, training, or education on the subject matter.” *See Chang*, 207 F.3d at 1172 (holding that “[t]o qualify as an expert, a witness must have ‘knowledge, skill, experience, training, or education’ relevant to such evidence or fact in issue”) (quoting Fed. R. Evid. 702). As a result, his testimony about DMT should be excluded.

B. Mr. Gerding’s Remaining Testimony Is Irrelevant.

Mr. Gerding’s testimony concerning peyote use in the Native American Church is not relevant to any issue in this case for two primary reasons. First, the NAC’s sacramental use of peyote has no bearing on whether Plaintiffs ought to be permitted to use ayahuasca tea, because Plaintiffs have not pled an equal protection claim based on the NAC exemption to the CSA. And second, because the NAC’s peyote use is not subject to the RFRA analysis which is at the heart of Plaintiffs’ case, the government did not undertake the compelling interest analysis for the NAC’s sacramental peyote use that RFRA requires the government to engage in here. *See* Section I, C, *supra*. Thus, although Mr. Gerding offers his perspective on the NAC’s

sacramental peyote use to serve as a source of comparison for Plaintiffs' religious use of ayahuasca here, his opinion on the NAC's practices with peyote are irrelevant here and should be excluded. *See* Gerding Statement at ¶¶ 5, 11, 15-16, 20, 22, 27-30, 34, 37-38, 43, 48 (e.g., stating that "in granting an exemption from the prohibition of taking peyote, the DEA has acknowledged the importance of set and setting by permitting the 'non-drug use of peyote' in Native American Church services").

Similarly, Mr. Gerding's testimony concerning the Oregon Pharmacy Board's decisions about sacramental use of peyote and ayahuasca is not relevant to this matter because Plaintiffs raise a claim under the United States Constitution and RFRA, a federal law. Under the supremacy clause, the federal constitution and laws supercede any contravening state law. *See Gonzales v. Raich*, 545 U.S. 1, 29 (2005) (holding that in the area of controlled substances "[t]he Supremacy Clause unambiguously provides that if there is any conflict between federal and state law, federal law shall prevail."). Moreover, Plaintiffs raise no claim that the CSA, a federal statute, violates principles of federalism – nor could they successfully do so. Therefore, Oregon state law and action is irrelevant to this case, and Mr. Gerding's testimony on the subject, also an impermissible legal conclusion, should be excluded. *See* Gerding Statement at ¶¶ 49-52 ("Because the Oregon Pharmacy Board found that the importation, distribution and ingestion of the tea does not implicate any danger to public health or safety in Oregon, it impinges on Oregon's sovereignty when the United States Attorney General threatens to arrest and prosecute Church members for religious activities that occur in Oregon.").

C. Even if the Court Takes an Alternate Interpretation of Mr. Gerding's Discussion of Peyote, It is Inadmissible as Impermissible Legal Opinion.

To the extent Mr. Gerding's discussion of the NAC peyote exemption compares ayahuasca to peyote on questions of whether the government has a "compelling interest" in banning either substance, *see id.* at ¶ 47 (stating that "it is my opinion that there is no compelling reason in this case to prohibit the members of the Santo Daime Church from taking their sacrament"), or draws a conclusion about whether the government's action as to each constitutes the "least restrictive means," *id.* at ¶ 48 (stating that "total prohibition [on ayahuasca] is not the least restrictive way in which the government can protect whatever interests are asserted"), his testimony consists of impermissible legal conclusions and should be excluded.

V. DR. WINKELMAN'S TESTIMONY SHOULD BE EXCLUDED TO THE EXTENT THAT IT IS OUTSIDE HIS EXPERTISE, LACKS FOUNDATION, OR IS IRRELEVANT.

Dr. Michael Winkelman, a professor at the School of Human Evolution and Social Change at Arizona State University, describes his expertise as "medical anthropology and particularly the study of physiological, psychological and emotional aspects of religious behaviors and healing practices." Amended Expert Witness Statement of Dr. Winkelman at 4. Dr. Winkelman's testimony, however, reaches far outside the boundaries of anthropology or religion into medical conclusions and chemical and pharmacological analyses, areas in which he is not qualified to testify. While as an anthropologist Dr. Winkelman may be qualified to testify to the "origins and practices of the Santo Daime religion, [and] . . . the social, cultural, behavioral, and spiritual processes" of Plaintiffs' use of ayahuasca., *id.* at 2, Dr. Winkelman's purported conclusion that Plaintiffs' use of ayahuasca does not pose any health threats and indeed, might be beneficial to the members is well beyond the scope of his expertise. Moreover, along with his anthropological analysis, Dr. Winkelman analyzes the chemical composition and

effects of ayahuasca, a task he is unqualified to undertake. *Id.* at 10. He also opines about the safety and efficacy of Plaintiffs' diversion control, which also ventures into areas far beyond his expertise. *See id.* at 14.

Under Rule 702, Dr. Winkelman's testimony must be limited in scope to his area of expertise: anthropology. Any other testimony must be supported by an expertise in that area or proper foundational support for the testimony, which Dr. Winkelman has failed to demonstrate. A trial court must ensure that an expert's testimony is based upon a reliable foundation, by determining whether the principles and methods used by the expert have a sound and reliable basis in the knowledge and experience of the expert's particular discipline. *See Kumho Tire*, 526 U.S. at 149; *Chang*, 207 F.3d at 1172 (holding that "[t]o qualify as an expert, a witness must have 'knowledge, skill, experience, training, or education' relevant to such evidence or fact in issue") (quoting Fed. R. Evid. 702). Under this standard, Dr. Winkelman's testimony regarding the pharmacology of ayahuasca and the safety or efficacy of Plaintiffs' alleged diversion controls should be excluded under Rule 702.

A. Dr. Winkelman's Testimony About Pharmacology and Toxicology is Inadmissible.

In his testimony, Dr. Winkelman presents a section entitled "The Pharmacology and Toxicology of the Sacrament Ayahuasca." Winkelman Statement at 10. Dr. Winkelman has no background experience in pharmacology or toxicology and thus he lacks the expertise to offer an opinion on either of these subjects. *See Chang*, 207 F.3d at 1172 (holding that "[t]o qualify as an expert, a witness must have 'knowledge, skill, experience, training, or education' relevant to such evidence or fact in issue") (quoting Fed. R. Evid. 702). Among the more glaringly inadmissible statements made by Dr. Winkelman are a series of conclusions about the health and

diversion risks of ayahuasca consumption. Dr. Winkelman describes the use of ayahuasca in Santo Daime as “a model of safe controlled use,” opines that “[t]here is good reason to believe that the Daime tea does not produce harm,” and concludes that “there is no public health threat” arising from Daime use in religious settings. *Id.* at 13, 15, 19. Finally, he makes the plainly erroneous statement that “there are no reports . . . of any toxic or other serious-negative [*sic*] side effects attributed to ayahuasca, either on a short or long term basis.” *Id.* at 17, *but see* Sklerov J, *et al. A Fatal Intoxication Following the Ingestion of 5-Methoxy-N,N-Dimethyltryptamine in an Ayahuasca Preparation*, Def. Ex. 1125; King Aff., Def. Ex. 1211. Lacking any medical or pharmacological training, Dr. Winkelman is in no position to opine on the health risks associated with ayahuasca consumption.

B. Dr. Winkelman’s Testimony About Diversion Control is Inadmissible.

Dr. Winkelman also addresses the question of diversion control. This testimony is inadmissible for two reasons. First, Dr. Winkelman is not offered as an expert in diversion control, and there is no foundation for him to proffer such an opinion. Second, even if there were a foundation for this testimony, his evidence is unreliable and does not meet the standard set in Rule 702.

Dr. Winkelman states that Plaintiffs have appropriate control measures in place to safeguard against any recreational use of ayahuasca. Winkelman Statement at 18. As evidence for this contention, Dr. Winkelman explains that Jonathan Goldman has confirmed that the church maintains “strict control” over the sacrament. *Id.* at 18. Such reliance on the representations of a named Plaintiff in this lawsuit cannot provide any meaningful foundation from which Dr. Winkelman could opine as to the diversion risks of Plaintiffs’ ayahuasca use.

See Daubert II, 43 F.3d at 1316. Dr. Winkelman, lacking any relevant diversion expertise, is unqualified to opine on this subject.

Dr. Winkelman also strays far afield from his expertise when, in support of his contention that ayahuasca is not used as a recreational drug, he explains that the tea is bitter and may cause vomiting. Winkelman Statement at 17. Such unpleasant side effects, however, are common among recreational drugs and rarely serve as meaningful deterrents to their recreational use. *See* Expert Witness Report of Denise Curry at 23. Setting aside his failure to establish a foundation, Dr. Winkelman is not presented as an expert in diversion control, so his opinions about whether a drug is likely to be used recreationally should be excluded. *See Kumho Tire*, 526 U.S. at 149.

Finally, Dr. Winkelman concludes that there is an “intolerant burden on this religious practice and that there are no compelling reasons to prevent the practice of this religion in the United States.” Winkelman Statement at 3. This statement constitutes an improper legal conclusion that should be excluded.

C. Dr. Winkelman’s Discussion of the Native American Church is Irrelevant.

As previously discussed, any opinions about or analogies drawn from the NAC or peyote are irrelevant to the case at hand and should be excluded. *See* section I, C, *supra*.

VI. DR. COZZI’S TESTIMONY ON DRUG CONTROL POLICY SHOULD BE EXCLUDED AS UNRELIABLE AND LACKING FOUNDATION.

Dr. Nicholas Cozzi’s testimony on “drug control policy” should be excluded because Dr. Cozzi is not qualified as an expert in drug policy. *See* Amended Expert Witness Statement of Dr. Cozzi at 2, 5. Dr. Cozzi has an undergraduate degree in toxicology and pharmacology, and a Ph.D. in pharmacology, and his professional experience is limited to the fields of pharmacology

and toxicology.³ In Dr. Cozzi's own words, his "knowledge of the pharmacology and toxicology of Daime comes from [his] reading of the medical and scientific literature, [his] participation in professional conferences, discussions with colleagues, and [his] own research over more than twenty-five years." *See* Cozzi at 2, Cozzi CV. Notably absent from this description is reference to any clinical experience treating patients, whether that be concerning ayahuasca consumption or otherwise.

Moreover, nothing in Dr. Cozzi's curriculum vitae indicates any education, experience, or expertise in the area of "drug control policy." *See* Cozzi CV. Thus, the section of Dr. Cozzi's testimony entitled "Drug Control Policy," which discusses federal drug control laws and regulations and the legal status of various sacraments, must be excluded. *See Chang*, 207 F.3d at 1172 (holding that "[t]o qualify as an expert, a witness must have 'knowledge, skill, experience, training, or education' relevant to such evidence or fact in issue") (quoting Fed. R. Evid. 702).

CONCLUSION

For the foregoing reasons, the Court should exclude the portions of testimony by Dr. Halpern, Mr. Gurulé, Dr. Winkelman, Dr. MacRae, Dr. Cozzi, and Mr. Gerding that fail to

³ *See* footnote 2, *supra*, for discussion of pharmacology as a discipline. Toxicology is a subfield of pharmacology, and involves "the study of the adverse or toxic effects of drugs and other chemical agents." *See* ASPET.

comply with the methodological and foundational requirements of Rule 702 and/or the relevance requirement of Rule 401 and 402.

REDACTED

From: [REDACTED]
To: <miriam@3riversspirit.com>
Sent: Friday, June 30, 2006 5:25 PM
Subject: RE: Research Study Update

Hi Miriam, Just wanted to let you know that I will be up on the 7th. I'm buying [REDACTED] truck and am coming up on Fri so I can register it up there. I'm not planning to come to the work. My mother and daughter are bring me up and were just having a girls weekend. But I would be willing to do an interview if it fits into a time schedual, sometime late Fri afternoon. Let me know if this works. I'll check my messages Sunday afternoon, before I go back up to Truckee for the week, other wise I won't get my messages until Thur evening when I get back home. Also I keep meaning ot ask you, did [REDACTED] get my socks I sent with you? Have a good work this evening, I'm always with you all in thought when I'm not phically there. Love to you.

>From: "Miriam Ramsey" <miriam@3riversspirit.com>
>To: "Miriam Ramsey" <miriam@3riversspirit.com>
>Subject: Research Study Update
>Date: Wed, 21 Jun 2006 20:56:53 -0700

>

>Dear All,

>

> Thank you for the enthusiast response to this study. I've heard from
>many of you and we still need more participants, so if you are still
>considering it or have further questions, please let me know.
>miriam@3riversspirit.com

>

> Updated Information:

>

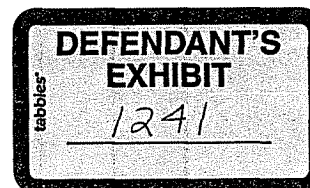
> 1) I've spoken with John Halpern, the researcher from Harvard. He
>has informed me that the interviews you will be participating in will range
>between 1-2 hours; so please allow this much time. In answer to many
>questions about being interviewed over the phone, email, etc; that won't be
>possible at this time. All interviews in Phase I must be done in person.

>

> 2) People who are currently taking any of the medications below or
>have conditions listed cannot participate in the study If you have signed
>up and you fall into one of these categories, please exclude yourself from
>the study at this time by letting me know.

>

- >1. Anti depressants
- >2. Anti psychotic
- >3. Opiates
- >4. Mood stabilizers (like lithium)
- >5. Benzodiazepine (like Valium routinely)
- >6. Anti-seizure



- >7. Someone with brain cancer.
- >8. Someone with a severe head injury requiring hospitalization.
- >
- > If you have any questions regarding your interview time and day,
- >please contact me. All interviews will be held at the Rose Center.
- >
- >Love & Blessings,
- >Miriam

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<http://messenger.msn.click-url.com/go/onm00200471ave/direct/01/>

An Opportunity to Help

June 2, 2008

Dear Ones,

On our path towards gaining the legalized right to practice our religion without threat of government interference, there are some questions that we ourselves must answer to the satisfaction of the courts or other agencies who will decide if we receive their protection to do so. One of the major ones is concerning the effects on the health of those who drink our sacrament in its ritual context. We have to show, in a way and a form that meets strict scientific and established legal standards, the truth of those effects.

Our lawyer, Roy Haber, has put together a team of top flight researchers, of the highest competency and respectability. The two researchers, John Halpren of Harvard and James Rutenber of the University of Colorado, have created a protocol for a preliminary study on the health effects of drinking Dalmé. It is scheduled to begin this summer. They have gained the approval for the study from their university scientific boards. In addition, the study received unanimous approval from the recent conclave of the Santo Dalmé churches. We have raised half the money for the study, enough to go forward. Now, each of us has to decide if we will become subjects in the study.

The study needs residents and citizens of this country who have drunk Dalmé for different amounts of time and in varying frequencies. It is not necessary to be an initiate. We need all levels of involvement to be represented.

The study is an epidemiological study. This means that the actual process of being "studied" involves interviews, not clinical tests. There is a questionnaire administered by trained people in individual interviews. The data is then correlated and compared to, ideally, both a control group and an established "norm" of what the health profile for a person of your age, sex, life station, etc, would be expected to look like. The results are then tabulated, written up, and presented to a review committee. When it has passed muster for its integrity and defensibility, it then will be published and used as the basis for applying for more money for a full scale study. Eventually, the study will be used to demonstrate to a court and/or other agencies, if necessary, the health effects of drinking the Dalmé on those who partake of it in the context of our rituals.

The study will not only benefit us in our process, but because it will be done by such respected researchers with the backing of such highly respected institutions, it will be of worldwide use.

We need a minimum of 50 participants. The more we get, up to around 150, the better. It will require initially about four hours of your time, divided into two parts. There may be follow up interviews as well. The researchers will come to Ashland. I assume they can come to Bend as well, if there are sufficient numbers of people to warrant it.

There are questions which naturally arise. How confidential is this information? How is it protected? How am I? Can the government get my name if it wants to? What if it does?

The names of participants is protected by being known only to the researchers, who are shielded by law from having to reveal the information in almost all circumstances. However, the information is not shielded in all circumstances. Your name will be well protected, but not guaranteed to never be revealed. That being said, the possibility of any legal action being taken against an individual who drank Dalmé is not real. This is because the possible offense one could be charged with under law is either possession or distribution, neither of which you are doing by having drunk Dalmé. Having drunk Dalmé at some time does not fall under any law. You may choose to not participate because of your particular situation or with your particular concerns you do not want to run even the slightest chance of your name being revealed in any arena. But the reason should not be the fear of direct legal action taken against you for drinking Dalmé. There is no precedent for that happening in any action taken by governments anywhere in the world. It is possible to imagine a scenario under which such a thing might happen, but it would be a farfetched one.

DEFENDANT'S EXHIBIT
1236

6/12/2008

CHLQ 000262

If you are willing to participate in this study, or you have questions that have not been covered in this letter, please let Minam know asap. Depending on the number of people who are available in our own circle, we will extend the request to other churches.

Jonathan

6/12/2008

CHLQ 000263