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IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF OREGON

CHURCH OF THE HOLY LIGHT OF THE)  
QUEEN *et al.*, )  
)  
Plaintiffs, )  
)  
VS. )  
)  
MICHAEL B. MUKASEY, *et al.*, )  
)  
Defendants. )

Civ. No. 08-03095-PA

PLAINTIFFS' OPPOSITION TO  
DEFENDANTS' MOTION *IN LIMINE*  
TO STRIKE PLAINTIFFS' EXPERTS'  
TESTIMONY

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## **I. INTRODUCTION**

Defendants have filed a Motion *in Limine* to exclude the testimony of all of plaintiffs' experts. This Opposition establishes that all of the plaintiffs' experts' direct testimony should be admitted based upon the standards set forth in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) (*Daubert*).

Plaintiffs are filing three additional motions: 1) a Motion to Exclude Cumulative Testimony being offered by defendants; 2) a Motion to Exclude all testimony regarding health and safety issues because the defendants have already lost those issues in the Supreme Court; defendants are using the same experts to make the same attacks on Dr. Charles Grob, an expert who testified in *O Centro Espirita Beneficente União do Vegetal* (UDV) (but who is not a witness in this case, although plaintiffs are using Dr. Grob's health study in this case similarly to the way it was used in the UDV case). Plaintiffs contend that the defendants should be estopped from making these arguments and presenting the identical evidence in this case that was presented in the UDV case.<sup>1</sup> Finally, plaintiffs are filing 3) a Motion *in Limine* to Strike Defendants' Experts' Testimony as being both scientifically unreliable and irrelevant to the issues in this case.

## **II. BURDEN OF PROOF**

Expert Witness Statements must be evaluated against the applicable burdens of proof that the party who offers the expert's opinion has regarding an ultimate fact in the case. In this case, defendants have the burden of going forward and the burden of proof to establish that

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<sup>1</sup> Plaintiffs initially raised the issue of collateral estoppel before the defendants had submitted their witness statements, and the motion was denied. Now that we see that the case they are putting on regarding the health issues is virtually identical to the UDV case, we have renewed the motion. Plaintiffs would be put to great expense to replicate that which the Supreme Court has already decided, and such unseemly duplication would also constitute a waste of judicial resources.

there are “compelling interests” regarding individual and public health that justify a complete ban on importing the tea. Defendants have the concomitant burden of proof to establish by a preponderance of the evidence that sacramental ingestion of the Daime tea is, to a medical probability, likely to cause significant ill health effects to a significant number of people who might imbibe the tea at Santo Daime religious services, and that the tea poses a significant danger to the public health. Plaintiffs contend that evidence does not exist, to a medical probability, to support the conclusion that the Santo Daime Church members’ religious use of Daime tea carries any significant health risk. Even under a more relaxed standard of proof, defendants’ experts are unable to demonstrate that there is any more than a mere “possibility” of harm from taking the tea sacramentally and they have no evidence that anyone has ever suffered significant ill health effects from taking the tea during the Santo Daime liturgy. Thus, defendants are not able to establish a “compelling interest” in health and related safety issues. *O Centro Espírita Beneficente União do Vegetal v. Ashcroft*, 282 F. Supp. 2d 1236, 1256 (D.N.M. 2002).

Plaintiffs’ experts, on the other hand, have established their *prima facie* case. The proposed testimonies of Dr. Winkelman, of Dr. MacRae, and of the plaintiffs establish that the Santo Daime is a religion and that the plaintiffs are sincere practitioners of the religion. Defendants’ experts have agreed that the Santo Daime is a legitimate religion. Although “centrality” of religious practice is no longer required under the Religious Freedom Restoration Act (RFRA), *see* 42 U.S.C. § 2000cc (“The term ‘religious exercise’ includes any exercise of religion, whether or not compelled by, or central to, a system of religious belief”), plaintiffs have demonstrated that banning the sacred tea would prevent them from engaging in their primary sacrament, a central aspect of their religious exercise. Plaintiffs’ experts, unlike the

defendants' experts, have reviewed and analyzed data with respect to Daime tea, and have established that there are no significant health risks associated with the sacramental use of the tea. Plaintiffs' experts Halpern, Cozzi, Gerding, and Winkelman have presented testimony and exhibits to rebut defendants' claims of a compelling interest in banning the tea. This Memorandum demonstrates that the testimony of plaintiffs' experts should be admitted into evidence.

After plaintiffs established their *prima facie* case, the burden of proof, and of going forward on the "compelling interests" defense, rests on defendants' shoulders. If the defendants are able to establish a *prima facie* case of a "compelling interest," then the plaintiffs have the burden, in turn, of rebutting defendants' *prima facie* case. A close reading of the defendants' expert reports establishes that:

- a. Giving the defendants every benefit of doubt, their expert reports establish only that there are some molecular similarities between DMT and other hallucinogenic substances.
- b. Defendants can only speculate about extrapolating potential harm from another chemical to plaintiffs' use of the sacred tea.
- c. Defendants are unable to establish that the amount of tea taken in ceremonies is likely to cause any ill health effects.
- d. Defendants have no evidence that anyone who has taken the tea in ceremonies has ever suffered injury, despite thousands and thousands of times people have participated in Daime and *hoasca* ceremonies.
- e. Defendants are unable to establish that taking the tea in the ceremonies is likely to cause a toxic reaction.

These facts do not constitute a *prima facie* case of a "compelling interest" in banning the tea. See Plaintiffs' Reply Trial Brief. Thus, plaintiffs do not have to rebut the defendants' medical/scientific experts' testimony. Nevertheless, plaintiffs' experts proffer reliable opinions that the existing medical/scientific evidence provides no support for defendants' speculation

regarding ill health effects.

### III. EVIDENTIARY STANDARDS

The standards broadly governing admissibility of expert testimony are familiar to this court. Useful general discussions may be found in the Federal Judicial Center's (FJC) MANUAL FOR COMPLEX LITIGATION (FOURTH) § 23, at 469-515 (2004), and in the FJC's REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 9-38 (2d ed. 2000) (chapter by Prof. Margaret A. Berger entitled "The Supreme Court's Trilogy on the Admissibility of Expert Testimony").

#### A. Admissibility and Sufficiency

Numerous decisions have affirmed the fundamental principle that, on a motion to exclude an expert's testimony under FED. R. EVID. 702, the issue is the admissibility of the expert evidence, not its sufficiency. *See, e.g., Maiorana v. United States Mineral Prods. Co. (In re Joint E. & S. Dist. Asbestos Litig.)*, 52 F.3d 1124, 1132 (2d Cir. 1995) ("The 'admissibility' and 'sufficiency' of scientific evidence necessitate different inquiries and involve different stakes"). *See Daubert*, 509 U.S. at 596. The Ninth Circuit has likewise held that the admissibility of testimony from a qualified expert depends on whether the testimony is relevant and reliable – not on its sufficiency. *See, e.g., Desrosiers v. Flight Int'l*, 156 F.3d 952, 960 (9th Cir. 1998), *cert. dismiss'd*, 525 U.S. 1062 (1999).

#### B. The "Daubert Factors" - Reliability

In *Daubert*, the Supreme Court rejected the previously prevailing "general acceptance" test for expert scientific testimony, first adopted in *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923), as unduly "rigid" and "austere." *See Daubert*, 509 U.S. at 588-89. By way of mandatory conditions for admissibility, the Court imposed two: (1) helpfulness to the trier of fact (a condition that "goes primarily to relevance," *id.* at 591); and (2) *reliability* – *i.e.*, "a

grounding in the methods and procedures of science,” *id.* at 590.

The *Daubert* opinion did observe that general acceptance “can yet have a bearing on the inquiry.” *Id.* at 594. “A ‘reliability assessment,’” said the Court, “does permit, explicit identification of a relevant scientific community and an express determination of a particular degree of acceptance within that community.” In the defendants’ expert reports, we see attempts to elevate speculation into scientific truth by suggesting that certain principles are generally accepted in science but, importantly, they do not reference the relevant scientific community that it is claimed holds these views. They have not done so because no such community exists separate and apart from the nascent community that comprises those who have been invited to defend this litigation. On the other hand, the testimony of plaintiffs’ experts is based on specific, germane studies, including the Brazilian Government’s extensive study of the Daime and *hoasca* tea.

It is important “whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for the purposes of testifying.” *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) (*Daubert II*). If generated for the purpose of a particular lawsuit, the report is “inherently suspect.” Defendants’ expert reports are primarily attacks on plaintiff’s experts Halpern and Cozzi and are generated solely for this litigation; moreover, they fail to provide support from independent reliable sources.

### C. *Daubert and Kumho Tire*

The Supreme Court’s opinion in *Daubert* set forth principles governing the admissibility of expert scientific testimony. Later, in *Kumho Tire v. Carmichael*, 526 U.S. 137

(1999), the Supreme Court applied an analogous reliability requirement to testimony by non-scientific experts whose opinions and judgments are often founded in substantial part on knowledge gained from professional practice and experience. The *Kumho Tire* Court emphasized – just as it had in *Daubert*, see 509 U.S. at 593 – that the standards for gauging reliability could not be reduced to any simple algorithm or checklist, but would vary according to the nature of the issue, the witness’ particular expertise, and the subject of the testimony. *Kumho Tire*, 526 U.S. at 150. The overarching goal common to both the scientific and non-scientific contexts, the *Kumho Tire* Court said, was to ensure “that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Id.* at 152. Plaintiffs will establish in this Opposition and in their Motion *in Limine*, that the defendants and their medical/pharmacology expert reports display a disturbing absence of “intellectual rigor” in their attacks on the testimony of Dr. Halpern and Dr. Cozzi.

Like the Supreme Court in *Kumho Tire*, and like other courts throughout the country, the Ninth Circuit has noted that some factors commonly useful in evaluating scientific testimony can be less helpful for testimony that depends substantially on an expert’s experience-based knowledge. See, e.g., *Hangartner v. Provident Life & Accident Ins. Co.*, 373 F.3d 998, 1017 (9th Cir. 2004).<sup>2</sup> The judgments and opinions of physicians and other health professionals, for example, very commonly rely not only on their familiarity with principles and findings from such scientific fields as biology or epidemiology, but also on a fund of

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<sup>2</sup> For example, Plaintiff Goldman has administered the tea and witnessed its effects for 20 years, experience that will prove valuable to this court’s understanding of these issues. Indeed, his practical experience far exceeds the professional experience of any of the defense “experts” regarding the actual, physical, and psychological effect that the Daimé tea has on human beings who consume the tea during the Daimé liturgy — as opposed to the effects of LSD on the general population, the focus of the testimony of defendants’ experts.

knowledge drawn from their experience and clinical practice.<sup>3</sup> The Ninth Circuit has held that, on at least some occasions, the *Kumho Tire* standards for experience-based testimony supply a “more apposite” framework than *Daubert* for analyzing medical causation testimony. See *Sullivan v. United States Dep’t of the Navy*, 365 F.3d 827, 833-34 (9th Cir. 2004) (causal link between surgery and infection). On other occasions, the Ninth Circuit has followed the *Daubert* framework, but in a manner acknowledging that a causation opinion may legitimately be grounded partly in a physician’s clinical experience and expertise. See *Kennedy v. Collagen Corp.*, 161 F.3d 1226, 1228-31(9<sup>th</sup> Cir. 1998) (causation of autoimmune disease); *Hopkins v. Dow Corning Corp.*, 33 F.3d 1116, 1124-25 (9th Cir. 1994), *cert. denied*, 513 U.S. 1082 (1995) (breast implants).

Because the statements of defendants’ experts are, to a large measure, attacks on plaintiffs’ experts, the subject of this Motion, we will analyze some of these statements as part of this Opposition. Most of the statements of defendants’ experts attacking plaintiffs’ experts’ statements have been generated solely for the purpose of the litigation and, thus, may be saved from an *in limine* motion only if the witnesses:

explain precisely how they went about reaching their conclusions and point to some objective source – a learned treatise, the policy statement of a professional association, a published article in a reputable scientific journal or the like – to show that they have followed the scientific method, as it is practiced by (at least) a recognized minority of scientists in their field.

*Daubert II*, 43 F.3d at 1318. The defense experts in this case have not compensated for their

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<sup>3</sup> In terms of weighing the evidence, which is not the subject of this Motion, Dr. Halpern and Dr. Grob (the UDV expert), both of whom are Board-certified psychiatrists familiar with controlled substances, are the only experts that have any “experience based knowledge” regarding the safety of ceremonial consumption of the tea. It is the complete lack of such experience that renders the defendants’ experts unqualified, yielding the result that their reports, as discussed below, are couched in non-scientific rhetoric or are pure speculation.

inherently suspect statements because they have not demonstrated strict adherence to the scientific method by presenting any of the above sources to establish that they have followed the scientific method.

Defendants' experts have failed to meet the *Daubert II* Panel's requirement that scientific experts describe their work in sufficient detail to permit a judicial determination of its reliability. *Id.* (citing *United States v. Rincon*, 28 F.3d 921, 924 (9th Cir. 1994), *cert. denied*, 513 U.S. 1029 (1994)); *see also Clausen v. M/V New Carissa*, 339 F.3d at 1056 (9<sup>th</sup> Cir. 2003) (same). As we note in detail below, this failure runs throughout the statements of defendants' experts.

A scientific expert's conclusions must indeed be founded on reasoning that reflects "the methods and procedures of science." *Daubert*, 509 U.S. at 590. And, to be sure, an expert may not offer opinions based on sheer *ipse dixit*. *General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997). The Reference Manual on Scientific Evidence, 2<sup>nd</sup> Ed. 2000, Federal Judicial Center (Ref.) states, at 15:

Trained experts commonly extrapolate from existing data. But nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered. *Joiner* (citation omitted).<sup>4</sup>

Dr. Michael T. Ghiselin, Chair of the Center for the History and Philosophy of Science at the California Academy of Sciences in San Francisco, an expert on the history of philosophy and epistemology, has been retained by plaintiffs to review the experts' statements in light of

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<sup>4</sup> But neither is it the court's function to weigh substantive disagreements between legitimate expert opinions, to decide who has the better of the argument on the merits of each detail. As the Supreme Court emphasized in *Daubert*, the focus must be "on principles and methodology, not on the conclusions that they generate." *See* 509 U.S. at 594-95.

whether their proposed testimony satisfies the standards of the scientific method under *Daubert*, *Kumho Tire*, and *Joiner*.

Scientific epistemology (the theory of knowledge) provides a basis for making judgments regarding the reliability of experts' methodologies in this case. Regarding scientific opinion, Dr. Ghiselin notes that: "[n]onetheless it is generally agreed that the premises of arguments are supposed to be true, and that the conclusions are justified by the arguments." Ghiselin at 1. Dr. Ghiselin points to many examples of the defendants' experts failing to use the tools of the scientific trade or appropriate scientific language in their analysis. See Ghiselin Statement.

This case is defendants' and their same experts' second attempt to convince a federal district judge of opinions that are grounded in what some scientists refer to as "junk science." There is no new evidence since the UDV case that alters the science. Because of that reality, defendants have concentrated significant resources to erect illusory barriers to admitting plaintiffs' evidence. This Memorandum establishes that plaintiffs' experts are qualified to testify, have testified reliably about the science, and that the testimony they are offering is relevant to the case.

**D. Extrapolation and Toxicology**

In *Joiner*, the Court noted that the plaintiff never explained "how and why the experts could have extrapolated their opinions" from animal studies far removed from the circumstances of the plaintiff's exposure. Ref. at 32. Similarly, the defendants' experts never explain how they extrapolate from the belief that there could possibly be a toxic dose, to opining that people who take the tea will suffer from a toxic dose. Upon careful reading of their reports, it is evident that they did not attempt to engage in any sort of methodological

extrapolation. They avoided that by offering, as the underlying premise for their unreliable opinions, speculation in lieu of data.

Defendants opine that they have a compelling interest in protecting the public from harm caused by ingesting the Daime and *hoasca* tea. Safety is one of their major themes. “Safety assessment is the area of toxicology relating to the testing of chemicals and drugs for toxicity. The first tenet of toxicology is ‘the dose makes the poison’; this implies that all chemical agents are intrinsically hazardous — whether they cause harm is only a question of dose. Ref. at 411.

The science of toxicology attempts to determine at what doses foreign agents produce their effects. The foreign agents of interest to toxicologists are all chemicals (including foods). The discipline of toxicology provides scientific information relevant to the following questions: What hazards does a chemical or physical agent present to human populations or the environment? What degree of risk is associated with chemical exposure at any given dose? Ref. at 411. Defendants’ experts offer no evidence to answer the scientific inquiry regarding the dose/risk continuum.

**E. The Factor of Relevance and “Fit”**

The Reference Manual summarizes the relevant cases:

[O]pinions have held that the “fit” prong of the Daubert test and the helpfulness standard of Rule 702 require courts to exclude. . . expert testimony that does not satisfy the (party’s) substantive burden of proof on an issue.

Ref. at 22.

Here the burden is on defendants to establish by a preponderance of the evidence that sacramental ingestion of the tea, to a medical probability, is likely to cause ill health effects to a significant number of people who might imbibe the tea at Santo Daime religious services,

and that the tea poses a significant danger to the public health. *See Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1398 (D. Or. 1996) (“Under Oregon law, the plaintiffs in this litigation must prove not merely the possibility of a causal connection between breast implants and the alleged systemic disease, but the medical probability of a causal connection”).

Where an expert leaps from the fact that a toxin can cause an injury to the conclusion that, therefore, it did, is the type of “*ipse dixit*” that the Supreme Court rejected in *Joiner*. Defendants wrongly assume that federal judges are free to speculate about causation and render decisions based on evidence and opinions about mere possibilities. The law is otherwise. In this case, there is little more than layer upon layer of *ipse dixit* conclusions, (an attempt by defendants to obviate their burden of proving compelling interests in banning the tea.) Even if one were to accept this unscientific methodology, none of the opinions “fits” because they do not provide evidence regarding the defendants’ burden of proof. They do not demonstrate that perceived harm is, to a medical probability, likely to ripen into actual, significant harm. Below we illustrate how the defendants’ logic and methodologies in attacking plaintiffs’ experts lack scientific rigor, and are otherwise unreliable. Defendants’ experts exhibit a remarkable variation in leaps of logic and *ipse dixit*. The defendants’ analysis of the reports of plaintiffs’ experts is grounded in a number of unreliable assumptions. Defendants attack plaintiffs’ experts based upon defendants’ mistaken scientific assumption that:

1. Because the existing data do not prove that the toxin cannot cause any injury, one can assume that it did.
2. Because the existing data do not prove that the toxin cannot cause the injury, it follows that any amount of the toxin can cause the injury.
3. Because the toxin is capable of causing injury at some unidentified dose, it is

likely to cause it at any dose.

4. Because we do not know at what dose the toxin may cause a negative effect, we will deem any exposure, no matter how small, a significant danger to health.

Other methodological or “fit” flaws:

1. Defendants’ experts make no attempt to quantify risk.
2. Defendants’ experts never argue that their testimony is offered to prove that the dose of Daime tea administered at services is, to a scientific/probability, likely to cause significant ill health effects to a significant number of current or future Church members. Defendants’ expert reports, therefore, are not relevant in that they make no attempt to meet the defendants’ burden of proof.

The expert analyses and opinions of defendants fail to meet the “fit” test because they are offered to establish that plaintiffs have not proven that the tea is “safe.” That is both a reliability and “fit” flaw in the defendants’ expert reports. It is against this background that plaintiffs offer this Opposition to Defendant’ Motions to Exclude Plaintiffs’ Expert Statements.

**F. Summary of Defendants’ Failure to Provide a Basis for Striking the Testimony of Plaintiffs’ Experts**

The curriculum vitae of defense expert Dr. Walker establishes that his only written work regarding these issues are opinions that were generated solely for the purpose of this litigation. Dr. Walker has not written expert reports about the use of hallucinogenics as a part of his professional research or other activities, unlike the vast and relevant professional background and expertise of plaintiffs’ expert, Dr. Halpern. Neither has Dr. Walker ever published any studies regarding the short- or long-term ill health effects of taking controlled substances referred to in his testimony, such as DMT, LSD, mescaline, peyote, and other such

psychoactive chemicals. None of the defendants' experts has written any scientifically acceptable analysis regarding the likelihood, to a medical probability, that the amounts of DMT or any hallucinogens used in conjunction with religious services will cause any significant ill health effects to a significant number of people. In fact, the only paper Dr. Walker has written on this subject, other than his Witness Statement in this litigation, is his identical criticism of Dr. Grob in the UDV case, which he inappropriately repeated in his Witness Statement in this case.

Dr. Ghiselin reviewed the Halpern and Cozzi testimonies and Dr. Halpern's study, noting that they are straightforward and are not subject to criticism on the basis of methodological flaws. The same cannot be said of Dr. Walker's testimony.

Dr. Walker's curriculum vitae does not indicate that he has any expertise or special knowledge regarding the biological mechanisms that would support a conclusion that the tea would be toxic at doses served in the Santo Daime services. Furthermore, defendants offer no evidence that there is a baseline risk for toxicity of the tea, nor do they offer any testimony about a dose response curve that one might try to construct with additional studies.

Dr. Walker is not qualified to render an opinion about the relationship between drinking the Daime tea and a toxic dose. He has no experience in this area or in any other closely-related fields to support any such opinion. This is likely why he frequently resorts to speculation. Similarly, Dr. Walker does not have the professional qualifications or the expertise to assess the scientific methodology or conclusions reached by the Halpern or Grob studies.

Dr. Walker is not qualified. He is not reviewing an epidemiological study. He is applying tools commonly used by experts in the field of drug prevention and abuse,

hallucinogenics, and, particularly, regarding the “set and setting” of drug use, and has no qualifications to opine in those areas that are the subject of his Witness Statement.

It is not enough, therefore, under the “intellectual rigor” test, for experts to venture hunches that they would never express or act upon in their everyday working lives. Experts must show that their conclusions were reached by methods that are consistent with how their colleagues in the relevant field or discipline would proceed to establish a proposition, were they presented with the same facts and issues. Ref. at 25.

#### **IV. THE STATEMENTS OF DEFENDANTS’ EXPERTS THAT ATTACK PLAINTIFFS’ EXPERT STATEMENTS SHOULD BE STRICKEN**

Dr. Ghiselin’s analysis of the status of this litigation provides accurate premises upon which to conduct the *Daubert* inquiry. His analysis illuminates the underlying issues and unpacks the defendants’ attempts to conflate this case with one they would like to have invented:

The government witnesses have sometimes been unclear, in the documents here discussed, what the litigation is about, and that sometimes that has led to logical errors such as the fallacy of irrelevant conclusion. A few important points that need to be emphasized should therefore be mentioned at the outset. The right of the plaintiffs to consume the substance in question has already been established by the Supreme Court. It is a situation in which benefits (religious freedom) have been given priority over possible harm. According to the law, the Church has a right to use the material in question in the context of its rituals. The defendants are being sued on the grounds that they are unlawfully depriving the plaintiffs of their established legal rights. Whether and to what extent the use of such substances should be discouraged is not an issue in the present litigation.

The logic of the situation is that the plaintiffs want to use the substance for a very limited purpose, i.e., as sacramental tea. The defense witnesses maintain that all sorts of imagined harm will occur if it is used for recreational or therapeutic purposes, if it is taken in higher doses than the plaintiffs employ, if it becomes a source of pure DMT, if there are as yet unforeseen consequences to developing organisms, and on and on. Blocking the importation of the tea for any use whatsoever, as the defendants have been doing, would of course be one

way of preventing undesirable effects. But such arguments, which implicitly presuppose that the ends justify the means, are irrelevant. I am advised that in order for the defendants to ban the tea they must give sound scientific reasons for concluding that there will be significant harm to a significant number of church members who imbibe the tea as the Santo Daime's sacrament at their ceremonies, and that the tea poses a significant risk to public health.

Ghiselin at 1-2.

Because each of the defendants' experts has fallen prey to what Dr. Ghiselin calls "the fallacy of irrelevant conclusion," their analysis, which was based upon this fallacious premise itself, is unreliable and doesn't fit the actual issues. This applies directly to their criticisms of plaintiffs' experts.

Below, we proceed to respond to the specific attacks on plaintiffs' experts. Our process with regard to Dr. Halpern begins with a citation to the defendants and their expert's statement in which plaintiffs' experts are criticized, followed by plaintiffs' response.

**A. Dr. Halpern's Witness Statement is Admissible**

Plaintiffs contend that there are so many unreliable statements in the Walker Statement, that to respond to all would take scores of pages. Here we will respond to several egregious examples, but not all. The defendants' attack on Dr. Halpern, which is based on Dr. Walker's Witness Statement, is that Halpern made the same errors Walker leveled against Dr. Grob in the UDV case. Such attacks were rejected by Judge Parker, and he ruled that they did not provide a reason to strike Dr. Grob's testimony. These same attacks should fare no better in defendants' criticism of Halpern than they did in their attempt to undermine the testimony of Dr. Grob. Additionally, Walker actually spent six pages leveling the same attacks on Grob in this case as he did in front of Judge Parker in UDV. Walker's Statement focuses primarily on attacking Dr. Grob and Dr. Halpern but offers no evidence in support of the defendants' burden

of proof. We believe this court should exclude this testimony in its entirety based upon principles of collateral estoppel.

**STATEMENT:** Defendants charge that: “[b]ecause Dr. Halpern’s study is based on flawed principles and unscientific methodology, any testimony regarding that study should be excluded.” Def. Motion *in Limine* at 6-12.

**RESPONSE:** Dr. Ghiselin evaluated Halpern’s study and Walker’s criticisms of the study.

We quote from Dr. Ghiselin:

In his Witness Statement, Alexander Walker, M.D. attempts to discredit Halpern’s study and statement. His approach is to invoke epistemological criteria that are routinely used by practitioners of his particular discipline in efforts to show that a new drug is safe to use. These include various ways of avoiding subjective bias and other measures that increase the reliability of a study but are not a necessary condition for admissibility as scientific evidence. For example, Dr. Walker suggests that the use of informed interviewers does not meet the standards of scientific evidence. But such observational work is routine practice among anthropologists and psychiatrists. He couples this criticism with the *ad hominem* argument claim that Halpern’s work is biased by virtue of the fact that he is an advocate for the rights of the plaintiffs. But the effects of such potential bias on the study under consideration are not substantiated.

Dr. Walker’s methodological strictures have to do with maximizing the probability that the dangers inherent in the use of a substance are detected and he argues that because of methodological “defects” along such lines the evidence is insufficient to establish that the substance is safe. The purpose of Halpern’s study, however, was not to establish that the substance is safe, but rather that in this particular case there is no evidence of harm having been done. Because the study was limited to the persons who volunteered as subjects, a brief discussion of Dr. Walker’s interpretation is useful.

Dr. Walker proposes that the sample of church members differs in social and psychological respects from the general population. On that basis he asserts that the conclusions are “speculative at best.” The suggestion that it would make a difference is itself speculative guesswork, an *ipse dixit*. The exclusion of former members from the study is another problem. Dr. Walker suggests that suffering harm would be a reason for leaving the Church and that, therefore the persons who have suffered the most harm are less represented. One could just as well speculate that whenever anyone suffers any adverse effect they leave the Church and therefore suffer less harm rather than more of it. His complaints about leaving certain persons out of the study highlight limitations that had freely been acknowledged but are irrelevant with respect to the arguments before the court.

Walker treats the small sample size as if it were a serious methodological flaw without clearly explaining what the problem is. The larger the number of observations the greater the probability of detecting infrequent events. Were the goal of the study to establish that there are no such rare events, which it is not, that would be a legitimate criticism. But even then, that would not be grounds for rejecting the evidence as inadmissible; instead the limitations in the study protocol might reduce the weight that the court might attach to the conclusions drawn from the data. The argument is simply that whatever the risks may be, the group under study appears not to be suffering any harm from this religious practice. Such negative results to be sure do not rule out the possibility of undesirable consequences. They do, however, provide evidence, as have earlier studies, that the putative harm is a matter of conjecture, not fact. The burden of proof with respect to the proposition that it is harmful rests with the defendants. Irrespective of Walker's ability to evaluate whether or not a study is methodologically pure from his own perspective, his methodological animadversions are beside the point. His entire argument is logically flawed and therefore inadmissible as evidence.

Ghiselin at 3-4

Below, plaintiffs establish that defendants' criticisms of Dr. Halpern by citing their expert, Dr. Walker, are without merit both in terms of reliability and fit and are therefore deserving of no weight in this litigation.

**STATEMENT:** 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. Def. at 11.

**RESPONSE:** Defendants never identify what they mean by "an expert in illegal drugs." This phrase simply has no scientific, technical or legal meaning and none was suggested. Defendants do not allege that Dr. Halpern is not an expert on Schedule I drugs or on the use and abuse of hallucinogens. Dr. Halpern does not suggest that any of the drugs be legalized in this case. Dr. Walker's statement is misleading in the extreme. Other than a statement by opposing counsel that it is "inappropriate that a psychiatrist with Dr. Halpern's qualifications"<sup>5</sup>

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<sup>5</sup> Halpern is Associate Director of Substance Abuse Research, Biological Psychiatry

opine on ‘whether use of a drug is licit or illicit,’” no expert has indicated in what way Dr. Halpern is not highly qualified to discuss the drug policy issues that are part of the routine practice and activities in which he analyzes circumstances under which humans are injured by use of Schedule 1 substances.

Defendants’ counsel submits: “[t]estimony about drug policy is plainly outside of Dr. Halpern’s area of expertise and is thus inadmissible under Rule 702.” If this is so plainly outside of the professional competence of a psychiatrist with Dr. Halpern’s credentials, why is there no citation to an expert or a treatise that holds that Halpern does not have the qualifications to opine on this subject? Taking into consideration his curriculum vitae, witness statement, and journal articles, drug policy is obviously a central issue in his work. His work in providing advice about the dangers of drugs and the set and setting wherein they should be used, all involves drug policy. His work for the National Institute of Drug Abuse, a policy making federal agency, is further tribute to how his work is used to assist in developing drug policy.

**STATEMENT:** Walker complains that Halpern’s study “interview involved open-ended questions about advantages and disadvantages of church membership and formal evaluations for the presence of current and past psychopathology.” Walker Statement at 7.

**RESPONSE:** Walker’s use of the term “open-ended” is of little value to this court without an explanation of what is meant by that phrase. It is common for psychiatrists to elicit information by asking the patient questions that will elicit useful subjective responses that reveal personality traits and the patient’s history. There is nothing intrinsically outside the realm of standard scientific methodology that is unsound here. Dr. Walker is not schooled in

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Laboratory, Alcohol and Drug Abuse Research Center, McLean Hospital, Belmont, MA.

psychiatry and is simply speaking about a specialty on which he is not qualified to opine.

**STATEMENT:** Walker’s complaint that, “[a]s a basis for establishing the safety of regular, ritual ayahuasca use, Dr. Halpern’s work suffered from all the defects of the Hoasca Project’s work a decade earlier, and added further defects in design.” Walker at 7.<sup>6</sup>

**RESPONSE:** Use of the term “defects” is not a relevant term to describe what may be limitations in the data in a scientific undertaking. Defendants cite no cases that refer to a “defect” as the basis for a finding that a scientific opinion is unreliable. The decision of Judge Parker does not substantiate the author’s claim that there were any “defects” in Dr. Grob’s study. There is no evidence, and the UDV Court did not find, that the methodology or conclusions were unreliable as that term is used in *Daubert*. If Dr. Walker meant “mistakes” when misusing the term “defects,” mistakes in the data gathered in a study do not render the study unreliable if the underlying methodology was sound.

Moreover, as we noted, Dr. Grob’s study was found to be reliable by Judge Parker. Dr. Halpern fully notes the limitations of the study, which meets the “intellectual rigor” requirement. One could argue that other study methods, if they were available, such as a double blind study or one with a “control” group, might produce results that might be more persuasive of the conclusions reached or could be used to test Dr. Halpern’s conclusions. Dr. Halpern fully addresses the limitations of conclusions that can be drawn from such a pilot study. However, such criticisms would only go to the weight to be accorded to the study, not its admissibility. Furthermore, the issue is whether Dr. Halpern’s conclusions can be tested. Clearly, they can be. It is very interesting that Dr. Walker is against spending funds on further

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<sup>6</sup> We note that the Grob and Halpern studies both establish no adverse effect. “Different studies that examine the same exposure-disease relationship should yield similar results,” Reference Guide on Epidemiology at 162.

study, which would provide a test for Dr. Halpern's conclusions. From a peer review perspective, one could only ask why, after leveling these unscientific criticisms of Halpern, Walker does not welcome further study but opposes it.

**STATEMENT:** Halpern used only an implied comparator group of "national norms" for the standardized tests administered. Walker 7-8.

**RESPONSE:** Again, we see what appears to be a criticism, but it is a statement without any meaning. It is not uncommon for a researcher to look for national figures when an attempt to create a local control group proves difficult. It is standard practice to use national rates for comparisons in many areas of the hard and social sciences. At most, if Walker is saying that the national averages don't really tell us much, that argument should be made as to the weight the court assigns to the conclusions of the report.

Walker's statement that the subjects who are the basis for these national figures are almost certainly far removed socially and probably psychologically from the regular Church attendees selected for the study, is speculative at best.

There is no attempt by Walker to state what the undefined social differences might be and what their relevance is to the data selection or to the opinions derived therefrom. On that basis, he asserts that the conclusions are "speculative at best." The suggestion that it would make a difference is itself speculative, an *ipse dixit*. Walker says there are differences and concludes that, therefore, there are. This is not scientific rigor. If there are social factors that differ, they must be identified. Absence of data renders Walker's opinion unreliable. It is just as likely that there are comparable social and personality traits that run the spectrum of the national average, and it is likely there is overlap. The problem here is that this is yet another categorical statement unsupported by any data. Even if we assumed that there were data to

support Walker's speculation, at most the argument would be that the study population, because of its very unique membership, requires some adjustments to make it comparable to the national average. Again, this begs the question. Walker does nothing to analyze his conclusions and does not provide this court with any basis on which to assess this conclusion for reliability. Finally, if one looks at the demographics of the 40-odd Church members, their professions and other factors represent a fair cross section of the general population. This renders Walker's criticism of Dr. Halpern's study on this point "unreliable."

**STATEMENT:** "The former members of Santo Daime not included in the study outnumbered study participants by a factor of more than three to one. Had regular ayahuasca consumption had deleterious physical or psychological effects, it might reasonably have led members to part ways with the church, and those individuals were omitted from the study." Walker at 8.

**RESPONSE:** Here we have another example of implying but not establishing that the data gathering techniques were less than optimal, a criticism that would go to the weight rather than the admissibility of the study. Walker does not address why absent potential study subjects were not contacted or did not respond. Although Walker's speculation is, of course, a theoretical "possibility," there is no current evidence to support it. All possibilities are just that, possibilities.

In fact, there is actually a good deal of testimony in the depositions of the plaintiffs about why people leave the Church. Walker had access to these depositions, but made no effort to acknowledge the reasons given in these depositions. He also fails to discuss the explanation of why the Halpern study team authors were able to contact mostly current members and not all who have been members at some time over the past 15 years.

**STATEMENT:** "Thus, an interview study of current, longtime members necessarily omits

precisely those people most likely to have suffered harm.” Walker at 8.

**RESPONSE:** This is the same argument that Walker put forth regarding the Grob study in the UDV case. Again, in a non-scientific milieu, the speculation might have some superficial appeal at casting doubt on the weight to be given to the study results. Again, Walker assumes people have suffered harm and assumes, further, that people were omitted from the Halpern study when there is no evidence to support such people ever even existed. This is the classic example of the fallacy of the irrelevant conclusion.

**STATEMENT:** “Irregular attendees at the ceremonies were omitted. In restricting the interviews to regular attendees, Dr. Halpern chose the group of ayahuasca recipients with the strongest social and psychological supports through the Church.” Walker at 8.

**RESPONSE:** “Irregular attendees” is not defined. The statement makes a broad assumption about an undefined “omitted” population. There is no evidence to support that irregular attendees were omitted from the study. The supposition that regular attendees have received more social and psychological support has no relevance to the issues this court must address. Whether those who join a group and remain in the group get more support than those who do not is a statement of such universal generalization that it has no value in isolating some methodological flaw in this study. People in the Church, as well as people no longer in the Church, may not receive their strongest social and psychological support from their Church. This value judgment does not touch on any disputed issue in this case. The only possible connection that Walker may be suggesting is that there is some bias or confounding factor here that renders the study unsound. Such factor is neither proven nor identified. Walker is just posing another question and speculating as to its answer. Not only is there only an inference, but the inference is a product of speculation.

**STATEMENT:** “Irregular attendees, deprived of these advantages of church membership, might well be at higher risk, and should have been included in the research.” Walker at 8.

**RESPONSE:** This statement must be characterized as “junk science.” Whatever the witness is attempting to communicate here is the product of conjecture, not science.

**STATEMENT:** “We do not know well whether any of the characteristics of the Santo Daime members uncovered in the standardized tests represent a change from their condition prior to first using ayahuasca.” Walker at 9.

**RESPONSE:** Although it is true that the standardized tests were not given before the subjects became members of the Church, that does not affect the reliability of the methodology. Nor, in this case, does it detract from the findings (not the issue on this *Daubert* Motion). At most, it represents a limitation that is common to many, if not most, studies that seek to obtain data in a situation where one could not know before an event that the event would be studied. Furthermore, every epidemiologist knows quite well that constructing historical data is a very complicated, expensive, and time-consuming task. This common problem is really only solved when the entire study is done under circumstances over which the researchers have control. In many instances, experimentation that would produce the most reliable information is not possible because current ethical standards prohibit many experiments on human beings.<sup>7</sup> While offering the criticism, Walker does not credit the circumstances prohibiting the ability of obtaining the historic data. He infers that the methodology was not what it could have been, but that is not the case. The methodology was sound. *See also* Dr. Ghiselin’s comments on this statement.

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<sup>7</sup> By way of example, historic data on the effects of radiation on human beings are very difficult to reconstruct; therefore, the best available data are unavailable, because we cannot ethically subject humans to radiation experiments.

**STATEMENT:** “Non-comparable comparators, ‘National norms’ would not be expected to represent a valid comparison measure for the test results of the Santo Daime Church members.” Walker at 9.

**RESPONSE:** This is merely Walker’s opinion, unsupported by any data and is not the product of intellectual rigor in any sense of the meaning of that rubric.

**STATEMENT:** “Interviewers and subjects who had full knowledge of Ayahuasca use and of the implications of the interview responses were at high risk for interjecting their personal views into what should have been an objective scientific assessment. The likelihood of erroneous evaluations was increased by Dr. Halpern’s strong prior advocacy for a right to use ayahuasca and the church members’ understanding that these interviews would be the basis of a public record.” Walker at 10.

**RESPONSE:** Most of these charges are speculation. Walker does not provide one citation to support his accusations that Halpern had previously advocated for a right to use ayahuasca. And if Dr. Halpern had published articles that reflect the current scientific information that the use of hallucinogens is not as dangerous as the general public, or even Dr. Walker, may believe, that would not suggest that Dr. Halpern is biased to the point of not being able to undertake such a study objectively. A review of Dr. Halpern’s journal articles reveals his concerns regarding illicit use of drugs. Apparently, the National Institute of Drug Abuse (NIDA) believes Dr. Halpern has credibility as evidenced by its support of his well-received peyote study.

**STATEMENT:** “Dr. Halpern’s testimony about peyote should be excluded.” Mot. at 12.

**RESPONSE:** Defendants’ first point in their Memorandum in Support of Motion *in Limine* to Exclude in seeking to strike Dr. Halpern’s Statement presupposes that the plaintiffs do not

allege an equal protection argument, and they thereby conclude that comparison to the UDV is irrelevant. This argument is disingenuous because it was so clearly rejected by the Supreme Court in the UDV case. Defendants also argue that Dr. Halpern's reference to the safety of peyote is irrelevant. The Supreme Court reviewed the peyote exemption, not to pass on an equal protection argument but, rather, to point out why the government's position regarding health was without merit.<sup>8</sup> The claims the defendants made in the UDV case that the system is closed are the same complaints being made here. In *Gonzales v. O Centro Espirita Beneficente União do Vegetal*, 546 U.S. 418, 435 (2006), the Court stated:

The well-established peyote exception also fatally undermines the Government's broader contention that the Controlled Substances Act establishes a closed regulatory system that admits of no exceptions under RFRA.

The Court noted, and established, that there was no evidence of ill health effects from ingestion of peyote in the religious context.<sup>9</sup> The Court stated:

Everything the Government says about the DMT in hoasca -- that, as a Schedule I substance, Congress has determined that it "has a high potential for abuse," "has no currently accepted medical use," and has "a lack of accepted safety for use . . . under medical supervision," 21 U.S.C. § 812(b)(1) -- applies in equal measure to the mescaline in peyote, yet both the Executive and Congress itself have decreed an exception from the Controlled Substances Act for Native American religious use of peyote. If such use is permitted in the face of the congressional findings in § 812(b)(1) for hundreds of thousands of Native Americans practicing their faith, it is difficult to see how those same findings alone can preclude any consideration of a similar exception for the 130 or so American members of the UDV who want to practice theirs. \* \* \*

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<sup>8</sup> Defendants' reargument of the *Morton v. Mancari*, 417 U.S. 535, 555 (1974), decision in this case is irresponsible and gratuitous. Def. at 12-13. This entire argument was rejected by the Supreme Court in *Gonzales v. O Centro*, 546 U.S. 418 (2006).

<sup>9</sup> Dr. Halpern's *Amicus* Brief to the Supreme Court discussed his study of the health effects of peyote. It was the only study provided to the Court establishing that, for those members of the Native American Church who used peyote regularly, there were no discernible ill health effects.

In other words, if any Schedule I substance is in fact always highly dangerous in any amount no matter how used, what about the unique relationship with the Tribes justifies allowing their use of peyote? Nothing about the unique political status of the Tribes makes their members immune from the health risks the Government asserts accompany any use of a Schedule I substance, nor insulates the Schedule I substance the Tribes use in religious exercise from the alleged risk of diversion.

*O Centro*, 546 U.S. at 427.

Defendants then go on to repeat the identical arguments that they made to the Supreme Court in the UDV case, each of which was categorically rejected. The two last paragraphs in Defendants' Motion, page 13 and on to 14, are made in bad faith. These arguments have been clearly rejected and no longer can claim to be supported by existing jurisprudence.

**STATEMENT:** "The research falls short of providing evidence on the health effects of ayahuasca for a number of reasons." Walker at 10.

**RESPONSE:** At page 10, Dr. Walker begins his attack on the Study done by Dr. Grob for the UDV in the *O Centro* litigation. Walker's comment that the Grob study "falls short" has no significance in terms of admissibility of the study or the weight to be assigned to its findings. First, to say that the study "falls short" is surprising to hear from an epidemiologist. Such terms have no meaning in epidemiology and it would be unlikely to encounter the phrase in a peer-reviewed paper.

Furthermore, stating that it falls short of providing evidence about health effects is simply incorrect on its face. On the contrary, it does provide evidence about the health effects on those study subjects who consumed it. It would have been proper for Dr. Walker to offer opinions that are consistent with the language of his trade. Any limitations in the Grob study go to weight rather than admissibility. Judge Parker considered Grob's study along with the

defendants' experts' criticisms and assigned some weight to defendants' criticisms. We believe that Judge Parker may have assigned greater weight to defendants' criticisms than were deserved because he did not have the benefit of an independent person with special knowledge of the nuances of epidemiology and the scientific method.<sup>10</sup> Finally, Dr. Ghiselin puts his finger on the issue:

The argument is simply that whatever the risks may be, the group under study appears not to have suffered from them.

Ghiselin at 4.

The Walker attack on Grob goes on for almost six pages. We will not respond to each individual statement because Walker already testified against Grob in the UDV case and his testimony here is a mirror of that testimony. Plaintiffs urge the Court to strike all testimony regarding Grob under principles of estoppel, which plaintiffs have articulated elsewhere. Plaintiffs do not wish to take another 5-6 pages to defend the Grob study. Judge Parker already passed on this. Should the court not exclude this part of Walker on estoppel or cumulative testimony, we will then respond more substantively.

**B. Dr. Kosten's Challenges to Halpern's Methodology**

Paragraph 28:

- a. Dr. Kosten attacks Halpern's point that one cannot easily consume a toxic dose.

Kosten's arguments that Halpern is wrong are not methodologically sound. Moreover,

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<sup>10</sup> While Judge Parker held that the evidence was "in equipoise" and that defendants had thus failed in meeting the compelling interest burden, we respectfully believe that the defendants' offering in the UDV case was speculation, as we urge here, and that it was entitled to virtually no weight. The expert testimony in this case more clearly illuminates both the reliability and relevance failures of defendants' experts' proposed testimony.

Kosten's criticism is irrelevant as Kosten is talking about a hypothetical situations, not the taking of the tea at Daime ceremonies. Note how Kosten does not include data regarding the amount of tea served at ceremonies. If he did, he could not argue that these doses might possibly be toxic because there are no data to support such an argument.

b. Kosten's disagreement with Halpern about the "non drug" use negates the set and setting of the use of hallucinogens. Kosten's failure to discuss the set and setting is a failure to include relevant data. If Kosten discussed the non drug use of peyote and ayahuasca and pointed to data to establish that the non drug use of Daime tea was sufficiently different to justify a different analysis, is methodology would have, at least, been sound. But he did not engage in that discussion. He simply invokes *ipse dixit* and says a drug is a drug.

c. Kosten's reference to Halpern's nuances regarding the term "hallucinogenic" is categorical in nature and again, reflects a failure to discuss the set and setting with which he could disagree if it had been discussed. It is the failure to address these data that renders Kosten proposed testimony unreliable.

d. Kosten attacks Halpern for saying it is his personal opinion that the Daime leadership considers it anathema to take the tea to get high. Halpern is not offering his personal opinion but rather reporting on his knowledge of the intention of the Church leadership and members regarding the sacramental use of the tea. Kosten does not seem to understand that the issue here is the sacramental use of the tea, not recreational use, and he displays a failure to discuss these data in his analysis, again rendering opinions irrelevant to the issues in this case.

Sections "e.-m." contain statements that Kosten offers, some of which raise reliability issues, but they are merely Dr. Kosten's disagreements with Halpern and this court will, of

course, give them the weight it deems appropriate. A methodological challenge to Kosten can be made because he negates the empirical evidence that exists from use of the tea thousands of times, from Halpern and Grob's findings for human studies, and from the Brazilian CONFEN report. Kosten jumps from the fact that DMT can be deleterious (in his view) to finding that it is, without regard to assessing the dose. This is an *ipse dixit* leap in logic.

**C. Professor Gurulé's Testimony is Relevant and Admissible**

When defendants' witness, Ms. Curry, as an attorney, ventures an opinion that the government has a compelling interest in banning the tea, the opinion is admissible, according to defendants. When Professor Gurulé, a law professor, ventures the opposite opinion, defendants object that it is a purely legal opinion. The "compelling interest" test is first a legal standard that can only be met by producing evidence. It, therefore, is a mixed question of law and fact.

Both Gurulé and Curry offer opinions on the same question. As former or current law enforcement officers, both Gurulé and Curry are offering drug policy opinions derived from data in light of applicable legal decisions. Ms. Curry indicates that her office had recently rejected an application for religious exemption. She made the RFRA inquiry and rejected it. Indeed, the Drug Enforcement Agency (DEA) has argued throughout this case that it is in the best position to undertake the RFRA balancing tests, evaluating the facts and applying the RFRA cases, more so than any federal judge, just as they argued to the Supreme Court in the UDV case.

Defendants are now arguing in their motion to strike that whether the government has any compelling interests is a determination for this court to make. Def. at 14. Defendants have

consistently argued the opposite, that the DEA, not the federal courts, have the requisite capacity to decide RFRA issues.

District courts, operating within the constraints of case-bound litigation, do not have the requisite capacity to evaluate and comprehend fully the far-reaching implications for law enforcement that attend any decision to exempt a Schedule I substance from the CSA's rigorous controls.

Merits Brief of Petitioners (the United States) at 23. This position was rejected by the Court. *See O Centro*, 546 U.S. at 439.

Gurulé's statements about the *bona fides* of the religious practice, that there is insufficient evidence of danger to the members of the public to warrant banning the tea, that diversion is unlikely, and that there are less restrictive means to satisfy any government interests than banning are the very same policy judgments that the DEA has made, albeit to the opposite conclusion. If Gurulé had agreed with the defendants, we would not hear this argument. In any event, the defendants' complaint is that Gurulé tends to establish that the balancing between the rights of the plaintiffs and those of the public tip in favor of not banning the tea. Gurulé's finding is that, because this case involves the "non drug" use of the tea, from a drug policy perspective, as noted by the Oregon Pharmacy Board, this is not a case that even belongs under the jurisdiction of the DEA.

**D. McCrea's Testimony is Relevant to All of the Issues to which He Testified**

While admitting that Dr. MacRae "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," defendants then go on to argue that Dr. MacRae has no expertise in diversion or drug control. A reading of his Witness Statement and writings dispel that misconception. He was also a member of the São Paulo State Council

on Narcotics for four years.

Again, while admitting to Dr. MacRae's impressive credentials, defendants argue that his testimony regarding the practices of the Santo Daime Church in Brazil are not relevant. Def. at 16. Defendants' argument seems to be that, because MacRae is discussing drug policy based upon his primary activities occurring in the country of Brazil, with different social and sociological concerns, extrapolating the data to drug policy in the United States is unreliable. This rather ridiculous argument is unsupported with even one example as to why Dr. MacRae's finding that the tea is appropriately recognized as lawful for religious purposes in Brazil would not apply to taking the tea in the United States. The human phenomenon of drug use and abuse obviously transcends national borders. Indeed, it is equally likely that the cultural similarities, which defendants do not acknowledge, make the testimony regarding Brazil easy to extrapolate to the United States. Indeed, in the area of drug abuse, both countries are signators to various international agreements regarding drug control.

Defendants rely on the methodologically unreliable statement by their religious expert, Dawson, that practices in Brazil have nothing to do with the United States. Again, defendants' argument is disingenuous in light of the fact that defendants' witness, Ms. Curry, spent many pages talking about the Santo Daime Church in Brazil based on information that was obtained from Dr. MacRae's writings, and draws comparisons and conclusions about the Church in the United States based upon aspects of the Brazilian practices.

Defendants argue that Dr. MacRae has no expertise in the health effects of drugs. As an expert, he has the absolute right to and does draw on the experience of other plaintiffs' experts as well as on that of the experts who sat on the Brazilian drug council with him. Defendants' argument in this regard is not well taken. Furthermore, although Dr. MacRae does

not have formal training in medicine, his 30+ years of experience in drug policy obviously provides him with the practical experience that was recognized by the Court in *Kumho Tire*.

Defendants attempt to use bootstrapping to compensate for the weaknesses of each of their arguments. Each of the criticisms of MacRae on pages 17-18 of defendants' motion is made of whole cloth. MacRae can opine about the practices of the Santo Daime Church in Brazil and can opine as an expert on drug policy that extra-religious use of the tea is not likely to occur to a significant degree. Defendants maintain that MacRae cannot say that religious use of the tea is a non-drug use, but they never state a basis for that conclusion.

Defendants then argue that MacRae cannot opine that the tea may serve to ameliorate drug habits because they claim he has no experience in this area. This is precisely what drug policy is about. MacRae has studied the Santo Daime and other religious use of the tea and has written about it throughout his professional career. One cannot imagine a person more experienced than Dr. MacRae in this regard. MacRae testified that:

Since 1987 I have been involved in Brazilian official drug prevention programs both at State and Federal levels. In this regard my main activities have been concerned with drug prevention among young adults, including issues such as distribution of illicit drugs and curbing HIV infection among injecting drug users. For some years now my academic research interest has also included the religious use of psychoactive substances.

MacRae at 2.

**E. George Gerding's Testimony is Both Reliable and Relevant to the Issues**

Mr. Gerding served as President of the Oregon Pharmacy Board for two terms. The mission of the Oregon State Board of Pharmacy is to promote, preserve, and protect the public health and safety and to ensure high standards in the practice of pharmacy by regulating the

quality, manufacture, sale, and distribution of drugs.<sup>11</sup>

Defendants' arguments regarding Mr. Gerding's qualifications are without any substance. Gerding possesses sufficient experience in the areas of concern to assist the court in evaluating the issues in this case.

The Oregon Pharmacy Board shares jurisdiction with the DEA in enforcing the CSA. The Pharmacy Board has many of the same powers and enforcement responsibilities as the DEA. To the extent that Ms. Curry may hold herself out as having expertise regarding drug policy, Mr. Gerding also possesses the requisite experience to act as an expert.

Mr. Gerding was responsible for reviewing the request of the Native American Church for an exemption for the religious use of peyote. As part of his duties, Mr. Gerding researched the very same issues that are presented in this case. Indeed, Mr. Gerding is the only expert in this entire litigation who has had the responsibility for assessing all sides of the compelling interest test. None of the defense experts has had the combination of professional experience in drug controls and administering both state and federal controlled substance laws and regulations as has Mr. Gerding.

Curiously, defendants challenge Mr. Gerding's qualifications because he has never tested ayahuasca to determine its chemical composition. None of the defense experts has tested ayahuasca for its chemical or psychoactive components. According to their own criteria, then, no defense expert qualifies in this case.

Defendants continue their *ad hominem* attack on Gerding, stating:

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.

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<sup>11</sup> [www.pharmacy.state.or.us/](http://www.pharmacy.state.or.us/)

Def. at 26. Again, if this is the criterion for qualifications, none of the defense experts has any training in botany or plant pharmacology and, thus, their testimony should likewise be excluded.

As an expert, Gerding is able to utilize the opinions and conclusions of experts in other fields to assist him in forming his opinions. This is a very typical methodology that the defendants cannot challenge. Defendants' attempt to distinguish pharmacy from pharmacology is similarly of no avail. Both involve knowledge of the chemistry of the drugs and their use and abuse, albeit from slightly different perspectives. Defendants are unable to articulate how this distinction affects the reliability of Gerding's testimony.

Mr. Gerding's qualifications certainly exceed those of Ms. Curry. Under "Qualifications," she lists as her academic training a Masters in Public Health and a law degree. She does not list any degree that involves pharmacology (as does a Pharmacy degree), yet her paper is an analysis of the health issues that the government wrongly labels as "compelling."

Defendants' argument that "[t]hus, Mr. Gerding can demonstrate no special knowledge, skill, experience, training, or education on the subject matter" also rings hollow. None of the defense experts has any such experience either. Not having handled DMT neither adds to nor detracts from any of the positions that either side has taken in this litigation. It is simply irrelevant. Are defendants suggesting, really, that if Mr. Gerding had "handled" DMT he would have more to offer the court in its deliberations? And, if one assumed that was the case, at most it is a challenge to weight, not admissibility.

Defendants' argument that Gerding's discussion about peyote is irrelevant repeats the earlier bad faith argument defendants made regarding Dr. Halpern. Defendants' arguments

that the analysis of the peyote exemption is not relevant are not based upon a reasonable reading of extant law.

**F. Dr. Winkelman's Testimony Falls Within his Expertise, and is Relevant**

Defendants' attempt to strike Winkelman is, as in the case of the others, groundless, and we will not, therefore, devote much text to this.

Defendants argue that:

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.

Def. at 23.

Defendants claim that Winkelman does not have the qualifications to opine on the subjects included in his statement, indicates a failure on defendants' part to read his curriculum vitae or his report in any detail. None of the defendants' experts who commented on Winkelman was able to present any arguments that he was not qualified to give his opinions. Dr. Winkelman has a B.A. in Psychology, B.A. in Social Sciences, a Masters in Public Health (M.P.H.), lectures in several Colleges' nursing departments, wrote his Doctoral Thesis on the cross-cultural and psycho-physiological study of religions and religious healing practices, with particular consideration of the effects of shamanic practices and sacraments called "hallucinogens" on health, well-being, and drug addictions. He has published articles in the International Journal of Drug Policy and the American Journal of Public Health. Of particular interest is his Post-Doctoral Fellowship at the National Institute of Drug Abuse, Arizona Center for Ethnographic Research and Training 2000-2001.

Based upon his international reputation and extensive studies regarding the religious practices of the Santo Daime and the UDV and his studies of alternative healing practices, Dr.

Winkelman was recently awarded a Fulbright Fellowship to conduct further studies of the health of Santo Daime Church members in Brazil, to begin in February, 2009. He is also Co-Publisher of the Yearbook of Cross-cultural Medicine and Psychotherapy.

Dr. Winkelman's Witness Statement at page 1 and his curriculum vitae are impressive regarding his qualifications to testify in this case. One cannot imagine a more qualified person to testify than Dr. Winkelman, who has multidisciplinary professional credentials and has conducted direct studies on all of the issues in this case.

Of particular note is that Dr. Winkelman's testimony in this case flows directly from his previous experience, as compared to virtually every one of the defense experts, who developed their opinions expressly for the purposes of testifying. *Daubert II*, 43 F.3d at 1317. If generated for the purpose of a particular lawsuit, the report is "inherently suspect." In the case of the defendants' experts in this case, the content of their reports confirms what was "inherently suspect" before they were read.

Dr. Winkelman's Witness Statement establishes that he reviewed all relevant reports of plaintiffs' other experts. Winkelman's formal training and his experience render him fully capable to review the other expert reports to form part of the factual predicate for his conclusions. He has experience in every area of concern in this case, including training at the National Institute of Drug Abuse and participating in ceremonies in Brazil with the Santo Daime and the UDV. Dr. Winkelman's publications are also on every area of concern in this case.

Dr. Winkelman proposes "to testify about matters growing naturally and directly out of research (he) ha(s) conducted independent of the litigation."<sup>12</sup>

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<sup>12</sup> As compared to defendants' experts who "have developed their opinions expressly for

Defendants claim Dr. Winkelman has no experience in pharmacology. Not only does the formal training he has had as a public health officer and at the National Institute of Drug Abuse provide training in this area, but a review of his publications reveals significant experience in these areas. He certainly is qualified to comment on the conclusions of other plaintiffs' experts.

**G. Dr. Cozzi is Qualified to Render Opinions Regarding Drug Policy**

Defendants claim that Dr. Cozzi is not qualified to discuss drug policy. They claim he is not an expert on drug policy. Defendants continue to fail to understand that there is no expert in this case that has a B.A., Masters or Ph.D. in "Drug Policy." We doubt such a degree exists. If it does, no defense expert has one. The relevant criterion for all of the experts is that they possess sufficient knowledge from formal training, education, or experience to assist the trier of fact.

The overarching goal common to both the scientific and non-scientific contexts, the *Kumho Tire* Court said, was to ensure "that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Id.* at 152.

Understandably, defendants do not mount a challenge to the reliability of Dr. Cozzi's methodology or its relevance. While not defining what they mean by "Drug Policy" expert, certainly it is within Dr. Cozzi's qualifications to refer to regulations governing use, abuse, and dispersion of chemicals. His testimony is admissible.

**V. CONCLUSION**

Plaintiffs' experts are qualified to testify. Their testimony is straightforward, and

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the purposes of testifying." *Daubert II*, 43 F.3d at 1317. If generated for the purpose of a particular lawsuit, the report is "inherently suspect."

defendants' criticisms are based upon unreliable methodologies.

DATED this 7<sup>th</sup> day of January, 2009.

Respectfully submitted,



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