Roy S. Haber, OSB No. 800501
haberpc@cyber-dyne.com
ROY S. HABER P.C.
570 East 40th Avenue
Eugene, OR 97405
Telephone: 541.485.6418
FAX: 541.434.6360

Don H. Marmaduke, OSB No. 53072
don.marmaduke@tonkon.com
TONKON TORP LLP
1600 Pioneer Tower
888 SW Fifth Avenue
Portland, OR 97204-2099
Direct Dial: 503.802.2003
Direct FAX: 503.972.3703

(Please see signature page for
names of additional counsel)

Attorneys for Plaintiffs

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF OREGON

CHURCH OF THE HOLY LIGHT OF THE QUEEN *et al.*,	Civ. No. 08-03095-PA
Plaintiffs,	MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION *IN LIMINE* TO EXCLUDE TESTIMONY OF DEFENDANTS' EXPERTS WALKER, FRANKENHEIM, JASINSKI, DAWSON, GLASS AND KOSTEN
VS.	
MICHAEL B. MUKASEY, *et al.*,	
Defendants.	

TABLE OF CONTENTS

I. INTRODUCTION……1

II. PLAINTIFFS' OTHER RELATED MOTIONS AND RESPONSES TO DEFEDANTS' MOTIONS……..……1

III. BURDEN OF PROOF AND EVIDENTIARY STANDARDS……...2

A. Defendants' Expert Testimony has been Generated Solely for this Litigation……..2

B. Defendants' Expert Testimony Speaks Only to Speculation, not Perceived Harm……...3

C. Defendants' Expert Testimony is Not Relevant……...5

D. Extrapolation and Toxicology……..6

E. Summary of Experts' Failure to Offer Reliable Relevant Testimony Regarding Defendants' Burden of Proof …….....7

i. Fit Flaws……..7

ii. Summary of Defense Expert Statements……8

F. Dr. Alexander Walker……...8

G. Dr. Jasinski's Testimony is Neither Reliable, nor Does it Fit……..9

H. Dr. Frankenheim's Testimony Should be Excluded as Unreliable and Irrelevant to the Issues in this Case…..……17

I. Dr. Dawson's Testimony is Unreliable and Irrelevant……...27

J. Portions of Dr. Glass' Testimony Are not Reliable and Portions are Irrelevant……...34

K. Dr. Thomas R. Kosten, M.D……...38

IV. CONCLUSION……...42

TABLE OF AUTHORITIES

Cases …….Page(s)

Allen v. Pennsylvania Engineering Corp.,
102 F.3d 194 (5th Cir. 1996)……7

Brumbaugh v. Sandoz Pharmaceutical Corp.,
77 F. Supp. 2d 1153 (D. Mont. 1999)……...8

Clausen v. M/V New Carissa,
339 F.3d 1049 (9th Cir. 2003)……..3

Daubert v. Merrell Dow Pharmaceuticals, Inc.,
509 U.S. 579 (1993)……..1, 4, 8

Daubert v. Merrell Dow Pharmaceuticals, Inc., (Daubert II)
43 F.3d 1311 (9th Cir. 1995)……..……..…2, 11

Domingo ex rel. Domingo v. T.K.,
289 F.3d 600 (9th Cir. 2002)……4

General Electric Co. v. Joiner,
522 U.S. 136 (1997)……..3

Hall v. Baxter Healthcare Corp.,
947 F. Supp. 1387 (D. Or. 1996)……..5

Hopkins v. Dow Corning Corp.,
33 F.3d 1116 (9th Cir. 1994)……..……...4

In Re Hanford Nuclear Litigation,
292 F.3d 1124 (9th cir 2002)……...12

Kennedy v. Southern California Edison,
286 F.3rd 763 (9th Cir 2001)……..7

Kumho Tire v. Carmichael,
526 U.S. 137 (1999)……20

McClain v. Metabolife Intern., Inc.,
401 F.3d 1233 (11th Cir. 2005)……6, 7

Cases (con't) …….Page(s)

Mitchell v. Gencorp, Inc.,
165 F.3d 778 (10th Cir. 1998)……..8

O Centro Espírita Beneficente União Do Vegetal v. Ashcroft,
282 F. Supp. 2d 1236 (D.N.M. 2002),
aff'd 389 F. 3d 973 (10th Cir. 2004) (*en banc*),
aff'd, 546 U.S. 418 (2006)……1

O'Hanlon v. Matrixx Initiatives,
2007 WL 2446496 (C.D. Cal. 2007)…….8

Rider v. Sandoz Pharm. Corp.,
295 F.3d 1194 (11th Cir. 2002)……6

Schudel v. General Elec. Co.,
120 F.3d 991 (9th Cir. 1997)…….6

United States v. Downing,
753 F.2d 1224 (3d. Cir. 1985)……...1

United States v. Rincon,
28 F.3d 921 (9th Cir. 1994),
cert. denied, 513 U.S. 1029 (1994)……...3

Weisgram v. Marley Co.,
528 U.S. 440 (2000)……..6

Miscellaneous

FED. R. EVID. 702……..3

The Reference Manual on Scientific Evidence,
2nd Ed. 2000, Federal Judicial Center……...3, 5

The Reference Guide on Medical Testimony……...8

I. INTRODUCTION

Plaintiffs are seeking to exclude the testimony of defendants' experts Alexander Walker[1], Jerry Frankenheim, Donald Jasinski, Lorne L. Dawson, George S. Glass, and Thomas R. Kosten, on the grounds that 1) they are not "reliable" scientific reports, s*ee Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and 2) their respective testimonies are not "relevant" and do not "fit" the issues germane to this case.

II. PLAINTIFFS' OTHER RELATED MOTIONS AND RESPONSES TO DEFEDANTS' MOTIONS

Plaintiffs have filed their Opposition to Defendants' Motion *In Limine* to Strike Plaintiffs' Experts ("Opposition"), a Motion to Strike Defendants' Expert Reports as Being Cumulative, and will shortly file a Motion to Strike all of the defendants' medical and pharmacology evidence because a) defendants already lost those issues in the Supreme Court and b) they are using the three of the same experts to make the same attacks on Dr. Charles Grob's health study in this case that they made unsuccessfully against Dr. Grob's health study in the UDV case eight years ago. Plaintiffs will, therefore, file a Motion for Partial Summary Judgment because there are no triable issues of fact regarding health and safety. Plaintiffs

[1] It should be noted at the outset that Dr. Walker offers no opinions to support the defendants' burden of proof. Rather, he offers a statement criticizing the witness statements of Dr. Halpern and the report of Dr. Grob. Dr. Grob is the expert in *O Centro Espírita Beneficente União Do Vegetal v. Ashcroft*, 282 F. Supp. 2d 1236 (D.N.M. 2002), *aff'd* 389 F. 3d 973 (10th Cir. 2004) (*en banc*), *aff'd*, 546 U.S. 418 (2006), whose report was admitted by Judge Parker. The principal reason to strike Dr. Walker's report is that it lacks relevance or does not "fit," using the parlance of *Daubert*. Expert testimony is relevant if sufficiently tied to the facts of the case such that it will aid in resolving the factual dispute. *Daubert*, 509 U.S. at 591 (*citing United States v. Downing*, 753 F.2d 1224, 1242 (3d. Cir. 1985)). This inquiry can be described "as one of fit." *Daubert*, 509 U.S. at 591. Dr. Walker's testimony neither supports defendants' position, nor does it offer evidence that either Dr. Grob's report or Halpern's report should be excluded under *Daubert*. It is more akin to a lay person's complaint rather than an intellectually rigorous challenge to the plaintiffs' expert reports, and it is based on an unreliable methodology.

believe 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 regarding health effects.[2]

III. BURDEN OF PROOF AND EVIDENTIARY STANDARDS

Plaintiffs' Opposition to Defendants' Motion *in Limine* sets forth the applicable rules regarding the burden of proof and of going forward, as well as the relevant guidelines for admissibility of expert testimony under, *e.g., Daubert* and its progeny.

A. Defendants' Expert Testimony has been Generated Solely for this Litigation

Defendants' expert reports have been generated in this case 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 v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1318 (9th Cir. 1995) (*Daubert II*). Plaintiffs will establish in this Motion that defendants' experts have not compensated for their inherently suspect statements because they do not reflect the intellectual rigor necessary to render their opinions reliable.

---

[2] 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 defendants are putting on regarding the health issues is virtually identical to the UDV case, we are suggesting again that defendants be estopped from repeating the UDV defense with the same witnesses. 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.

B. Defendants' Expert Testimony Speaks Only to Speculation, not Perceived Harm

One of the most consistent examples of a failure to meet *Daubert* reliability tests is the defense experts' attempts to elevate speculation into scientific truth by stating, without citation, that certain principles are generally accepted[3] in science. Defendants' experts attempt to evade the reality that their conclusions are *ipse dixit* by resorting to categorical phrases suggesting universal truth. "The trial court's gatekeeping function requires more than simply 'taking the expert's word for it.'" FED. R. EVID. 702 advisory committee's note (2000).

Plaintiffs' epistemological expert, Dr. Michael Ghiselin, points to many examples of the defendants' experts failing to use the tools of the scientific trade. 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. 43 F.3d at 1318. *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* 1049, 1056 (9th Cir. 2003) (same). As we note in detail below, this failure runs throughout the statements of defendants' experts.

The experts' testimony in this case, as described *infra*, is replete with the classic sheer *ipse dixit* forbidden by the Court in *General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997). The Reference Manual on Scientific Evidence, 2nd 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.

---

[3] As we note in our Opposition, "general acceptance" is no longer the reliability test. *Daubert, supra.*

Joiner (citation omitted).[4]

The expert's testimony must be based on "scientific . . . knowledge," implying a "grounding in the methods and procedures of science" and must connote "more than subjective belief or unsupported speculation." Id. The inquiry is to be a flexible one, and "must be solely on principles and methodology, not on the conclusions that they generate." *Hopkins v. Dow Corning Corp.,* 33 F.3d 1116, 1124 (9th Cir. 1994), *citing Daubert*, 509 U.S. 579, 113 S. Ct. at 2795 (1993). *See also,* Plaintiffs' Opposition to Defendants' Motion *in Limine* (hereinafter, "Opposition"), pp. 6-10.

> Defendants wrongly assume that this Court is free to speculate about causation and render an opinion based on conjecture and opinions about mere possibilities. The law is otherwise. It is true, as Domingo contends, that *Daubert* does not require that every aspect of a theory of medical causation be supported by research on the identical point, and that it is not necessary to show how a particular act or event caused an injury. See *Daubert II*, 43 F.3d at 1314. There must, however, be "sufficiently compelling proof that the [event] must have caused the damage somehow." *Id.* (emphasis in original). The reasoning between steps in a theory must be based on objective, verifiable evidence and scientific methodology of the kind traditionally used by experts in the field. *Kennedy* [*v. Collagen Corp.*], 161 F.3d [1226,] at 1230 [(9th Cir. 1998)].

Domingo ex rel. Domingo v. T.K., 289 F.3d 600, 607 (9th Cir. 2002) (emphasis added).

Defendants' proof is little more than layer upon layer of *ipse dixit* conclusions, not the "sufficiently compelling proof" required.

Plaintiffs will provide a multitude of examples wherein the conclusions and opinions of defendants' experts display "simply too great an analytical gap between the data and the opinion proffered" to be considered reliable under *Joiner.*

---

[4] But neither is it the court's function, when determining admissibility, 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.

C. Defendants' Expert Testimony is Not Relevant

As we note in our Opposition Memorandum, "opinions 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 significant ill health effects to a significant number of people who might imbibe the Daime 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"). Even if one were to accept defendants' unreliable statements, the vast majority of them simply do not "fit" because they do not provide evidence regarding the defendants' burden of proof. They do not demonstrate that the perceived harm is, to a medical probability, likely to ripen into actual, significant harm. Defendants rely completely on analogies to other chemical substances, including LSD, to make the unsubstantiated leap that toxicity of such analogues necessarily implies toxicity of the Daime tea. Such reasoning is routinely soundly rejected by the courts.

> Dr. Morton did not establish it was scientifically acceptable to draw general conclusions about the neurotoxicity of TCA and Perc from studies of other chemicals; indeed, the testimony indicated small differences in molecular structure often have significant consequences.

Schudel v. General Elec. Co., 120 F.3d 991, 997 (9th Cir. 1997), *abrogated on other grounds*, *Weisgram v. Marley Co.*, 528 U.S. 440 (2000). *See also McClain v. Metabolife Intern., Inc.*,

401 F.3d 1233, 1246 (11th Cir. 2005) ("[E]ven small differences in chemical structure can sometimes make very large differences in the type of toxic response that is produced" (citation omitted)); *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1201 (11th Cir. 2002) ("Even minor deviations in chemical structure can radically change a particular substance's properties and propensities").

D. Extrapolation and Toxicology

Defendants' experts make no attempt to quantify any of the perceived risks that they discuss. Please see "Section D" of Plaintiffs' Opposition at pages 9-10 for a more complete discussion. As we begin our analysis of defendants' expert reports, we emphasize the first principle of toxicology that "the dose makes the poison." Opposition at 10.

E. Summary of Experts' Failure to Offer Reliable Relevant Testimony Regarding Defendants' Burden of Proof

Below we set forth a summary of examples of how the defendants' logic and methodologies lack scientific rigor, abound in sophistry, and are otherwise unreliable. Defendants' experts exhibit a remarkable variation in leaps of logic and *ipse dixit*. Some examples that stand out include:

1. Because the existing data do not prove that the tea cannot cause any injury, one can assume that there is sufficiently compelling proof that it does.

2. Because the existing data do not prove that the tea cannot cause injury, one can assume that there is sufficiently compelling proof that any amount of the tea can cause injury.

3. Because defendants claim, but cannot prove, that the tea is capable of causing a toxic effect at some unidentified dose, one can assume that there is sufficiently compelling

proof that it is likely to cause toxicity at any dose.

4. While the existing data in the Halpern study establish that the long term users of the tea who were part of the study experienced no ill health effects, that is irrelevant because the absence of negative data does not mean that there are no ill health effects.

i. Fit Flaws

1. Defendants' experts make no attempt to quantify risk.

2. Defendants' experts fail to provide testimony that tends to prove that the dose of Daime tea administered at services is, to a medical probability, likely to cause significant ill health effects to a significant number of current or future Church members. *See McClain*, 401 F.3d at 1241-42 ("The expert who avoids or neglects this principle [of the dose-response relationship] without justification casts suspicion on the reliability of his methodology"). "Scientific knowledge of the harmful level of exposure to a chemical plus knowledge that plaintiff was exposed to such quantities are minimal facts necessary . . . ." *Allen v. Pennsylvania Engineering Corp.*, 102 F.3d 194, 199 (5th Cir. 1996). Defendants' expert statements, therefore, are not relevant in that they make no attempt to establish the defendants' burden of proof.

3. Defendants' experts speculate that, because they believe that DMT can cause harm, then any amount can cause harm. They pay no heed to the first rule of toxicology that it is the dose that is the poison. In *Kennedy v. Southern California Edison*, 286 F.3rd 763 (9th Cir 2001), the court held that, to satisfy the burden of proof, the plaintiff had to establish that she was exposed to more than an infinitesimal or theoretical dose. "Guesses, even if educated, are insufficient to prove the level of exposure in a toxic tort case." *Mitchell v. Gencorp, Inc.*, 165 F.3d 778, 781 (10th Cir. 1998) (citing *Daubert*, 509 U.S. at 589). Here the experts simply

opine that, in their view, any dose is dangerous. That is simply not enough to meet the defendants' burden of proof. [5]

ii. Summary of Statements of Defendants' Experts

The defendants' experts fail to discuss whether the risk of harm increases with dose or why the evidence that the human body will reject the tea entirely at certain doses is not reliable. None of this is explored in any sound methodological manner.[6]

These experts only offer speculation that the tea may cause a toxic effect.

None of the experts actually defines what a toxic dose would be for the Daime tea.

Defendants' experts are unable to locate any findings in the scientific literature to suggest toxicity of the Daime tea at the doses provided in the religious services of the Church.

F. Dr. Alexander Walker

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 rituals. Furthermore, defendants offer no proof 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

---

[5] Courts routinely reject such testimony. *See, e.g., O'Hanlon v. Matrixx Initiatives,* 2007 WL 2446496, at *3 (C.D. Cal. 2007) ("Even if Dr, Jafek were correct that the olfactory systems in mice is comparable to those in humans, he still fails to explain how he would calculate or determine a toxic dose. . . . In short, Dr. Jafek fails to explain how much Zicam is necessary to be toxic"); *Brumbaugh v. Sandoz Pharmaceutical Corp.*, 77 F. Supp. 2d 1153, 1156 (D. Mont. 1999) ("Testimony extending general conclusions about similar drugs does not meet Daubert's requirement of reliability").

[6] The Reference Guide on Medical Testimony states that, in assessing causation, physicians must take into account the relationship between dose and risk. *Id*. at 469.

the Daime tea and a toxic dose. He has no experience in this area or in any other sufficiently 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 and hallucinogenics, particularly in the setting of drug use, and has no qualifications to opine in those areas that are the subject of his Witness Statement. Walker has no training or experience in these areas.

Plaintiffs seek to exclude the testimony of Dr. Walker for the reasons cited in our Opposition to Defendants' Motion to Exclude Dr. Halpern.

G. Dr. Jasinski's Testimony is Neither Reliable, nor Does it Fit

We preface this discussion by noting that Dr. Jasinski testified in the UDV case about the same subjects he testified to in this case; therefore, his testimony should be excluded under principles of estoppel.

We refer this court to the rebuttal testimony of Drs. Halpern and Cozzi, which establish that, although there are similarities in the chemical structure of LSD and DMT, there are also differences; and it is those differences that can result in different physiological reactions to the two.

From the standpoint of a routine *Daubert* analysis, we note that Jasinski begins his discussion by noting the similarities of the molecules. From there, and without a balanced discussion of the differences, Jasinski talks about all of the possible negative reactions that

"LSD-like hallucinogenics" may cause. He assumes, without demonstrating, that all LSD-like hallucinogenics act the same way in every circumstance. His first *ipse dixit*, then, is in concluding that, because these drugs have some molecular similarity, they cause the same reactions. He provides no evidence to support this extrapolation.

He then summarizes his finding by stating:

> These established disorders and diagnoses, in addition to the public health problems and risks briefly summarized above, may be reliably associated with the LSD-like hallucinogens, including DMT.

Jasinski Statement at 9.

Jasinski's statement has no discernable scientific value. His pronouncement that certain disorders "are reliably associated" with DMT fails to advise the court which ones, if any, are to a medical probability likely to occur at ceremonies of the Santo Daime Church. Dr. Jasinski then attempts to link MAO inhibitors with LSD-like reactions by innuendo rather than data, and makes assumptions based upon hypothetical rather then real doses. He also states that the "mental effect" of the tea is the same as taking the "LSD-like hallucinogen DMT." Jasinski at 10. He appears to be saying that the trace amounts of DMT in the tea that become active orally and at a slow rate cause the same "mental effect" as synthetic DMT snorted or smoked. The scientific evidence presented by plaintiffs' experts and the Strassman study cited by both parties negates this, but the *Daubert* issue is the failure of the expert to discuss this and distinguish data that are vastly different. Another *ipse dixit*.

Similarly, at page 11 Jasinski suggests again that the LSD-like hallucinogenics can produce serotonin reactions and that they "would be expected" to interact with foods. He never explains which foods, or to whom this would be expected to occur. And no literature is cited to support this conjecture. He then goes on to suggest that such interactions with *ayahuasca* can cause death, but does not advise whether that has ever happened and, if so, the

level of risk of death, or at what doses this has ever occurred. Plaintiffs contend there are no data to support Dr. Jasinski, and if there are, he failed to cite them. He provides only a theoretical causative connection between the tea and health risks, not enough to support a "compelling interest" finding regarding health and safety. His testimony is, therefore, irrelevant.

At page 11, he goes on to state that "[t]he effects of ayahuasca in general appear to be similar to those described for synthetic DMT." He never advises what he means by "appear." Has there been an empirical observation in the laboratory? We don't know. Jasinski's conclusions are simply unsupported by demonstration of any testing or a rigorous analysis of the chemistry and pharmacology. It is simply absent from the testimony. He simply makes the leap of logic that because A has some properties similar to B, then A and B are the same for all purposes. See, *Daubert II,* 43 F.3d at 139, ("However, the party proffering the evidence must explain the expert's methodology and demonstrate in some objectively verifiable way that the expert has both chosen a reliable scientific method and followed it faithfully").

Jasinski raises "[s]afety issues with ayahuasca use and the need for further study." Defendant witnesses such as Jasinski suggested further study regarding the "safety" of ayahuasca. Jasinski repeats this again eight years later but does not mention whether anyone from the government has undertaken such studies. No one at the Drug Enforcement Agency (DEA) has ever attempted to obtain funding for or by the National Institute of Drug Abuse to conduct the kind of study Dr. Halpern undertook regarding peyote. It is as though there is a tacit understanding in the government and amongst its scientists not to do more research as it will only confirm that there are no significant ill health effects associated with the ceremonial consumption of the tea, as noted in the studies by CONFEN, Grob, and Halpern.

Jasinski's suggestion that further studies be made must be stricken because it does not

provide any testimony regarding the issues in this case. It is not relevant to the burden of "compelling interest" that defendants must satisfy. As the Supreme Court noted in *Daubert*, supra., science is constantly evolving but scientists must deal with the existing data in offering opinions. The expert opinions must tend to establish the burden of proof required by the proponent, or the report is not relevant. *In Re Hanford Nuclear Litigation,* 292 F.3d 1124 at 1139 (9th cir 2002).[7]

Indeed, Dr. Jasinski's testimony in the *O Centro* litigation is sufficient for this court to exclude his testimony in this case under the "fit" criteria. *O Centro v. Ashcroft,* Trial Testimony October 29, 2001:

Page 1027 Jasinski Cross Examination

Q. So when we are talking about evidence of withdrawal or abstinence syndrome, you don't have any evidence of that in relation to DMT, do you?
A. No.
Q. Or ayahuasca?
A. No.
Q. And addiction is also defined, and you defined it as, "A behavior that exhibits a compulsive reliance on a drug?"
A. Yes.
Q. But you don't have any evidence that the members of the UDV who take hoasca exhibit any compulsive reliance on their sacrament, do you?
A. I don't know. I haven't examined the UDV, and I am not aware of evidence -- I am not aware of the evidence or I wasn't specifically asked this question in looking at the UDV. And I am not aware of whether -- of what has happened to the UDV members. I just don't -- I just can't answer that.
Q. So you don't have any evidence of it? That would be fair to say, wouldn't it? You don't have any evidence, do you?
A. No, no, no. I would answer that question,

[7] Of course, the fact that an expert's opinion may be relevant to supporting an ultimate fact or a position does not mean that the opinion was sufficient to establish that fact or position.

1028

which is the question, which, again, being a scientist, no data doesn't mean there is no evidence. I have no data. So no data doesn't speak to whether there is a phenomenon there or not. I just don't know. I have no data to make that judgment.. . .

1039

Q. Now, peyote, that also contains one of the LSD-like hallucinogens, correct?
A. Yes.
Q. And in fact, in this chart, in Martin and Sloan, Defendants' Exhibit YYY, where you have the LSD-like drugs, you have mescaline as the first one in there, correct?
A. Yes.
Q. Now, have you made any effort to determine -- do you know what Phalaris grass is? Are you aware that there is something called Phalaris grass that contains DMT?
A. Yes. Only from reading. And I actually

1040

learned about that from reading on the Internet. The Internet describes Phalaris grass and some other commonly-available plants from which one could extract DMT and harmine.
Q. Syrian Rue, was that the other one?
A. Syrian Rue, yes.
Q. Syrian Rue being the one from which you can extract harmine?
A. Harmine, yes.
Q. And Phalaris grass from which you can extract DMT, correct?
A. Yes.
Q. And are you familiar with San Pedro Cactus?
A. No.
Q. Do you know or have you made any effort to determine whether Phalaris grass has a potential market?
A. No. Again, only from when you go to the sites on the Internet, and that is where it described it and gave recipes for making ayahuasca from Phalaris grass and Syrian Rue.

1042

A. Okay.
Q. You're right. You're not saying that the experience of someone taking LSD is the same as the experience of someone taking hoasca as a sacrament within the UDV, are you?
A. I don't have any basis for making that -- it's only a supposition from the basis assuming that dimethyltryptamine is an active drug and that they are experiencing dimethyltryptamine indirectly. But again, there has been no comparison/control studies which would provide data to precisely answer that question. There has been no comparison of LSD with ayahuasca.[8]

1046

Q. Now, you haven't written about hallucinogens except for one paper in the 1970s about LSD; is that correct?
A. Yes.
Q. And you haven't done any research on hallucinogens since the '70s; would that be correct?
A. I have done research on hallucinogenic drugs. In the context that hallucinogens -- there are a number of drugs that produce hallucinogenic effects. The subclass of these are the hallucinogens which are the ones which are, you know, classified as those which don't produce physical dependence, produce tolerance, produce very little autonomic effects, that sort of class which -- it's been done before. So what I have done -- so with the classic hallucinogens, no, not since what would be the late '60s or '70s.
Q. But Dr. Schuster has, hasn't he?
A. I think so.
Q. And I assume you would agree with what Dr. Schuster said, that is going to be written up in the NIDA research monograph from the symposium, where he says, and I quote, "In fact, the limited evidence

1047

that exists suggests that the classical

[8] Dr. Jasinski's failure to discuss this striking change in positions between his UDV testimony and his claim now that ayahuasca has the same effect as LSD-like DMT renders his opinion unreliable.

hallucinogens are aversive in animals and will serve as negative reinforcers. This is in accord with the observations of humans ingesting drugs such as mescaline, psilocybin, or the ayahuasca tea containing DMT and the beta-carbolines, who frequently show nausea, vomiting or diarrhea and rarely the type of euphoria associated with drugs of abuse." You would agree with him, would you not?

1050

Q. And when you were involved in studying hallucinogens, you gave LSD to these prisoners in a research environment for long periods of time, correct?
A. Yes.
Q. Up to 30, maybe 40 days in a row, correct?

1051

A. I can't remember how long we gave it to them. There were very -- whether -- I can't remember how long we gave it to them in the cross-tolerance experience.
Q. But you wouldn't be surprised if the article said 30 days, would you?
A. No.
Q. And in your opinion, they didn't suffer any harm as a result of that, correct?
A. No.
Q. And in fact --
MS. GOITEIN: I am going to object, Your Honor. This is going outside the scope. He is here as an expert on the abuse liability of the substance, not the medical effects of the substance. That was Dr. Genser.
MS. HOLLANDER: May I ask my last question, Your Honor?
Q. (By Ms. Hollander) And in fact, you would do it again, wouldn't you?
A. Yes.

1059

RECROSS-EXAMINATION
BY MS. HOLLANDER:
Q. Just as -- you understand that the use of hoasca by the UDV in Brazil is legal, correct?
A. Yes.

1060

Q. And the use of peyote in the Native American Church is legal, correct?
A. Yes.
Q. So by definition, then, they are not drugs of abuse when used, ayahuasca in Brazil or hoasca in Brazil and peyote in the United States in the Native American Church, correct?
A. Right.

Dr. Jasinski's proposed testimony is not relevant in supplying this court with evidence that tends to meet the defendants' burden of proof on their affirmative defense. Dr. Ghiselin summed up the main reason why Dr. Jasinski's testimony does not meet the "fit" criterion of *Daubert.*

> In his Witness Statement Donald R. Jasinski likewise treats the substance in question as if it were being evaluated for medicinal use. Such research is obviously an important goal of the medical research community, which aims to reduce the amount of risk that might occur from the use or abuse of a substance. At the outset it should be noted that the litigation does not concern whether the substance in question should be approved for therapeutic use. . .
>
> He categorizes dimethyltryptamine, one of the active ingredients in the ayahuasca tea, as an LSD-like hallucinogen. Because it falls under a class having some properties in common, he claims that one may extrapolate from the properties of one substance to those of another. But since minor differences in the structure of a molecule can have important consequences on its physiological and other effects, such extrapolation is itself of only limited value. He admits that dimethyltryptamine has not been adequately studied. . . .
>
> Dr. Jasinski goes on to argue that dimethyltryptamine can be, and indeed has been, abused. He characterizes DMT and other members of the class as having "pharmacological characteristics seen with drugs such as alcohol and opiates that lead to abuse, regardless of the lack of evidence of physiological dependence." But it is common knowledge that alcohol and opiates, and for that matter other alkaloids such as caffeine, are not necessarily abused by their users. And indeed he goes on to discuss all sorts of ways in which those who abuse the class of substances to which the active ingredients in the tea belong suffer ill effects. But describing the effects of abuse is irrelevant to the case, for there is no evidence that the substance in question is in fact abused by the Church.

Ghiselin at 4-5.

H. Dr. Frankenheim's Testimony Should be Excluded as Unreliable and Irrelevant to the Issues in this Case

Dr. Frankenheim states:

> "the complexity and variability of the human pharmacological responses to ayahuasca, and the variability inherent in predicting threshold dosages (acute and chronic) for undesired or toxic responses in humans all make it extremely difficult, and not presently possible, to predict a "safe" dosage for ayahuasca. Given that a psychosis-like, visionary effect (section **7.e.)** is sought by the user of ayahuasca, it must be questioned whether any dosage of ayahuasca is safe.

Frankenheim Statement at 3.

Frankenheim's statement applies to determining threshold doses for any toxin. Variability in concentration of the toxin in the delivery system, exposure (dose), human uptake, and transport within the body to organs are all common challenges. While this court might be interested intellectually in learning about the complexities of the entire subject of dose/response in toxic exposure, that is beside the point and irrelevant. Dr. Frankenheim's statement must be rejected as irrelevant.

He states that, "[a]fter extensive research, I am not aware of any scientifically-established benefits of the use of this drug." Frankenheim's use of the phrase "scientifically-established benefits" itself does not represent a reliable scientific statement. He does not describe what is meant by that phrase. Does he purport to be commenting on data from other peer-reviewed publications that there are no benefits to participating in the religious use of the sacrament? As Dr. Ghiselin notes below, it would appear that Frankenheim is offering a medical model opinion. This case is not about medical benefits. Again, as in the case of

many of the defendants' experts, Dr. Frankenheim's opinions are driven by a fallacious premise. The premise is that the religious use of the tea should be judged by the standards for placing a new pharmaceutical on the market. If this court were searching for guidance regarding potential medical benefits of using ayahuasca, then Dr. Frankenheim's research might be relevant to that inquiry; but it clearly does not fit the burden of proof defendants have in this case. The testimony should also be excluded as irrelevant.

Phrases such as "it must be questioned whether any dosage of ayahuasca is safe," are not relevant to this court's inquiry. First, questioning whether any dose is safe is a question a lay person may ask. It is not the scientists' inquiry. The question for the scientist would be whether there are sufficient data available to quantify risk. Secondly, as we keep noting, the issue for resolution is what dose of DMT taken in the form of the sacred tea is, to a medical/scientific probability, likely to cause significant ill health effects. Dr. Frankenheim does not endeavor to provide evidence on this, the relevant inquiry.

Frankenheim's categorical disagreement with his employers regarding the "non drug" use of mescaline when taken ceremonially by Native American Church members is worthy of mention. Frankenheim states:

> The ayahuasca sacrament is intended to be pharmacologically active (McKenna, et al., 1984; Pomilio, et al., 1999; McKenna, 2004; Gable, 2007). Thus, even in the context of religious, ritual, shamanic, or ceremonial use, ayahuasca must be considered to be a drug, even when used as a sacrament,

Id. at 4.

Frankenheim's statement is that, if the intended use of a Scheduled I substance is to produce a "pharmacologically active" state, it is a drug use; however, this conclusion is contrary to the DEA's reference to the "non drug" use of peyote by the members of the Native American Church. Of greater significance to the unreliability of his conclusions is that he

presents no evidence that the plaintiffs' use of the sacred tea is intended to produce a psychoactive reaction. Frankenheim offers no support for this illusory premise. We note that, although the witness is qualified to opine on the subject of drug policy, in this instance he is simply offering a personal opinion that was formed without engaging in intellectual rigor. "I call it a drug; therefore, it is a drug," is oblivious to all of the scientific evidence that indicates that the "set and setting" are the determinative factors. Frankenheim never acknowledges this guiding principle in drug policy.

Frankenheim states:

> Stored plant material, such as ayahuasca, is also subject to contamination with bacteria, fungi, and other environmental infestations, causing risk of infection, especially to users whose immune systems are weakened by old age, malnutrition, cancer chemotherapy, bone marrow transplantation, AIDS, and other disorders and procedures. These immunocompromised individuals are susceptible to infections that healthy immune systems usually conquer.

Id. at 9-10.

Any substance, controlled or not, is subject to contamination. Such undifferentiated fear of human beings becoming contaminated from exposure to any contaminated substance is testimony that, on its face, is not related to the issues in this case; it should, therefore, be stricken. There is no evidence that the tea has ever been contaminated. This is mere speculation and should be rejected.

Frankenheim states, further, that

> [t]he psychological effects of hallucinogens are unpredictable. They depend on the amount ingested and the user's personality, mood, expectations, and surroundings.

Id. at 10.

Indeed, the variables to which he points are very typical and are also known as

"confounding factors." However, he offers this categorical generalization to the conclusion that one cannot predict psychological effects. But only a few paragraphs before this, he very clearly describes the effects: "The classical hallucinogenic . . . produce[s] changes in thought, mood, and perception with little memory or intellectual impairment, and produce[s] little stupor, narcosis, or excessive stimulation, and produce[s] minimal autonomic side effects." His categorical generalization obfuscates rather than contributes to any greater scientific understanding of the issues in this case.

The evidence presented by plaintiffs and their experts establish that there are thousands and thousands of ceremonies where the tea has been served to the Church members. The religious leaders have observed the effects of the tea for almost a century and are in a unique position to observe the variations that occur, depending on the concentration of the tea. These Church elders have the personal experience and training over scores of years to have the kind of expertise that the Supreme Court has recognized in *Kumho Tire v. Carmichael*, 526 U.S. 137 (1999). There is no attempt by Frankenheim to explain why this information is not adequate to provide a degree of safety.

The Santo Daime has communicated many times to the government its desire to cooperate in undertaking studies. It would not be difficult to fashion studies that could include observing dose and the related effects.

Plaintiffs' experts emphasize the importance of the set and setting as a factor in the use of hallucinogenics. While Frankenheim may disagree with the importance of set and setting, when he refers to "surroundings," one would have expected him to make reference to this well-accepted phenomenon of "set and setting." In the religious set and setting of Daime, all of the experts have offered opinions that the ingestion of the tea causes no short- or long-term ill health effects. Frankenheim never mentions the Brazilian CONFEN report finding

that there are no ill health effects in the set and setting within which the teas are taken. The failure to discuss these data renders his opinion unscientific.

Frankenheim goes on:

> The nonlinear kinetics of DMT elimination (discussed in section **11.a.iii)** and the persistence of MAO inhibition after ayahuasca ingestion (Riba, et al., 2003) make the effects of large or quickly-repeated ("stacked") ayahuasca dosages especially unpredictable, in the direction of greater-than-expected effects.

Frankenheim Statement at 10.

This hypothetical bears no relationship to ingestion of the tea at Santo Daime ceremonies. Frankenheim does not discuss the purgative effects of the tea, preventing the body from retaining large doses. And he fails to mention that the tea is not served in "quickly repeated" or in "large" doses. The evidence clearly establishes that the tea is served every two hours during the liturgy of the Santo Daime. Again, we see a failure to discuss data. Frankenheim's testimony presents a classic example of data selectivity.

His testimony also includes the following:

> Risk of accidental injury and death. Fatal accidents have occurred during LSD use. This is a potential problem with the use of any psychoactive substance, especially one that causes cognitive and perceptual changes, pseudohallucinations and hallucinations, and may alter judgment. Based on what is known about other hallucinogenic drugs, the potential for accidental injury and death does exist for users of ayahuasca.

Id. at 11.

The opinion that "the potential for accidental injury and death does exist for users of ayahuasca," of course, applies to every prescription and over-the-counter drug as well. "The potential for accidental injury and death does exist for" every chemical. Again, we note an obvious scientific truth that is completely irrelevant to the issues in this case. The above opinion regarding the Daime and *hoasca* tea is without any value in assisting this court in

assessing the likelihood of a person being harmed as a result of taking the tea in the controlled environment of the Church services.

To the extent that plaintiffs' hypothesis is that the tea taken in the ritual setting is safe, this expert presents no information to disprove that. To the extent that the defendants claim the tea is dangerous, there is no empirical evidence to support that hypothesis; moreover, it has been tested in studies by Grob, Halpern, and by the Brazilian government, as well as anecdotally for a hundred years. Frankenheim must be rejected both on grounds of reliability and fit.

> Persistent psychoses. Post-LSD psychoses are unpredictable, and sometimes follow a single dose, but are more common in people with prior psychopathology. Post-LSD psychoses resemble schizoaffective disorders, and are frequently accompanied by visual disturbances (Abraham, et al., 1996). The extent of this problem with the other hallucinogens is not known. Thus, individuals with previous and current psychiatric diagnoses and/or family histories that suggest vulnerability to development of mental disorders, particularly those characterized by psychosis, are at risk for adverse psychiatric consequences from the use of hallucinogens including ayahuasca.

Id. at 11.

First, Frankenheim acknowledges here that "post-LSD psychoses are unpredictable" and then states that "[t]he extent of this problem with the other hallucinogens is not known." Frankenheim is acknowledging that there is no scientific evidence of any persistent psychosis as a result of taking the Daime tea. Therefore, his opinion in this regard does not fit and should be stricken as both irrelevant and as unscientific speculation.

> [T]he term flashback has been supplanted by HPPD [hallucinogen persisting perception disorder]. . . Though there are no data documenting the presence or absence of these persistent psychophysical changes related to the use of ayahuasca, this is likely due to the relative lack of knowledge regarding ayahuasca, compared to the knowledge about LSD.

Id. at 11-12.

This statement is likewise unhelpful as it suggests that an unknown is compounded by another unknown. In neither instance is there any attempt to offer data in support of the hypothesis. The statement is of no value in assessing whether the government has a compelling interest in banning the tea and should be stricken as irrelevant.

> One such study (Halpern, et al., 2008) found 19 of the 32 study subjects met lifetime criteria for a psychiatric disorder, and 24 of the 32 subjects had drug or alcohol abuse or dependence histories. The possibility that people with psychiatric and drug use disorders may seek to use ayahuasca, even within a church setting, is a concern because, as detailed in this report, these populations are particularly vulnerable to many of the risks of ayahuasca use.

Id. at 13.

Frankenheim here speculates that there is a "concern" that members who had previous bouts with drugs and alcohol are more vulnerable to the risks of *ayahuasca*. First, the Halpern article goes on to note that most of these people had resolved their drug and psychiatric problems after joining the Church. Frankenheim omits these data. He then adds the gratuitous comment that they are "particularly vulnerable to many of the risks of ayahuasca use." He does not identify to which risks this so-called vulnerable population is subjected. Rather, he injects the conclusion that there are "many risks" as though it were an established fact, rather than the ultimate opinion or conclusion that Frankenheim attempts to make it in his statement. It is another classic *ipse dixit* and outside of the *Daubert* standards of reliability.

> Some ayahuasca-church members did not volunteer for the Halpern study (Halpern, et al., 2008), so the sample of volunteers may be skewed towards church members who are in better health than the non-volunteers. The Halpern study (Halpern, et al., 2008) also did not survey the much larger number (110, according to the study) of potential subjects who had left this church.

Id. at 13-14.

Here, Frankenheim falls into one of the classic failures in the scientific method. He only

discusses what was not done in the study rather than what *was* done.

Frankenheim continues down his irrelevant path with the following:

> Though this study found "no evidence of personality or cognitive deterioration," and "high functional status," it also found that their matched control subjects (with no prior history of ayahuasca ingestion) had "significantly higher yearly incomes than" the ayahuasca users, possibly indicating subtle deficits related to ayahuasca use, though this disparity may have been due to an artifact caused by the methods the researchers used to recruit the control subjects.

Id. at 14.

The best available data are found in the studies of Grob and Halpern. Regarding Grob, rather than discussing the data in any depth, Frankenheim discounts its considerable significance (having no data to dispute either Grob or Halpern) by suggesting that the positive results may be "possibly indicating subtle deficits. . ." This rather remarkable addition of pure speculation is unreliable on its face.

Frankenheim here engages in what Dr. Ghiselin refers to as the fallacy of irrelevant conclusion:

> Non-compliance with established medical therapies. The Halpern et al. (2008) study of ayahuasca-church members found a history of psychiatric and substance use disorders. It is a concern that ayahuasca users with psychiatric and substance use disorders may choose to forego conventional, established medical therapies.

Id. at 19.

The title of the section itself "[n]on-compliance with established medical therapies" suggests that for those people who may choose not to adopt traditional western therapies, they are in "non-compliance" with some universal principle or standard. That argument would apply to any of the non-western medical treatments, such as Chinese herbs, acupuncture, acupressure, etc. While we may disagree on the best medical model to treat certain illness, there is nothing that Frankenheim offers to support his views. The statement is irrelevant to the

issues in this religious freedom case.

Frankenheim commits the ultimate *Daubert* failure to engage in "intellectual rigor" by failing to discuss these data and attempting to explain why the existing data do not tend to negate the government's compelling interest argument. This failure to engage in any scientific debate renders this testimony unreliable. Even if there was such a debate, the opinion is irrelevant to the issues in this case and should be stricken under the "fit" prong because it does not tend to provide any evidence to support the burden of proof defendants must meet.

Frankenheim:

> Conclusions about the pharmacology and toxicology of ayahuasca. The sacramental use of ayahuasca results in pharmacological effects from the ayahuasca, and can result in toxicological effects.

Id. at 20.

Finally, to report that taking the tea "can result in toxicological effects" is not supported in his statement with any data. Even if one accepted as fact that it "can result in toxicological effects," Frankenheim makes no attempt to discuss under what circumstances the sacramental ingestion of the tea would likely result in a toxic reaction. Again, the possibility that there are circumstances under which the tea could be toxic does not fit the burden of proof that defendants must establish and, thus, this statement should also be stricken.

Frankenheim:

> There remain many gaps in our knowledge of the consequences of ayahuasca use. No benefits of the use of this drug are scientifically established, while many risks, some severe, are substantiated or are reasonably predicted. These risks include persistent psychosis and **HPPD,** the central serotonin syndrome and other interactions involving MAO inhibition, *in utero* effects, accidents, and more.

Id. at 20.

There is a risk in taking any chemical. This witness provides no evidence at what dose

a significant risk may occur. We note that the Supreme Court, in rejecting this same testimony in the UDV case, compared the experts' claims of health risks to the use of peyote and did not find that the health risks of *hoasca* were greater than from ingestion of sacramental peyote.

Frankenheim:

> Dr. Cozzi entitles the third section of his declaration, starting on page 2, "Is daime toxic?" Posing the question in this way oversimplifies the issues at hand. It is only to be expected that there are "no reports in the medical literature of overt toxicity resulting [from] Daime use," because it would be extremely difficult and arduous to systematically examine such a complex and variable collection of chemicals, with differing actions, and synergistic interactions, that constitutes ayahuasca (please see sections **6., 8.,** and **9**.)

Id. at 22.

Frankenheim argues that Dr Cozzi oversimplifies the issues. This is not a challenge to the admissibility of Dr. Cozzi's report, but at best would go to the weight to be given to his findings if, that is, the oversimplification claim had any scientific merit. It is based upon Frankenheim reciting how difficult it would be to conduct an epidemiological study because of many confounding factors regarding the consumption of the tea. The confounding facts in this instance are no greater then those that exist in virtually every epidemiological study involving the cause and effect relationships of human exposure to toxins. In fact, there are only two chemicals in the tea; thus, Frankenheim's concern that it would be "arduous" to examine the chemicals is not even accurate. Determining the chemical components of "soups"[9] and isolating which component causes certain illnesses is a very typical scientific endeavor. Frankenheim is inventive in his given excuse as to why the tea has not been studied. The testimony is irrelevant to any of the issues in this case and should be excluded.

We refer this court to the Rebuttal Witness Statement of Dr. Cozzi, further pointing out

[9] A "soup" is a liquid mixture that may contain a variety of molecules or chemicals, including those not easily identifiable.

the unreliability of Dr. Frankenheim's testimony.

I. Dr. Dawson's Testimony is Unreliable and Irrelevant

Dr. Dawson testified in the UDV case about the same matters he testified to in this case. His testimony should be stricken under principles of estoppel.

Dr. Dawson opines on a number of subjects, some of which he is qualified to address, such as religions, and others on which he is not, such as medical/pharmacological matters.

> First, with the information available, and in light of important issues raised by the sociology of new religious movements, what reliable conclusions can be drawn about the nature of the Plaintiffs' religious practices?

Dawson at 3.

Dr. Dawson has the qualifications to opine on religious matters under *Daubert.* Dr. Dawson correctly describes the Santo Daime religion as a *bona fide* religion, thereby disagreeing with his employer's (DOJ's) claim that defendants do not have enough evidence to state whether the Santo Daime is a religion.

Dawson described the UDV in his testimony and states that the UDV ceremonies "are more controlled" than those of the Santo Daime. *Id.* at 7. But then goes on to admit that "[n]ot much is known about União do Vegetal."

Not having described what he means by "controlled" and not stating in what way the control differs, this statement must be excluded as unreliable. There are no data to support his conclusions. It is clear that Dawson is speculating here.

> Second, with the information available, what reliable conclusions may be reached about the nature and safety of the religious use of ayahuasca (i.e., Daime) in the Santo Daime religion, particularly as practiced by Plaintiffs?

Id. at 3.

Dr. Dawson has absolutely no educational or professional qualifications to act as an expert

witness on any matters relating to health or safety issues implicated in the taking of the Daime tea. All of his testimony regarding these issues should be excluded.

> In light of the cumulative impact of the substantive and methodological limitations detected in the existing social scientific research the attempt to make positive and reliable conclusions about the practices of The Church of the Holy Light of the Queen and the safety of the religious use of Daime (or ayahuasca in general) is premature.

Id. at 8.

The statement has no scientific or technical meaning. The phrase "positive conclusions" is not defined so as to enable this court to attach any value to it and it, therefore, should be excluded as unreliable. It is also contrary to the previous description of the religion given by Dawson. Dawson's conclusion that "existing social scientific research" makes reliable conclusions "premature" suggests that, with further study, more might be known. However, he does not identify what is not known about the religion and, more importantly, how that information might be of assistance to this court in rendering a decision in this case. The testimony is irrelevant to the "compelling interest" burden of proof. Finally, Dawson's unscientific methodological requirements would require Dawson to say that about all religions.

Dawson's paragraphs 17-19 are admittedly speculation without citation to journal articles or other data and should be stricken as unreliable.

> Methodologically, I cannot confirm the positive conclusions reached in the [plaintiffs' expert] declarations.

Id. at 10.

As we noted above, Dawson should not be permitted to provide this court with medical and pharmacological evidence. Secondly, his statement is irrelevant. Dawson's inability to "confirm" Dr. Halpern's findings is of no moment in this court's evaluation of the evidence. Further, Dawson is not an epidemiologist and his curriculum vitae does not reveal any studies that would give him

practical experience (although there may be some that are not obvious by their titles.) His failure to understand health studies becomes obvious when one examines his specific complaints. *Id.* at 10-16. He seems to believe that the study was an epidemiological study with control groups. Halpern defines what his study is and is not. Dawson lacks qualifications even to discuss Halpern's explication of what the study is and is not. For Dawson to comply with the requirements of *Daubert*, he would have had to have discussed what the Halpern study does. The Halpern study indicates that people who have taken the tea for extended times fare as well or better than the nation's control group. Dawson offers no data to contradict Halpern's findings. Dawson's critique of Halpern, Grob, Winkelman, Cozzi, and Gerding are the opinions of a layman and do not meet both qualification and reliability standards mandated by *Daubert.*

Dawson:

> Most new religions are committed to a policy of some secrecy, which can pose a significant challenge to those seeking, as outsiders, to study them.

Id. at 16.

This statement on its face is a gross generalization that also applies to many ancient religions and is useless to this court. This statement is so speculative that it calls into question the reliability of every other statement that this "expert" offers.

> It is not credible to assume that information acquired about the Uniao do Vegetal and Santo Daime in the cultural and social context of Brazil, especially in Amanzonas, is applicable without qualification to the lives of members of Plaintiff organizations in the United States.

Dawson at 18.

Dawson never tells us what he means by "without qualification." That itself renders the opinion unreliable as he fails to advise what is missing and what relationship the unmentioned qualifications might have to this court's analysis of the issues. This criticism is methodologically flawed and should be excluded. Furthermore, it is irrelevant to any issue that the defendants have

the burden of proof to establish. Neither does it rebut any of the plaintiffs' *prima facie* case and thus does not "fit."

> The loose organizational structure, orientation to charismatic leadership, and schismatic origins of CEFLURIS make it difficult to determine how the religion is developing, and will develop in the future, in the United States.

Id. at 19.

This statement has no bearing on any issue in this litigation and should be excluded. Jesus Christ, Buddha, Guru Maraji, Gandhi, Abraham, and scores of other religious or spiritual charismatic leaders have inspired the world. At any given moment in time, only a soothsayer might opine on the future practices of any religion. *Daubert* does not recognize the art of soothsaying as reliable science.

Dawson's tedious discussion of charismatic leaders, his discussion of the "cult of personality," his comparisons to the UDV, etc. are all irrelevant. *Id.* at 20-27. The entire testimony is not worth parsing. This testimony is junk science.

Dawson's discussion of Mary Row is replete with irrelevant observations about her lack of knowledge of certain mythologies about the origin of the Church, which evidently surprises Dawson. *Id.* at 29-32. He contradicts himself because earlier he noted the secrecy that generally surround new religious movements. "Most new religions are committed to a policy of some secrecy." This testimony is also irrelevant.

Dr. Dawson spent 12 pages offering unsound criticism of the Grob and Halpern studies. Dawson already criticized Grob when he testified in the UDV case. We will not parse each of Dawson's statements here. We urge that he is not qualified to discuss these medical/pharmacological/scientific studies and should be estopped, in any event, from commenting again about Grob.

Plaintiffs could parse sentence after sentence in the Dawson testimony and analyze its many deficiencies for another twenty pages. Plaintiffs respectfully urge that virtually every paragraph in

the Dawson proposed testimony is either irrelevant to any existing issues, speculative, or based upon extrapolation from generalities to the Santo Daime without their being any factual predicate for such extrapolation.

Finally, below we cite from Dr. Dawson's testimony in the UDV case, which establishes his lack of qualifications or knowledge of the two religions. It should be noted that Dawson's two reports, in the UDV and this case, were generated solely for the purposes of litigation and did not flow from any research on the South American religions or use of *ayahuasca*. *O Centro,* Hearing on Preliminary Injunction, October 25, 2001.

CROSS-EXAMINATION
BY MS. HOLLANDER

Page 768

Q. You don't serve as a reviewer on medical journals, though, do you?
A. No, I don't.
Q. And you're not a doctor, are you?
A. No.
Q. And you are not a psychiatrist?
A. No.
Q. And you certainly wouldn't have been qualified to be a reviewer for the Journal of Nervous and Mental Disease, would you?
A. No.
Q. And before they published the article, "Human Psychopharmacology of Hoasca: Plant Hallucinogen Used in Ritual Context in Brazil," they wouldn't have asked for your opinion, would they?
A. It's not likely --
Q. Yeah.
A. -- because of the disciplinary boundaries.
Q. That's right. They would ask for the opinion of a psychiatrist or a medical doctor, correct?
A. Yes.
Q. And even as a student of religion, as I assume you describe yourself, as someone who studies

769

religion, you primarily study the religions in North America, the majority religions and what you have described as cults, correct?
A. Correct.
Q. You have never studied Brazilian religions, have you?
A. No, I haven't.
Q. And so you don't know, and until this case, you said you had never even heard of the UDV?
A. Yes, that is correct.
Q. And you have never attended a single session, have you?
A. No, I haven't.
Q. You have never talked to a single member, have you?
A. No, I haven't.
Q. You have never ingested hoasca, have you?
A. No, I haven't.
Q. And you are not familiar with any of the other religions in Brazil that use sacramental plants, either, are you?
A. No, not directly. I mean I have read the article about religions in Brazil that probably mentioned them, but just out of reading.
Q. This was an article you read on the

770

Internet, wasn't it?
A. No, no. I mean in the past I have read things.
Q. But you are not familiar with the Santo Daime, are you?
A. No, I am not.
Q. And you are not familiar with the Barquinha Religion, are you?
A. No, I am not.
Q. You have never even heard of that, have you?
A. No.
Q. And you don't really know anything about the religious practices of people in general in Brazil, do you?
A. Well, as I said, I do, yes, in parts because in the field, it's absolutely essential to know something about what is happening in Brazil, as it's a primary focus of religious change in terms of --

Q. But you haven't studied the religions an you are not familiar with the ones I mentioned, correct?
A. No.

774

Q. Now, you have never -- have you ever before been asked to critique a psychiatric or medical study?
A. No.
Q. So this is the first time?

785

Q. You don't question the accuracy of Dr. Grob's statements discussing the details of physiological tolerance of hoasca in healthy individuals, do you?
A. No.
Q. You don't question the accuracy of Dr. Grob's statements discussing the low potential for adverse drug interactions, do you?
A. No.
Q. You don't question the accuracy of Dr. Grob's statements discussing the chemical and botanical composition of hoasca, do you?
A. No.
Q. You don't question the accuracy of Dr. Grob's statements discussing the UDV's minimization of risk for participants, do you?
A. Well, that, again, can fall under the same consideration because he -- I guess it's based on two things. I would have to go to the text. I mean I assume it is based on what they tell him they do. So this raises the same issue. And it may -- but I can't remember him specifying that in the article –

786

Q. And you wouldn't question his accuracy to report his own observations, would you?
A. No.
Q. And you wouldn't question the accuracy of his statements discussing the lack of signs of addiction with hoasca, would you? You don't have any --
A. Well, it depends. I mean, obviously not on a physiological basis

799

Also, thirdly I would say that you have the element of the dominant religious practices within Brazil overwhelmingly are Catholicism or Protestant Pentecostals. Knowing both of those traditions, I know that they would definitely look askance at both the esoteric teachings and the sacrament of this religion.[10]

Finally, Dawson admits:

801

Q. (By Ms. Hollander) You don't have any evidence, do you, to a reasonable degree of scientific certainty, that hoasca is damaging to the health when used within the context of the UDV, correct?

A. No. I have no evidence that it definitely has been shown to be damaging, no.

J. Portions of Dr. Glass' Testimony Are not Reliable and Portions are Irrelevant

Dr. Glass is qualified to give his expert opinion in this case, but some of his opinions are not derived from the scientific method and some are simply irrelevant.

At paragraph 28, Dr. Glass takes only a portion of Plaintiff Goldman's testimony to establish that, if someone is taking a drug on the contra-indicated drug list, they are not automatically disqualified. Dr. Glass fails to mention that Mr. Goldman indicated that, in the two instances he could remember, there was a referral to their medical doctor. Goldman Dep. at 46-48. This testimony fails to account for all of the data in the Goldman deposition and is thus unreliable. Had Dr. Glass discussed Goldman's explanation of how he handles the screening and criticized it, then the opinion would have been reliable, but he did not go on to mention Goldman's additional explanation. This type of selectivity in choosing data is a

[10] MacRae points out that the Santo Daime is well received and respected by the Catholic Church in Brazil.

failure to apply intellectual rigor.

Dr. Glass seems to believe that the screening process done by the Church is akin to a medical facility taking medical histories. It is not that, and it is not intended to be more than a vehicle for informing people of possible interactions with the tea. Dr. Glass, a physician, should know that it would be an unsound practice for a lay person to be discussing a medical case with someone's private physician. In paragraph 71, he "accuses" the interviewers of not having consulted with the person's medical doctor. That would not be appropriate without there being an actual physician/patient relationship. As noted in the plaintiffs' depositions, the prospective members may be advised to consult with their doctors. Dr. Glass' opinion is based upon a false underlying premise that the Church is acting as a medical facility. He extrapolates the standards a medical doctor might be required to follow when discovering a medical problem to the interview process undertaken by the Church. His testimony in this regard is irrelevant to this lawsuit and should be rejected.

In paragraph 31, Dr. Glass "suggests" that the two doctors who are members of the Church "may be biased." This is his lay opinion and should be rejected as unscientific. What Dr. Glass also fails to do is to take into account that these physicians who have participated in the ceremonies for a long time are in a better position then he is to evaluate the health effects. Dr. Glass' failure even to consider this evidence and discuss it renders his report deficient in intellectual rigor.

In paragraph 35, Dr. Glass suggests that, because the guardians consume the Daime tea, they are being irresponsible because, as he puts it, "they are under the influence." Again, he fails to consider that they are generally elders in the Church who have a great deal of experience with the tea. He also fails to account for the fact that there have never been emergencies or situations that could not be handled by the guardians. He can only consider

one possibility and does not discuss others rendering that opinion methodologically unsound.

In paragraph 36, he refers to the Daime tea as "a tea with significant adverse physiological and psychological effect" without any data to support this claim. This is *ipse dixit* and should be rejected. He notes that, because the tea is so dangerous, non-medical people should not administer it. Dr. Glass again operates on a false premise -- that this is a medical society. He does not take into account that thousands upon thousands of people have taken this tea and the *hoasca* tea and that those who administer it know what they are doing, as the plaintiffs' experts and plaintiffs have established and as the Brazilian CONFEN report has established. Again, Glass fails to discuss the relationship between the safety of the sacrament and the fact that there have never been any reported health problems associated with the tea when taken as a sacrament. The obvious bias in reporting the data infects the entire report.

In paragraph 38, Dr. Glass engages in unprofessional speculation about the people who join this Church and denigrates the positive changes in their lives that result. He calls them unhappy, vulnerable, fragile, and lost. These are lay opinions unsupported by any reference to medical or psychiatric text for support. Dr. Glass presents no data to compare these people to those who join any church. That some percentage of the Santo Daime Church members may have been seeking to improve their lives by joining the Church is twisted by Dr. Glass. He comes to sweeping conclusions about all of the members of the Church from "bits of life stories of many" of the people who filled out the application forms. He gives no specific reference to examples, and he does not tell us how "many" he reviewed. Dr. Glass' sweeping generalizations about the Church members is contrary to all of the actual evidence that appears in the Halpern, Grob, and CONFEN studies. Glass' testimony should be stricken because he fails to account for the empirical evidence of improved lives and levels gratuitous deprecating criticism of the plaintiffs.

Glass refers to the tea as taking a shortcut, but never reveals what would be the better route for people to improve their lives than participating in a community of Christians who live the work of their God. "People like this are particularly vulnerable to, and a set up for anybody who would offer them some type of hope and a way to improve their own situation, particularly with an easy and almost magical solution." Glass at 15. Dr. Glass does not define what he means by magical solutions. Is this scientist claiming that the Daime tea is some "magic" potion? This sort of commentary does not fit within any expanded concept of "science" and should be rejected. This statement also has no bearing on the defendants' claim that taking the tea in a religious setting is to a medical probability likely to cause ill health effects.

Paragraph 39 is particularly lacking in intellectual rigor. Despite all of the empirical data to the contrary, Glass refers to the Santo Daime religion as a "maladaptive solution that got them into difficult drug use." This sort of personal opinion is unsupported by any data and should be rejected outright.

Finally, it must be said that the intellectually bereft language that pervades this testimony reveals deep-seated bias. Making the analogy to the book "Electric Kool Aid Acid Test"[11] would not pass peer review. It should also be noted that, although this gentleman can opine on data that suggest to him that there may be dangers associated with taking the tea, his gratuitous disrespectful rhetoric renders the testimony unfit to pass the high standards that the Supreme Court demanded in *Daubert* of federal judges when deciding what testimony to admit in their courtrooms.

In Paragraph 40, Dr. Glass gives his concluding opinion that taking the tea "in a

[11] Glass incorrectly attributes the book to Ken Kesey. The book was written by Tom Wolfe.

religious ceremony is a dangerous procedure." First, a religious ceremony does not involve a "procedure." Using that term again suggests a fallacious underlying premise upon which Dr. Glass has based his methodology -- the medical model.

Dr. Glass' concern is that lost souls with a history of past drug abuse are somehow going to suffer somehow under undefined conditions. Again, his failure to consider and discuss the empirical data renders his exercise without intellectual rigor. One could imagine an intellectually rigorous report acknowledging that this is a religion that is accepted as *bona fide* in Brazil, that the CONFEN report suggested that the harm from actual use was not evident from the Brazilian government's study, that the studies of Halpern and Grob do not reveal ill health effects of the Church members, and then offer data to rebut this empirical evidence. Instead, Dr. Glass used unhelpful rhetoric attacking the character of Church members. This sort of rhetoric has no place in an expert's report under *Daubert.*

K. Dr. Thomas R. Kosten, M.D.

First, we note that Dr. Kosten is a psychiatrist who is generally qualified to opine on the subjects under review. He apparently was not provided with a copy of the Brazilian Governments' CONFEN report and was thus without the benefit of important empirical data that was available to him. His report is, therefore, on the face of it, not objective because of the selectivity of data. In this regard, we are not faulting Dr. Kosten but, rather, pointing out the limitations of his report.

The Summary of Conclusions itself warrants the striking of the report. First, Dr. Kosten does not advise us what "vulnerable populations" has to do with the defendants' burden of proof. Next, he jumps to the conclusion that it is a failure on the part of the plaintiffs not to have a "comprehensive screening to prevent" certain people from participating in ceremonies,

but he fails to take into account that there have been no adverse effects as a result of the existing screening process. Dr. Kosten failed to engage in rigorous research, which would have revealed that the UDV and Native American Church communities using Schedule 1 hallucinogens have not reported ill health effects even though they include members of vulnerable sub-populations.

He claims that the *ayahuasca* "reverses the effects of medications used to treat major psychiatric disorders," but he does not define what he means by "reverses the effects of medications." He seems to be referring to the different responses to the chemicals in the brain. What relationship that has to defendant's burden of proof is not apparent. There is no evidence in this case that 1) anyone ever took the tea while taking one of the "drugs" that Dr. Kosten is referring to, and 2) there is no evidence that anyone ever stopped taking needed prescription drugs without a medical consultation before engaging in the sacrament.

Next, he claims that the tea is unsafe because the process to produce it is not standardized. The very opposite is true, as noted in the plaintiffs' and their experts' declarations as well as other exhibits on file. For almost one hundred years Santo Daime Church elders have been brewing the tea in carefully supervised ceremonies, as is evident in the exhibits. Kosten fails to discuss the expertise of these Church members or why their years of practical experience is somehow not adequate for the purposes for which the tea is brewed. Again, we see the expert looking through the wrong lens -- the medical model -- which requires standardizing the contents of prescription drugs.

Kosten argues that individual sensitivities can result in "substantial toxicity due to overdosing." While this <u>may</u> be a possibility, this fear has no basis in reality. All of the evidence to date shows that one cannot consume a toxic dose and that no report has ever revealed any toxic effect. Dr. Kosten fails to discuss any negative probabilities associated with

taking the tea in the context of the Santo Daime ceremonies. Kosten conjures up all kinds of possibilities that are unrelated to the empirical evidence available to him.

Kosten discusses what can happen if a person with a mental illness is on a certain anti-depressant drug and takes Daime, but this has never happened. No one is permitted to take Daime until they have stopped the anti-depressant, which only occurs when their own physician believes it is the correct thing to do. This is an example of the fallacy of the irrelevant conclusion. The dire consequences discussed here have nothing to do with the Santo Daime.

All of the dangerous interactions that Kosten mentions in paragraph 18 can occur with a multitude of over-the-counter and prescription drugs and thus provides no scientific evidence that there is a "compelling" reason to ban the tea. The testimony is simply not relevant.

Dr. Kosten's protocol, at page 19, for screening people for medical disasters that he is concerned with is extensive, but not necessary or appropriate in the context of the arguable Santo Daime responsibility to advise people of a possible drug interaction. Paragraph 19, if it were an important activity to be undertaken to protect people who might desire to take the tea, would obviously apply equally to taking the *hoasca* tea by members of the UDV and to screen the 250,000 Native Americans who consume peyote. Dr. Kosten's failure to address the public health consequences of this requirement for 250,000 Native Americans, but stressing it for 100 Daime members does not suggest intellectual rigor on his part.

In paragraph 22, Dr Kosten notes the difficulty of the medical profession in determining how many people will suffer persistent abnormalities after taking hallucinogenics. This statement is simply wrong. There are many studies he could have cited that do track this information. One of them, Dr. Halpern's peyote study, is not discussed. Dr. Kosten makes no attempt to quantify the risk of persistent disorders after use. Dr. Halpern's peyote study

suggests there is none. *See* Halpern Report. The point seems to be that there are no data suggesting that there is a likelihood to a medical probability that Church members will suffer persistent abnormalities; therefore, the testimony is irrelevant.

In paragraphs 23 and 24, Dr. Kosten voices concerns about the variation in concentration and in individual response to the tea. These are the same concerns expressed by the other experts but, again, the failure to discuss the data regarding the brewing of the tea and the knowledge of the concentrations renders the testimony unreliable. These experts cannot simply disregard the empirical evidence gathered for nearly one hundred years and fail even to discuss it.

Dr. Kosten theorizes that the half-life of the tea will differ in individuals and that the person who has been taking the tea for some time and administering it may have a shorter half-life of digesting the tea. This hypothetical bears no relationship to the actual practices as demonstrated. The evidence is that the tea generally is given at two-hour intervals. But, even if a particular person digests the tea more slowly, there are no data to support Kosten's hypothesis that that difference would actually result in people being given a dose that was somehow dangerous or toxic. He provides absolutely no data regarding the amount of tea it would take to produce such a reaction, and these possibilities have nothing to do with the actual practices of the Santo Daime Church in administering the tea.

On page 13, "b," Kosten's presumption that the brew masters who are more used to the tea will serve more than they should is sheer speculation and cannot be received into evidence under *Daubert.*

Most of the rest of the Kosten report attempts to refute Halpern and Cozzi. We do not challenge those arguments under *Daubert,* but do contend that the statements reviewed above should be excluded.

IV. CONCLUSION

The defense experts proposed testimony, for the most part, and relative to the ultimate issues in this case, are not reliable and do not tend to prove the facts that defendants have the burden of proof to establish as part of their affirmative defense that they have a "compelling interest" in criminalizing the sacramental use of Santo Daime tea.

Respectfully submitted,

/S/ Roy S. Haber

Roy S. Haber, OSB No. 800501
haberpc@cyber-dyne.com
ROY S. HABER P.C.
570 East 40th Avenue
Eugene, OR 97405
Telephone: 541.485.6418
FAX: 541.434.6360

/S/ Don H. Marmaduke

Don H. Marmaduke, OSB No. 53072
don.marmaduke@tonkon.com
TONKON TORP LLP
1600 Pioneer Tower
888 SW Fifth Avenue
Portland, OR 97204-2099
Direct Dial: 503.802.2003
Direct FAX: 503.972.3703

Gilbert Paul Carrasco, California Bar No. 90838
(Appearing pro hac vice)
carrasco@willamette.edu
No. 451
245 Winter Street SE
Salem, OR 97301

Telephone: 503.370.6432
FAX: 503.370.6375

Jack Silver, California Bar No. 160575
warrioreco@yahoo.com
(Appearing pro hac vice)
PO Box 5469
Santa Rosa, CA 95402-5469
Telephone: 707.528.8175
FAX: 707.528.8675