EDITED SUBMISSIONS RECEIVED IN RESPONSE TO THE NOTICE INVITING FURTHER SUBMISSIONS IN RELATION TO DELEGATES' INTERIM DECISIONS ON RECOMMENDATIONS FROM THE:

Advisory Committee on Chemicals Scheduling – 18 October 2011 (ACCS#3);
and
Advisory Committee on Medicines Scheduling – 19 October 2011 (ACMS#4).

Regulation 42ZCZQ, Therapeutic Goods Regulations 1990 (the Regulations)

A delegate of the Secretary of the Department of Health and Ageing publishes herein all public submissions made in response to the invitation contained in the December 2011 Reasons for delegate's interim decisions (accessible at www.tga.gov.au/industry/scheduling-decisions-interim.htm).

The call for further submissions (as required under subsection 42ZCZP of the Regulations), invited comments on the delegates' interim decisions from the applicant and parties who made a valid submission in response to the original invitation for submissions (published on 10 August 2011 at www.tga.gov.au/newsroom/consult-scheduling-acmcs.htm).

In accordance with the requirements of subsection 42ZCZQ of the Regulations these further submissions have been edited to remove information that a delegate considers to be confidential.

As advised in the notice inviting public submissions, it was up to the person making the submission to highlight any information they request be considered as confidential. Material claimed to be commercial-in-confidence was then considered against the guidelines for the use and release of confidential information set out in Chapter 6 of the Scheduling Policy Framework (SPF), issued by the National Coordinating Committee on Therapeutic Goods i.e. a request for material to be confidential did not automatically classify that material as confidential. The SPF is accessible at www.tga.gov.au/industry/scheduling-spf.htm.

Discrete submissions are grouped by item. However, where submissions relate to multiple items, these are separately grouped.

LIST OF SUBMISSIONS

1. SUBMISSIONS ON INTERIM DECISIONS ARISING FROM RECOMMENDATIONS BY ACCS#3

Nil

2. SUBMISSIONS ON INTERIM DECISIONS ARISING FROM RECOMMENDATIONS BY ACMS#4

Item	Number of submissions
2.2.6 Synthetic Cannabinoids	2
2.2.7 Piper methysticum (kava)	1

Submission to
The Scheduling Expert Advisory Committee

SUBMISSION IN RESPONSE TO:
REASONS FOR DELEGATES' INTERIM DECISIONS, DECEMBER 2011

13 January 2012

SUBMISSION IN RESPONSE TO:
REASONS FOR DELEGATES' INTERIM DECISIONS, DECEMBER 2011

Illicit drug use in Australia is escalating by all accounts – both official and non-official. In front of educated and intelligent members of a Committee such as this, there is no need to recall and recount these figures. Every record-breaking drug bust that is reported in the media only serves to remind us of the record amount of drugs being manufactured or imported that are *not* being seized.

It is an unwinnable war being waged by politicians and bureaucrats that must be as depressing for them as it is for the people caught up in the trenches. The Canberra Times cartoonist, Geoff Pryor, said it better than any words can describe in this satirical look at the Howard government's policies on drug prevention.

In the face of what we all know to be true, we urge this Committee to consider a different approach to the regulation of synthetic cannabinoids and not go down the same old disastrous route of prohibition that has been the standard response to recreational drugs in Australia for the last 50 years. You don't have to be Einstein to see that there is more illicit drug use in Australia now than there ever has been and that prohibition demonstrably does not work to minimise drug use or to make it safer for the community.

Synthetic cannabinoids offer governments and regulators the best chance in decades of developing an alternative regulatory model for illicit drugs because they are:

1) Significantly less harmful to the user than most other illicit drugs and certainly less harmful than the legal drugs of alcohol and tobacco

2) There is already an established retail network of age-restricted premises retailing these substances
3) There is widespread acceptance and use of them in the community
4) There is widespread use of them for pain relief and other medicinal uses as well for recreation

On this last point it is incumbent on the Committee to at least enquire and report on the medical applications of synthetic cannabinoids. We have anecdotal evidence from thousands of people (pages 6 and 7) who do not use illicit drugs normally but who have turned to synthetic cannabinoids for relief of a number of common ailments. We have attached a few random examples of emails, at the end of this submission, that one of our members has received. The reports invariably mention the lack of side effects in the analgesic applications of these substances. No doubt this is a reason for the large pharmaceutical companies and other groups who represent the legal drug industry to bring pressure to bear on governments and possibly even on this committee to prohibit these substances altogether.

The major and glaring abnormality with the federal Poisons Schedule is that there is no place to list recreational drugs. This results in alcohol being treated effectively as a foodstuff and nicotine being listed as a Schedule 2 poison – safe to use! The plethora of TV ads for nicotine patches and other 'quit' options would appear to make that listing somewhat suspect in the eyes of the average person. If we are to be totally objective on this matter and dispense with the politics of drug prohibition (the need to be 'tough' on drugs), ignore the big business side of things and be honest about the personal drug use patterns of drug regulators, then cigarettes and alcohol are drugs in the same way that synthetic cannabis is - except that they carry potentially far greater harmful effects than synthetic cannabinoids. When the federal health Minister talks tough on cigarette packaging and advertising she shows her Achilles heel on this subject and her gross hypocrisy, in that cigarettes (nicotine) are listed on the Poisons Schedule as safe to use with advice. The truth is that they are a mass marketed poison that kills hundreds of thousands of people each year. Synthetic cannabis has not killed one person that we can find.

As mentioned in our previous submission we represent the Australian producers, distributors and retailers of certain synthetic cannabinoids. Currently there are tens of thousands of Australian adults regularly purchasing and using these substances. Many have now been consuming these substances for a number of years. It is naïve to think that if these substances are prohibited from sale that people will just stop using them. Australians will just go off shore and purchase from international businesses, off the internet or from backyard drug dealers. How does this protect public health?

The Committee's December 2011 report refers to anecdotal information about possible harm and side effects but provides absolutely no evidence to support the decision to list these substances as Schedule 9. Before making broad and draconian decisions on synthetic cannabinoids that will see more young people jailed and an even larger black market than we already have, would it not be in

the public interest to commission some original Australian research to get some solid facts and information about the nature and effects of these substances?

It is difficult for us to respond explicitly to this enquiry when it is still unclear exactly what the Committee is proposing to schedule in five month's time. The term *synthetic cannabinomimetics* is so broad, our members are having difficulty defining what would be included. For example paracetamol would easily fall under this definition as it is converted to AM-404 in the body. Some medical research could also be impinged as we believe that JWH-015 and 133 are progressing to human trials. Bans on all cannabinoid agonists run the risk of banning common herbs like Catnip. We would request that prior to the interim decision being finalised, further information is provided to the industry and further research is undertaken by the Committee.

The broad groupings proposed by the committee are not compliant with Section 52E, which requires substances to be treated individually. These groups will prohibit substances that, if reviewed individually under section 52E, would not be scheduled - especially not as Schedule 9.

Such a broad and poorly defined definition appears to conflict directly with one of the core statements of Section 52E of the Therapeutic Goods Act 1989, namely that the risk assessment process that must be carried out by the Committee should be conducted on 'a substance'. The definition of 'substance' in 52A provides only that this means any medicine or poison. It does not make clear whether this can include large groups of substances with widely differing pharmacological effects, potencies and toxicity profiles.

These proposed broad definitions threaten to undermine the evidence basis of the risk assessment process. It is telling that there are no group entries in the Poisons Standard for broader classes such as 'AMPHETAMINE-TYPE STIMULANTS' or 'OPIOID ANALGESICS', despite these classes being mentioned in other legislation and policy documents.

Clearly there is an acknowledgement that these classes of substances, despite being comparable in certain ways to synthetic cannabinoids, are in other aspects such large and divergent groups of compounds with such disparate risk profiles, especially between the weakest and strongest members of the class, that it would not be appropriate to assess their risk as a group. In other words, the group as a whole cannot be considered "a substance" for the purpose of s 52E.

This same principle must be applied to the synthetic cannabinoid agonists. Of the several thousand compounds comprising this group, only a select subset of compounds that combine potent cannabis-like effects, with a simple and easily synthesised structure, have ever become subject to unauthorised sale for non-medical uses. The majority of cannabinoid ligands have, after all, been developed by pharmaceutical companies with the aim of minimising abuse potential and maximising analgesic or anti-cancer activity. Consequently, most of these have little real prospect for abuse. To consider all the members of this vast and varied class to be considered a single "substance" for the purpose of risk assessment

under s 52E of the Therapeutic Goods Act 1989 would thus be both scientifically inaccurate and legally questionable.

[redacted] recommends that:

- The committee recommend a new schedule for low risk recreational substances such as synthetic cannabinoids
- The committee does not proceed with further scheduling until they have undertaken further research into these substances
- The committee does not use broad groupings to define these substances
- Prior to the interim decision being finalised, further information is provided to the industry and further research is undertaken by the committee.

Below is small but indicative sample of unsolicited emails from people using synthetic cannabis for medical problems. We would be pleased to gather a much larger sample of these messages ,and a number of the writers to appear as witnesses to the Committee if it decides to investigate these claims further.

-----Original Message-----
From:
Sent: Thursday, 17 November 2011 8:46 PM
[redacted]

Does your msg mean this today Thursday or next Thursday? Why are the dumb police banning all this legal highs? Went to all my usual places today and found they had just been raided and took Everything. Hate them. I use legal highs cause
1 its fing legal and
2 I have an uncureable condition called Neuropathy from the waist down-its like lying and walking on cut glass, so very painful. I find these legal herbs help me sleep.

-----Original Message-----
From
Sent: Friday, 2 December 2011 4:02 PM
[redacted]

Hi it is now Friday and I received your email that my order will be sent to …. and I have chronic chronic back pain and can not leave house until order arrives due to my pain and I have been waiting a month now, is it still coming and is it delivery truck or Australia post? I do not mean to be pushy its just I went off pain meds 2 months ago and I want to try the aromatherapy and if it works I will bulk order for me kind regards
[redacted]

From:
Sent: Saturday, 31 December 2011 9:11 PM
[redacted]
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was just wondering if this is still legal in south australia i live in seaford and want some for my arthritis as when i gave up smoking my pain came back its the only thing thats gets rid of it i hate taking pills full of chemicals

From:]
Sent: Wednesday, 11 January 2012 11:43 PM
[redacted]

[redacted] i am 70 and need something relaxing,and enjoyable, i dont smoke any more so i have to have tea blends ,id like a pep up of a morning and a relaxant of a night,at the moment i am taking strong pain killers of a night, just to get me relaxed enough to sleep . im sure i am becoming resistant to them, i do hope you can help, i have so much to do yet... creative wise.....and i cant if im tired or strung out.....
regards

From:
Sent: Tuesday, 15 November 2011 8:58 AM
[redacted]

[redacted]

I personally suffer from cronic pain as a result of a vicious attempt on my life and I'm unable to leave my rented home for extended periods. I therefore remain indoors watching T.V. alone and life would be so much more enjoyable if I was able to afford some pain and boredom relief once in a while! Don't get me wrong, I'm certainly not asking for handouts, however if you want to make a lot more money I firmly believe lowering your prices would be of emormous benifit to you and the company.

Please try to understand that the reason cannabis is so expensive is because of the legal complications it carries with it. I have been a smoker for almost forty years and I would give my right arm to see the day when either pot is decriminalised or thirty
bucks a bag(or deal) again. May-be one day I will personally achieve this dream myself, unless of course some brilliant entrepeneur doesn't beat me to it! Anyway people, I'm a disabled pensioner who can't afford to get stoned because of a group of feral teenagers who decided I was too good looking and needed some facial re-arrangements. I now have just one eye and make the elephant man look like Bradd Pitt, the government won't give me my compensation money because I was dependant on opioids. I have a sixteen year old son to feed and take care of and I should be able to afford a smoke every day because it actually grows on trees in case no-one told you! If pot was legal it would be as cheap as chips and you would not be in such a possition to charge people very good money for lawn clippings.

Think about it, and if you are old enough to remember the days when a bag was not even weighed, it was full to the brim with excellent buds and cost $30 or less, then join me in my dream to make getting high inexpensive, the way it was meant to be!

Lower your prices..... PLEASE!!!

[redacted]

To "smp@health.gov.au" <smp@health.gov.au>
cc
bcc
Subject SUBMISSION [SEC=No Protective Marking]

DOCUMENT NOT YET CLASSIFIED

To the Scheduling Committee,
After reading through your reasons for your interim decisions I have a few points to make in response. As the gist of my argument for the regulation as opposed to banning of synthetic cannabinoids remains largely unchanged from the previous submission, I will only refer briefly to them, and then address some new concerns.
Although the Committee is attempting to prevent public health issues with regards to these substances, I firmly believe that scheduling in schedule 9 will be counter-productive to this aim. This will only drive synthetic cannabinomimetics underground, funding the criminal black market and increasing the risk of harm to the user. There is significant world-wide evidence to show that banning a substance does not greatly reduce its use, but only increases its harm.
Beyond the issues raised previously, I have some further concerns about the loose terminology used to classify synthetic cannabinomimetics. The original motivation behind the initial research that discovered synthetic cannabinomimetics was to develop new pharmaceutical drugs to replicate the outstanding pain-relieving and appetite-restoring qualities of cannabis. As you have surely noted by now, there is an overwhelming amount of anecdotal evidence that some of the synthetic cannabinomimetics (most of the evidence is with regards to JWH-018) have superior pain-relieving properties to cannabis. Unclear terminology in the group scheduling could seriously hamper developmental research into these compounds for therapeutic use, and even other relatively un-related compounds! An S9 scheduling of "cannabinomimetics" would affect research and development of genistein and similar isoflavones and their synthetic derivatives, such as the prostate cancer drug candidate KBU2046 because of their negligible cannabinomimetic activity, which is not via CB1/CB2 receptor agonism.

While the TGA frequently claims that S8/S9 scheduling does not inhibit legitimate research, it has acknowledged in discussion on other scheduling matters that scheduling below S8 is desirable "for balancing the misuse concerns against the need for professional access (without the added burden of Schedule 8 controls) for research and supervised clinical trials." [NDPSC, record of reason feb 2010]
What's more, An S9 scheduling of "cannabinomimetics" would affect research into the fatty acid ethanolamides [in particular their synthetic derivatives used in neuropathic pain research] because even though these amides are not CB1/CB2 agonists, they are known to cause an accumulation of endocannabinoids and hence have cannabinomimetic activity.
Similarly such a broad scheduling would affect research into synthetic derivatives of N-acylethanolamine-hydrolyzing acid amidase (NAAA) because it helps to accumulate palmitoylethanolamide, which in turn helps to accumulate endocannabinoids and hence has cannabinomimetic activity.

Clearly such unneccessarily broad scheduling will negatively affect innovation in this country when no other country has chosen such a broad and vague definition. One would hope that the TGA and in particular the NDPSC could draw on its scientific resources and come up with a neat scientific definition rather than a bureaucratic one. As you have pointed out yourselves, echinacea and spilanthes are two herbs that act on the CB1 and CB2 receptors, so research into the therapeutic potential of synthetic derivatives of these could be inadvertently hampered by these poor definitions.

The committee raised concerns about synthetic cannabinoids being addictive and having 'similar negative

effects to cannabis', and clearly stated that there is a lack of adequate scientific evidence to assess the long-term health risks posed by these substances. A lack of evidence of safety does not mean that something is unsafe. In our justice system we clearly take a policy of 'innocent until proven guilty' (although it seems that this may be at risk, if we consider the wider implications of recommendations in your recent paper that the onus be on the person possessing a substance to prove that it does not fall under the proposed schedule!), so why do we take the approach of 'dangerous until proven otherwise' to medicines, herbs, and drugs? Unfortunately it seems that there is a plethora of unscientific, badly-researched legislation popping up world-wide that places a real burden on the executive and judiciary arms of government, costing unnecessary millions to police, enforce and process. I strongly advise that the TGA take measures to avoid falling prey to this tendency.

While of little relevance to my comments and opinions put forward in this and previous submissions, I feel I should point out what other chemists have relayed to me in regards to the type of blanket scheduling that is being proposed. It has been suggested that the definition of "synthetic cannabinomimetics" is ridiculously broad and quite possibly beyond the intention or even comprehension of those suggesting that terminology. These regulations are supposed to be aimed at cannabinoid receptor agonists that have effects which the TGA regards as being subject to abuse, yet by using the much broader terminology (that goes well beyond receptor agonisms) yet will inadvertently include important and common industrial chemicals and pharmaceutical research that is in no way connected to the original aim of preventing abuse.

One also has to wonder whether the definition of "synthetic" includes synthetically manufactured cannabinoid agonists that are also known to occur naturally. Oleamide is a common substance found in many seeds. Industry produces vast quantities of oleamide synthetically and uses this as a lubricant in plastics extrusion. Is this oleamide synthetic or natural by the NDSCP definition? How about the oleamide and other fatty acid derivatives that are used similarly, are known or presumed to be cannabinoid agonists [no matter how feeble], but which do not have natural counterparts? These industries have likely not responded to these proposals because they would never consider that any government might try and restrict such compounds, but we remain curious whether the NDSCP has considered the far reaching implications of this type of group scheduling.

[redacted]

SUBMISSION BY [redacted] IN RESPONSE TO THE RECOMMENDATION ON KAVA BAN BY THE ADVISORY COMMITTEE ON MEDICINE SCHEDULLING (ACM) ON 19 OCTOBER 2011

(13/01/12)

Traditional, Aboriginal and Pharmaceutical uses

1. The issue of kava in Australia should first distinguish the traditional use of kava with water by Moanan migrants (Pacific Islanders) who are now citizens of the nation and citizens of global democracy from the use of kava with water and other modern mixtures by Aboriginal people, as well as, by the general public/consumers through buying kava tablets from the Chemists by authorized prescriptions (pharmaceutical use);
2. The health, social, political, medicinal, moral, economic and cultural effects of the traditional use of kava, the Aboriginal and general public are different, apart from the Western claim of liver problem, which is purely Western oriented;
3. Their processes of manufacturing or making are different and also the degree of dilution or mixture including different ways of consumptions for different purposes;
4. For the traditional use, it is a result of a mixture of kava powder and water with different ways of dilution in conjunction to the nature of cultural or social activities;
5. For the Aboriginal use, there is clear-cut evidence of mixing kava and water with alcohol and lack of traditional knowledge in looking after themselves physically;
6. With the kava tablet, it is a product of mixing of kava powder and acetone and ethanol (both alcohol) that have caused immediate deaths among Western people worldwide but not in Moanan communities;
7. For aboriginal use and kava tablet, both are dangerous because of the mixing of kava with alcohol, and the latter is regarded by Pacific elders as the 'enemy' of kava, and in their words, "Never mix kava with any other chemical except water";
8. It is shown from the ACM's recommendation on the 19 of October that there is no respect of the 'traditional knowledge with scientific, therapeutic and medicinal aspects of Pacific Islanders', as it is clearly shown in the denial and rejection of our First Submission in August 2011;
9. Kava has been drinking in cultural and socialized ways by Moanan people for over 20 centuries with no major problems and immediate deaths as it is now observable in Western societies but not Moanan nations and communities abroad;

10. The traditional use of kava by Moanan Islanders in Australia falls into the following categories which have never been seriously considered by the Australian Government with no cultural and human sensitivity:

- Cultural purpose
- Moral purpose
- Political purpose
- Economic purpose
- Social purpose
- Religious purpose
- Medicinal purpose
- Therapeutic purpose
- Sexual purpose;
-

11. It shows that the lack of understanding and respecting has led on to the amalgamation of kava in traditional use, with kava by Aboriginal and kava tablets in pharmacies as a result of the works of medical and industrial experts;
12. Among these three groups it is indicated that the pharmacists have earned million dollars from kava tablets which have killed about 100 Westerners worldwide with no clear data and evidence of Moanan Islanders in Australia and worldwide of immediate deaths from kava in traditional use;
13. Overall, it is very unfair and unjust to penalize Pacific Islanders and their kava traditions and cultures as a result of the misuse and abuse of such a substance by the Aboriginal people, as well as, the cause of deaths in Europe with one death in Australia from consumption of kava tablets from the pharmaceutical methods and not from the traditional use of kava by the Moanan migrants who are now citizens of Australia, with the same cultural, social, economic, political and human rights with the wider majority of the population;

Health, Cultures, Human Rights and Citizenships

14. After studying the ban of kava in Australia and in Europe by the [redacted] and the Lo'au Research Society (LRS) worldwide, including the decision of the WHO, it is very obvious that the issues on health, culture, human rights and citizenships are opposed to one another in the overall process of interaction;
15. In the case of Europe and Australia, health undermines cultures, human rights and citizenships with very unjust action, in the sense that the same logic and principle that are applied to kava should be applied to alcohol, tobacco, pharmaceutical medications and so forth, but unfortunately this is not really the case in Australian and most Western societies;

16. For instance, alcohol is the main cultural and socialized drink for the majority of the Australian population but in according to Australian Health Authority, it kills about 3000 people every year but why is not banned and why Moanan kava drinkers is the question;
17. No records and data of deaths on the streets from drinking kava as we see every day on news and every Australian holidays including Christmas and New Year due to drinking alcohol, why the kava is only banned;
18. If we follow the same logic and principle, there are countless products in Australia that should be banned to make things fair, and for justice sake to be prevailed in this nation;
19. Coca Cola and McDonald diets have killed thousands of people in Australian, and why are not banned but why is kava;
20. The cultural and social practices of kava by Moanan migrants and citizens in Australia are not considered as important, as well as, the human rights of such Moanans to exercise their cultural, social, moral, economic, political, medicinal and therapeutic rights which all contribute to the creation of their human rights and social harmony and beauty in cultural arts as shown below in some of our studies;
21. If human and cultural rights are determined by laws as it is spelled out in the Universal Declarations, why is kava not treated in the same manner with alcohol, tobacco, coca cola, McDonald and so forth, and this brings into mind the undemocratic and unjust nature of this legislation on kava in Scheduling 4 with its contradictory nature to the Custom Importation Laws 1956 which permits the importation of 2k of kava per person over 18 years old;
22. Culture is a part of human kinds, and the rights for them to exercise in a civilized and a clear-cut defined manner of hygiene should be respected especially if they are citizens of the nation and citizens of global democracy;
23. Health is vital to human kinds but if its legal nature applies the principle and logic of unfairness and injustice, it must be amended and adjusted and be equally treated the same for all, but not in the manner that it is shown in the classic book of "The Animal Farmer" with its theme, "All are equal but some are more equal than others", and this is the impression we Moanan Australians are now experiencing with regard to the ban of kava;
24. Citizens in Australia should be treated equally, if kava is banned because of health reasons why not alcohol with more health problems which cannot be compared to kava with one dead in Australia and about 100 worldwide for consuming kava tablets and not traditional mixture of kava and water;
25. In terms of health, the first ban of kava in Europe was a result of liver related problems for consuming kava tablets with acetone and ethanol, and Professor J. Malani from the University of the South Pacific in Fiji was one of the first scientists to conduct a study with experimentation between traditional use of kava and the modern use by the West in herbal medicine in pharmaceutical terms;

Scientific studies on kava and its traditional mixture with water in relation to kava tablets

26. Professor Malani concluded by saying,

> "Although kava has been consumed for centuries, concerns for the liver toxicity of kava has become a health concern only since 1988. Since that time 32 reports have suggested the involvement of kava in liver disease. Out of those reports, 3 have been published in major medical journals and 31 were reports forwarded to the German and Switzerland health authorities. Of the 32 reports, only one is involved with traditional consumption of kava and 31 involved herbal kava extracts… The large number of case reports concerning herbal kava extract and liver toxicity is concerning since this effect is not seen with the traditional kava consumption. These reports need to be properly evaluated since the evidence so far points to the consumption of herbal extract and to a smaller extent to the consumption of traditional kava powder. It is also unlikely to be related to the dose of kava since the herbal extract doses used in the reported cases are relatively smaller compared to kava consumed in the pacific islands. If however, there is a reasonable suggestion of liver toxicity, then it is of utmost importance that the claimed herbal kava extract cases are properly evaluated to see if there is an idiosyncratic hepatotoxic effect, interaction with other drugs,… enzyme deficiency in some cases, coincidental liver disease, herbal extract preparation or the change in chemotypes are the important factors. There is no recorded idiosyncratic effect of kava on the liver observed in pacific islanders and Europeans traveling into the pacific islands over the past 3 centuries. Interaction with other drugs is a possibility but there are many pacific islanders who consume kava while taking antihypertensive, cardiac and diabetic and other medications. A deficiency in P 450 enzyme that metabolises kava is a possibility but its clinical manifestation should also have been observed in pacific islanders or Europeans consuming kava over the past century. A recently new chemotype of kava extract and also it preparation method needs to be properly evaluated since this concern has come to light since the recently new herbal extract preparation";

27. Professors Joji Malani's Summary are as follows:

> "Summary points
>
> 1. There is no convincing evidence so far indicating direct kava toxicity to the liver when consumed using traditional methods. There is however evidence that there are health problems associated with very heavy kava consumption including poor nutrition and rise in liver enzymes.
> 2. There is a concern regarding liver toxicity when using herbal kava extract as reported to the German and Switzerland Health Authorities. The evidence concerning #2 needs to be clearly evaluated. Based on evidence on the pacific population, it is

probably not the kavalactone but the preparation. It would be unlikely to be dose related since herbal kava extract dose is relatively smaller compared to that consumed in the pacific. It is impossible to make any conclusion from the cases reported in Germany until more information is known about the details of individual cases.

3. There is an urgent need to examine the gastrointestinal effects of kava using a properly designed study (Malani, Joji, "Evaluation of the effects of kava on the liver", Senior Lecturer, Fiji School of Medicine, 2002)";

28. Dr Jerome Sarris who is a strong supporter of [redacted] and his associates in science and medicine have conducted and produced countless experiments and written documents in the past decade or so regarding the medicinal and therapeutic effects of kava in a positive manner on human systems. Their works included the followings:

- **Topic**: "An explorative qualitative analysis of participants' experience of using kava versus placebo in an RCT" by Professors E. LaPorte1, J. Sarris, C. Stough and A. Scholey.
  Purpose: "Many randomised controlled trials (RCT) have been conducted using *Piper methysticum* (kava), however no qualitative research exploring the experience of taking kava during a clinical trial has previously been reported &
  Results: Kava use did not cause any serious adverse reactions although a few respondents reported nausea or other gastrointestinal side effects. This represents the first documented qualitative investigation of the experience of taking kava during a clinical trial. The primary themes involved anxiolytic and calming effects, with only a minor theme reflecting side effects. Our exploratory qualitative data was consistent with the significant quantitative results revealed in the study and provides additional support to suggest the trial results did not exclude any important positive or negative effects (at least as experienced by the trial participants) (J. Sarris, J.Adams, D.Kavanagh in Australian journal of Medical Herbalism, 2010 22(1))."
- "Neurocognitive effects of kava (Piper methysticum): a systematic review"
  "Rationale Kava (Piper methysticum) elicits dose-dependent psychotropic effects and thus may potentially deleteriously affect cognitive performance. Clinical trials have assessed the effects of kava on cognition, however, to our knowledge no systematic review has been conducted in this area.
  Objective To systematically review the effects of kava on cognition, providing an analysis of the individual study's methodological quality, results and effect sizes.
  Methods A systematic review was conducted of publications up to June 15th 2010, using the electronic databases MEDLINE, PsychINFO, CINAHL, Web of Science and The Cochrane Library. The search criteria involved kava and cognition related terms, e.g. memory and attention.
  Results Ten human clinical trials met inclusion criteria (acute n¼7, chronic n¼3). One acute study found that kava significantly improved visual attention and working memory processes while another found that kava increased body sway. One chronic study found that kava significantly impaired visual attention during high-cognitive demand. Potential

enhanced cognition may be attributed to the ability of kava to inhibit re-uptake of noradrenaline in the pre-frontal cortex, while increased body sway may be due to GABA pathway modulation.

Conclusions The majority of evidence suggests that kava has no replicated significant negative effects on cognition (E. LaPorte1, J. Sarris, C. Stough and A. Scholey, human psychopharmacology, Hum. Psychopharmacol Clin Exp (2011), Published online in Wiley Online Library, (wileyonlinelibrary.com) DOI: 10.1002/hup.1180)".

- **Topic**: "The Kava Anxiety Depression Spectrum Study (KADSS): a randomized, placebo-controlled crossover trial using an aqueous extract of Piper methysticum" by Professors Jerome Sarris , Emma LaPorte , Isaac Schweitzer.

"**Abstract**"

"**Rationale** Piper methysticum (Kava) has been withdrawn in European, British, and Canadian markets due to concerns over hepatotoxic reactions. The WHO recently recommended research into "aqueous" extracts of Kava.

Objective The objective of this study was to conduct the first documented human clinical trial assessing the anxiolytic and antidepressant efficacy of an aqueous extract of Kava.

Design and participants The Kava Anxiety Depression Spectrum Study was a 3-week placebo-controlled, double blind crossover trial that recruited 60 adult participants with 1 month or more of elevated generalized anxiety. Five Kava tablets per day were prescribed containing 250 mg of kavalactones/day.

Results The aqueous extract of Kava reduced participants' Hamilton Anxiety Scale score in the first controlled phase by −9.9 (CI = 7.1, 12.7) vs. −0.8 (CI = −2.7, 4.3) for placebo and in the second controlled phase by −10.3 (CI = 5.8, 14.7) vs. +3.3 (CI = −6.8, 0.2). The pooled effect of Kava vs. placebo across phases was highly significant ($p < 0.0001$), with a substantial effect size ($d = 2.24$, h2p¼ 0:428). Pooled analyses also revealed highly significant relative reductions in Beck Anxiety Inventory and Montgomery–Asberg Depression Rating Scale scores. The aqueous extract was found to be safe, with no serious adverse effects and no
clinical hepatotoxicity.

Conclusions The aqueous Kava preparation produced significant anxiolytic and antidepressant activity and raised no safety concerns at the dose and duration studied. Kava appears equally effective in cases where anxiety is accompanied by depression. This should encourage further study and consideration of globally reintroducing aqueous rootstock extracts of Kava for the management of anxiety (J. Sarris & D. J. Kavanagh & G. Byrne & K. M. Bone & J. Adams & G. Deed, Received: 29 January 2009 / Accepted: 15 April 2009# Springer-Verlag 2009). "

- **Topic**: "Kava: a comprehensive review of efficacy, safety, and psychopharmacology"

"**Overview:** Kava (*Piper methysticum*) is a South Pacifi c psychotropic plant medicine that has anxiolytic activity. This effect is achieved from modulation of GABA activity via alteration of lipid membrane structure and sodium channel function, monoamine oxidase B inhibition, and noradrenaline and dopamine re-uptake inhibition. Kava is available over

the counter in jurisdictions such as the USA, Australia and New Zealand. Due to this, a review of efficacy, safety and clinical recommendations is advised.

Objective: To conduct a comprehensive review of kava, in respect to efficacy, psychopharmacology, and safety, and to provide clinical recommendations for use in psychiatry to treat generalized anxiety disorder (GAD).
Methods: A review was conducted using the electronic databases MEDLINE, CINAHL, PsycINFO and the Cochrane Library during mid 2010 of search terms relating to kava and GAD. A subsequent forward search was conducted of key papers using Web of Science cited reference search.
Results: The current weight of evidence supports the use of kava in treatment of anxiety with a signifi cant result occurring in four out of six studies reviewed (mean Cohen ' s d _ 1.1). Safety issues should however be considered. Use of traditional water soluble extracts of the rhizome (root) of appropriate kava cultivars is advised, in addition to avoidance of use with alcohol and caution with other psychotropic medications. Avoidance of high doses if driving or operating heavy machinery should be mandatory. For regular users routine liver function tests are advised.
Conclusions: While current evidence supports kava for generalized anxiety, more studies are required to assess comparative efficacy and safety (on the liver, cognition, driving, and sexual effects) versus established pharmaceutical comparators (Jerome Sarris , Emma LaPorte , Isaac Schweitzer, Aust NZ J Psychiatry Downloaded from informahealthcare.com by University of Melbourne on 04/02/11)."

- **Topic:** "Kava, the anxiolytic herb: back to basics to prevent liver injury?" by Professors Rolf Teschke, Jerome Sarris, Xaver Glass & Johannes Schulze

"The use of the anxiolytic herb kava has caused toxic liver injury in Western countries and economic problems in South Pacific Islands due to tthe regulatory ban on kava. This analysis shows poor quality of kava raw material as a cause for its toxicity and suggests preventative measures by going back to the traditional use of kava for the sake of the patients and the South Pacific economy."

"Introduction

The credit for the first detailed description of the kava plant is given to George Forster [1, 2], a member of the sailing crew of Captain James Cook on his second voyage around the world on the 'Resolution' (1772–1775) [3]. In 1777 George Forster named the kava plant *Piper methysticum* or 'intoxicating pepper' [2]. Its extracts are used as recreational beverages for social events in South Pacific Islands [1–6], as unregulated dietary supplements in the United States [4–6] and also worldwide due to internet access [5], or as regulated herbal anxiolytic products approved in Australia [7]. A Cochrane study confirmed the efficacy of kava extracts for anxiety disorders, and also considered major side effects such as drug tolerance observed with synthetic alternatives like benzodiazepines [8]. Since 2002 due to concerns of liver toxicity, kava has been banned from consumption in several countries including the United Kingdom, Germany, Switzerland, France and Canada, but surprisingly not in the United States [5]. This

has caused profoundly harmful socioeconomic effects on poor Pacific Island countries that rely on this export [5, 6]. Furthermore, patients with anxiety disorders in restricted areas may receive this effective anxiolytic herb only illegally via the internet. As a consequence, a highly qualified WHO expert group recently convened to assess the hepatotoxic risks of kava, and to provide potential solutions [5]. This was a critical WHO imperative as the kava ban has caused economic problems in the South Pacific which are causing follow-on public health ramifications from the resultant increase in poverty."

"**Conclusions**

Liver injury caused by medicinal and traditional kava extracts as a consequence of inappropriate kava raw material has undermined consumer confidence in modern herbal medicine. A current approach is being made to overcome lack of standards and to suggest criteria for good kava quality, both in Western countries and in the South Pacific Islands. Thorough safety control measures are now required as mandatory for the sake of both the patients who want the anxiolytic herbal kava extracts and those individuals who like the relaxing properties of traditional kava drinks. This approach should also be of potential benefit to the future economy of the Pacific Islands. The critical next step forward in assisting the Pacific Island people with the re-introduction of their valuable export commodity and cultural icon, is to go back to basics, back to using water extracts of peeled noble kava rhizomes and roots (Rolf Teschke, Jerome Sarris, Xaver Glass & Johannes Schulze, British Journal of Clinical Pharmacology, DOI:10.1111/j.1365-2125.2010.03775.x)."

- **Topic**: "Life and Culture 101" - Course at Massey University of Albany Campus in NZ by Professor Sitaleki 'Ata'ata Finau

  Purpose: This paper on "Life and Culture 101" is coming in due Pacific course, but albeit suffice to state that it will begin with: "Life is a symbiosis of lives in equilibrium. The equilibrium is maintained and driven by biopsychosocial forces of which culture and personality feature prominently. Both are dependent on: environment, ethnicity, religion, wealth, and technology"

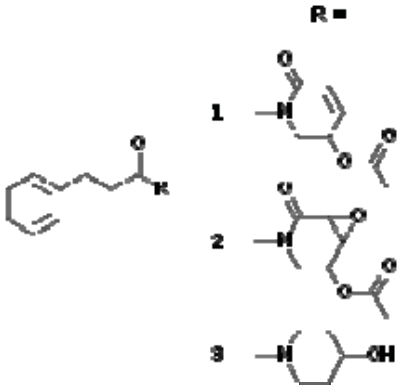
  "Basic research on anti-cancer potential: February 2006, the *Fiji Times* and Fiji Live reported that researchers at the University of Aberdeen in Scotland and the Laboratoire de Biologie Moleculaire du Cancer in Luxembourg had discovered that kava may treat ovarian cancer and leukemia. Kava compounds inhibited the activation of a nuclear factor that led to the growth of cancer cells. The Aberdeen University researchers published in the journal *The South Pacific Journal of Natural Science* that kava methanol extracts had been shown to kill leukemia and ovarian cancer cells in test tubes.[28] The kava compounds were shown to target only cancerous cells; no healthy cells were harmed. This may help explain why kava consumption is correlated with decreased incidence of cancer." Fiji Kava Council Chairman Ratu Josateki Nawalowalo welcomed the findings, saying that they would boost the kava industry. For his part, Agriculture Minister Ilaitia

Tuisese called on the researchers to help persuade members of European Union to lift their ban on kava imports. In November 2008, the EU announced its lifting of the kava trade ban, which had been imposed due to accusations made in 2001 and since debunked through scientific review of the facts."

"**Allegations of liver damage incidents and regulation"**

"In 2001, concerns were raised about the safety of commercial kava products.[31] There were allegations of liver toxicity in some people who had used dietary supplements containing kava extract (but not in anyone who had drunk kava the traditional way). The allegations of liver damage consequently prompted action of many regulatory agencies in European countries where the legal precautionary principle so mandated. In the UK, the Medicines for Human Use (Kava-kava) (Prohibition) Order 2002 prohibits the sale, supply or import of most derivative medicinal products. Kava is banned in Switzerland, France, and the Netherlands.[32] The health agency of Canada issued a stop-sale order for kava in 2002. But legislation in 2004 made the legal status of kava murky to many, especially since not everyone is aware that a stop-sale order does not constitute a ban such as that applies in several European countries. Kava is not illegal in Canada and doesn't fall under any of the Food and Drugs Act & Regulations. Many retailers have been ignoring the no-sale order without further consequence than having Health Canada issue warnings about the product's safety. At least one US manufacturer of kava products who had suspended export to Canada in 2002 has since lifted the restriction and resumed shipping kava to Canada after obtaining confirmation that it wasn't illegal for Canadians to import kava. The United States CDC has released a report expressing reservations about the use of kava and its possibly adverse side effects (specifically severe liver toxicity), as has the Food and Drug Administration (FDA). In Australia, the supply of kava is regulated through the National Code of Kava Management. The sale and supply of kava is prohibited in Western Australia and the Northern territory. The Australian Therapeutic Goods Administration has recommended that no more than 250 mg of kava lactones be taken in a 24 hour period. According to the Medicines Control Agency in the U.K., there is no safe dose of kava, as there is no way to predict which individuals would have adverse reactions, if any. In a 2009 study by the University of Queensland, Australia, researchers found that the study's participants did not show any signs of potential liver damage, contrary to concerns that prompted European, British and Canadian authorities to ban kava sales in 2002. Kava products sold in those countries were based on ethanol or acetone extracts of the kava plant, not the water-soluble extracts used traditionally by Pacific islanders and approved for sale in Australia. It has been suggested that Flavokawain B is the hepatotoxic chemical in Kava. It is not known if this chemical survives traditional preparation of the herb."

“Toxicology of pill from kava extracts with stems and leaves”



Piperidine alkaloids from the kava plant

The legal intervention of several countries stimulated research, and hepatotoxic substances were found in the stems and leaves of the plant. Researchers from the University of Hawaii at Manoa found that an alkaloid called pipermethystine (formula 1), contained in stem peelings and leaves but not in the roots, had toxic effects on liver cells *in vitro*[41] and *in vivo*.[3] In rats fed with 10 mg/kg pipermethystine for two weeks, indications of hepatic toxicity were found. Comparable signs of toxicity were not detected with kava rhizome extracts (100 mg/kg, 2 weeks),[3] (73 mg/kg, 3 months).[4]

Flavokavain B, found in the plant's rhizome (large horizontal underground stem), may also contribute to toxic effects.[42] It is also known that some of the kavapyrones block several subtypes of the enzyme cytochrome P450,[43] which can result in adverse interactions with other drugs used concomitantly.

Hawaiian researchers learned from a trader in Fijian kava that European pharmaceutical companies eagerly bought up the stem and leaves peelings when demand for kava extract soared in Europe in 2000 and 2001. Before 2002, substantial amounts of aerial parts of the kava plant were being exported to North America and Europe and obviously used for the production of commercial pill extracts. For traditional use in the South Pacific, stem peelings and leaves are discarded, and only the rhizomes are used and extracted with water. This may explain why native populations that make heavy use of kava experience side effects that are mild, temporary, and confined to the skin, whereas industrialized countries that have newly adopted kava occasionally show severe, acute responses.”

“Toxicity of traditional kava beverage preparations”

“In April 2003, University of Hawaii scientists reported to have discovered that traditionally discarded stem peelings and leaves of kava contain a toxic alkaloid—not present in the plant's roots. European pharmaceutical companies are known to have purchased such peelings when demand for kava extract soared in 2000-2001. Two studies still allege changes in liver function, with the first describing the effects as temporary and reversible when discontinuing kava use. There is evidence of health concerns among heavy alcohol drinkers, including poor nutrition and a rise in liver enzymes typically

associated with liver damage (S.A.Finau, University of Massey, Albany Campus, NZ, 2011, paper presented at the Kava Conference, Australian National University, 2011)".

- **Topic:** "Kava, the "partial" versus the "total:" A way out of the impasse?" by Hufanga Professor 'Okusitino Mahina

  "By a "total" approach, I hereby refer to the extreme significance for a fuller, thorough-going knowledge and understanding of the totality of the physical, psychological, and social dimensions surrounding the thinking and praxis of *kava*. To dwell discriminately on the physical alone and exclude the psychological and sociological is indeed "partial," leaving us in the dark as to the totality of the intertwined but integrated physicality, mentality, and sociality connected with the thinking and praxis of *kava*.

  Not only is *kava* physical in nature, it is also both psychological and social in character. As a physical substance, *kava* possesses a number of bio-chemical, molecular-biological, and narcotic properties that require systematic research. Such a research focuses primarily on the conflicting bio-chemical, molecular-biological relationships between plant and body as physical entities. Besides the rich existing literature on the subject, our very own Tongan scientist the late Mr Tēvita Holo, along with Mr Uili Lousī, did some interesting research many years back on the physical composition of *kava* as a naturally occurring substance. As a plant, *kava* is transcended beyond the physical domain to both the psychological and social realms [see Biersack 1991; Bott 1972; Feldman 1980; Helu 1999; Māhina 1992; Newell 1947]. In attitudinal ways, the consumption of *kava* is principally for reasons of group solidarity, where established albeit cherished positions and responsibilities in the society at large are constantly formalised, revised, and standardised in the social process for the greater good of all.

  Herein, the constant formalisation, revision, and standardisation of *kava* generally deal with cultural and historical conflicts in the overall ordering and altering of the wider society [see Biersack 1991; Bott 1972]. Mind you the ingenious integration of the opposed physical, psychological, and social characteristics of *kava* as a plant into a unified social institution of some immense aesthetic and ceremonial significance mirrors the independent operation of society and vice versa [see Anderson 1962, 2007; Helu 1999; Māhina 1999, 2004]. In its original formulation, the social institution of *kava* was concurrently made by Lo`au, the famous *tufunga fonua* material artist of ecological-psychological-sociological designing into a ceremony and an artform of enormous beauty and utility [see Māhina. Ka`ili & Ka`ili 2006; Māhina 2011]. That is, that *kava* as a social institution was created not only to be immensely beautiful but also to be greatly useful, especially as an effective apparatus for a harmonious cultural ordering and historical altering of society.

As a ceremony and an artform, *kava* functions chiefly as a vehicle through which cultural and historical conflicts in the social process are symmetrically mediated transforming them from a condition of *felekeu* crisis to a state of *maau* stasis to produce harmony [see Biersack 1991; Bott 1972; Māhina 2010a, 2011]. This state of harmony is itself beauty, ecologically, psychologically, and sociologically measured in terms of productivity, prosperity, and stability. By consuming the mixed beverage, people are physically and psychologically transformed by the physical properties of *kava* from a situation of *hoha`a* restlessness to a state of *fiemālie* restfulness [see Bott 1972; also Māhina 2008]. In this state, both body and mind are cleansed of subjectivity of the here-and-now, opening them up to a world of objective understanding, where they as unity of bodies and minds collectively search by way of *talanoa* talking-critically-yet-harmoniously for new ideas that are both aesthetically beautiful and socially useful [see Māhina 2004a, 2004b, 2008].

It is also thought that the consumption of *kava* is for reasons of *faito`o* or medicine, as in the classical Tongan thinking and practice of *kava ongosia* wearied *kava*, consumed after a hard day at work [see Bott 1972; Māhina 1992]. In accordance with this thinking and practice, *kava* is said to heal both body and mind/soul. In effect, the consumption of *kava* "suppresses" unsettled feelings of physical and emotional fatigue, misery, and anxiety, allowing for both body and mind/soul to heal in the process. So, *kava* as a narcotic drink is, in this sense, a "depressant," in contrast to alcoholic beverages, which can be considered a "stimulant."3 This distinction has been popularised in *kava* circles, where it is often uttered that when one drinks *kava* one feels like a *lami* lamb, or, for that matter, a *lupe* dove and when consuming alcoholic drinks one becomes a *laione* lion.

In more generalised contexts, *kava* as a highly evolved, complex social institution evokes an imagery of a group of people gathering around a bowl drinking *kava* [see Figure 1], where stories of both factual and fictional nature, as well as those with both comic and tragic character, are told and retold by way of *talanoa* with great mastery, sophistry, and oratory in creative and original ways. These are, at times, interspersed with beautiful singing and dancing [see Māhina 2008]. Also, *kava* provides a rare opportunity for the telling and retelling of *talatukungutu* oral traditions, where they are passed through generations by word of mouth [see Māhina 1992]. In all these instances, *kava* is often alluded to by elders as the Tongan *falealea* or parliament. The dynamics of *kava*, however, led both the late Professor Epeli Hau`ofa and the late Professor Futa Helu to have named a popular Tongan-English literary journal "Faikava," which provided a forum for the promotion of creativity and originality [see Hau`ofa 2005; Helu 1979; Māhina 1992; also see Irwin 1981] ('Okusition Mahina, Paper presented at the Kava Conference, Australian National University, 2011)."

- **Topic**: “Thinking about Kava” by Anthropologist Kirk Huffman

The story of kava covers a third of the earth’s surface; possibly goes back over two thousand years, and its recent entry into the ‘White Man’s World’ exemplifies much of the cultural arrogance and cultural misunderstanding that seem to be the main characteristics of our ‘modern’ societies *vis-à-vis* the more ancient surviving traditional societies of the world. Certain members of our own societies often tend to think that our modern technological superiority reflects cultural superiority and that those ‘isolated tribes’ that come into contact with us should be suitably impressed. Some get rather offended when the latter often do not seem impressed at all. There is a fundamental difference, though, between the ‘How’ cultures and the ‘Why’ cultures of the world. Our modern Euro-American cultures are prime examples of ‘How’ cultures: ‘How can we go faster, live longer, buy more gadgets, live life on the edge, look younger and avoid death’? The more sensible cultures on earth would say ‘Why’? to most of that. And that is what Pacific islanders are saying about Europe right now: ‘Why’?

Let me explain. For nearly a decade, many health food shops in the UK have stocked bottles of tablets labelled ‘*Kava*’ or ‘*Kavakava*’: ‘To be taken to Alleviate Stress or Anxiety’. In Germany, medicinal ‘kava extract’ has been used as an ingredient in anti-stress medicines for decades, and in fact German medical scientists have been working with kava extracts since 1860. Kava tablets have also been available in the US since the mid-1980s and became the ‘in thing’ in New York in 1998, drug stores and pharmacies there displaying big posters indicating ‘Yes, we have KavaKava !’, etc. In 1999 certain Spanish Health Food and Alternative Living magazines announced that kava would soon be coming to Spain. I remember thinking periodically over the last decade how long it often takes our modern cultures to really accept something new from the so-called ‘Third World’ (I should point out here that I consider this term rather derogatory and that it is really our own ‘modern’ world that should be called by that term, it being so removed by many steps from its real roots). In late January (2002) my wife and I visited one of the major *Farmacias* in the *Calle de las Farmacias* of *Vila* (Eivissa/Ibiza Town), and I asked if they sold any kava extract medecines. I was told they had been selling them, but had recently taken them off the shelves as they had, earlier that month, received a circular from the Spanish National *Farmacias* Institute in Madrid to withdraw stocks until further notice. In a nearby health food shop there was a gap on the shelves where bottles of kava tablets should have been. No explanations. Nobody really knew why, just that they had received an official circular. As often happens, it is quite possible that those responsible for the circular did not really know either: they were merely copying others.

Kava is the name for a plant, for its root, for a drink made from its root, and now for tablets and extract from that root sold in the West. The plant grows only in the Pacific. It

first came to the attention of the English-speaking world after Captain Cook's first visit to Tahiti in 1769, when he and his scientists were invited to drink it ceremonially. They were suitably impressed, but slightly put off by the taste. It had a rather pleasing effect, and Cook's scientists originally dubbed the plant it was made from as *piper inebrians*, then changed that *piper methysticum*, it being a distant relative of the pepper plant. Early European explorers found that a drink made from the roots of this plant was drunk ritually throughout much of Polynesia, from Tonga to Samoa to the Cook Islands and back to Fiji. In Hawai'i it is called *Awa*, in Tonga *Kava*, in Fiji *Yaqona* (pronounced 'yanggona'). The root of these terms comes from an early proto-Polynesian term meaning 'bitter'. 'Kava' is the name that has stuck and spread worldwide, rather like the origin of our word 'coffee' or even 'tea'. Historians, explorers, writers and academics for long assumed that it was essentially a purely Polynesian drink. Little did they know: back in a hidden corner of the southwestern Pacific lay the real homeland of kava; the volcanic archipelago of Vanuatu, keeper of so many of the Pacific's secrets.

Traditionally there was no alcohol in the Pacific islands. But Pacific islanders had something better: a Gift from the Gods, from the Spirits, from the Mother Earth. It is Spirit in plant form. It is Peace. It is Respect. It is Harmony. It is Sounds from the World of the Ancestors. It is the Way of Prayer. It is (in some areas) Woman, so therefore changeable in mood, bestowing her favours gladly one day, denying them the next. It is (in some areas) Man, and therefore forbidden to women. It is Kava. The Gift of the Gods to the Pacific and the Gift of the Pacific to the World.

But the Gift was first given to a group of clans in northern Vanuatu. There, possibly over two thousand years ago, ancestors of still-surviving clans discovered how to artificially 'clone' a drinkable variety of the kava plant from a wild, non-drinkable, parent plant. This wild source is a variety of pepper plant known by scientists as *piper wichmannii*, and this grows only in western Melanesia (that area comprised by West Papua, Papua New Guinea, the Solomon Islands, and Vanuatu). Extracts from the roots of this wild plant are undrinkable, but modified forms are sometimes used in traditional medicines. Through generations of observation and experimentation, those wise men in northern Vanuatu managed to develop from this plant another variety – and then more – whose roots provided a drinkable extract whose effects are remarkable. These roots contain no alcoholic substances, but an extremely complex array of 12 to 14 chemicals (* that was the known situation in 2002; it is now known that there are over 40 chemicals, 19 of which are psychoactive) – mostly analgesics and anaesthetics – that are linked in such a complex interrelationship that it is almost impossible to reproduce by modern methods. It is also extremely difficult to tell which are the absolutely essential ingredients for the effect the root extract gives when drunk. The psychoactive ingredients have been dubbed 'kavalactones' by modern scientists. The ingredients, when drunk, work on the

central nervous system, through a reduction of activity in the spinal area, reducing cardiac rhythmn and then stimulating and relaxing respiration. The whole effect is one of extremely pleasurable relaxation, with the mind remaining clear, with a sometimes-increased focus. It is an extremely effective soporific, and a mild narcotic, but non-addictive. Effects last only a few hours and the drinker wakes the next morning feeling fresh and revived. Medicinally, it cleanses the kidneys through its diuretic action, flushes out minor illnesses of the urino-genitary system (and a good practical note for certain readers: if you happen to be in the first stages of a bout of gonorrhoea, it will get rid of that as well), removes aches and pains, gets rid of headaches, can assist in getting rid of skin pimples, and so on – the list is almost endless. On a practical note for European readers, it is also one of the most effective slimming aids known (and you don't have to waste hours running or jogging, waiting for that 'joggers high') and you can say goodbye to constipation problems (although this is not a topic of great concern for Pacific Islanders!). But each subspecies of kava – and there are over 80 of them in Vanuatu – has its own special effects and use. Some are better for ritual/spiritual purposes, some better for medicinal use. One type can be used as a liver cleanser. Other types are of particular medicinal use for women – to ease pre-menstrual aches and pains, to give a painless childbirth, to facilitate lactation after birth, to eradicate menopausal flushes, fevers and aches – and so on (Kirk Huffman, paper presented at the Kava Conference, Australian National University, 2011)."

- **Topic**: "Moanan-Tongan **Fatongia** and Obligation in Ancient Greco-Rome: **Fiefia**, happiness, of **tauelangi**, climactic euphoria, and '**alaha kakala**, permeating fragrance – **Malie**! ***Bravo***! By Social Theorist Siosiua Lafitani Tofua'ipangai"

4.1. Introduction

The Chapter is divided into four main sections. The first section is a discussion of **kava** as a plant, which includes some ideas on how it is made, as well as, its other siginificant behaviours. With the second section, it higlights and examines the myth, **fananga** or **talatupu'a**, of Kava'onau, or **Kava** in short, which Tongans believe to be associated with the begninning of **kava** ceremony under the advice of **Ha'a** Lo'au. The third section is about **Ha'a** Lo'au, who were the masterminds for the institutionalization of the ceremony. The last section is a concern with the **fatongia**, obligation, of certain **ha'a**, lineage, **hou'eiki,** chiefs, and their **kainga**, extended families, in the ritual of **kava**. This includes some of their **fatongia** like making the **kava**beverage and delivering speech, **malanga**, including the **fatongia** for the **fahu** in the **Taumafa Kava**, Royal **Kava,** and Chiefly **Kava, 'Ilo Kava**. In general, I believe that almost all the above were

institutionalized by the **Ha'a** Lo'au and Tu'i Tonga Momo with the purpose for preserving **langilangi** [social rank], **mafaipule** [political power] and **fekau'aki fakata'ata'a** [blood relationship], and in effect this has reinforced the surviving of **fatongia** within the **kava** ceremony since the 10th Century (Mariner, 1817; Collocott, 1927; Gifford, 1929; Newell, 1947; Bott, 1982; Hu'aku, 2011a, 2011b; Filihia, 1990; Māhina, 1986, 1992, 2006; Biersack, 1982, 1990; Herda, 1987, 1990).

Māhina (2011b, 2011c) interprets this socio-political engineering, **tūfunga fonua**, by the Lo'au as an art work of beauty, **faka'ofo'ofa**, in the performance art, **faiva**, of **tauhivā**, moral respect, in the aesthetic structure of **tatau** and **potupotutatau** behaviours for preseving political harmony, **maau**. This was why the **Ha'a** Lo'au used the nick name, Capenter of Land-People, **Tūfunga Fonua**, and for Māhina, this was a beautiful work of art in performance and material arts which should be admired. His view is very similar to the theoretical outlook of Ka'ili (2008a) in Chapter III regarding the **faka'ofo'ofa** of **fatongia** when exchanging process is synchronic, **tonu**, in intensifying of **tā**, time, and re-arranging of **vā**, space, repeatedly in a symmetrical mode of exchange. In my knowledge of the historical importance of such a ceremony in Moanan cultures generally, it may be logically valid to say that 'Moanan-Tongan culture is **kava**', and reversely, '**Kava** is Moanan-Tongan culture.' In the particular situation of Tonga, it is hard to talk about the culture without alluding to **kava** ceremony, and vice-versa. It is like talking about the culture of democracy without alluding to the ***philosophia*** of the ancient Greeks (Collocott, 1927; Gifford, 1929; Newell, 1947; Bott, 1982; Hu'akau, 1989; Filihia, 1990; Māhina, 1992, 2006; Biersack, 1982; Herda, 1987, 1990).

I am not saying that such a ceremony was a necessary condition for the emergence of **fatongia**, and vice-versa. As Hu'akau (2011a, 2011b) has argued that **kava** ceremony was used by the Lo'au as a 'socio-political mechanism' for building a structure not only for a new society but new Empire for the Tu'i Tonga dynasty. In fact, this was the beginning of the so-called Tu'i Tonga Empire, or Empire for the King of Tonga, which ruled its neigbouring islands such as Fiji, Samoa, Futuna-'Uvea (Wallis), Niue, Rotuma, Rarotonga (Cook Islands), among others, for centuries. As Hu'akau has propounded that

this ceremony was perhaps used by the Lo'au as a scapegoat for social and political control in the structure of a new Empire and beyond.

Following this conception, the discussion portrays that **fatongia** was not the creation of **kava** ceremony due to the fact that the former did exist long before the establishment of the latter. Prioir to this social and political re-construction, Tongan society, according to Hu'akau (2011a, 2011b), was still very fragmented without some well-defined socio-political system and standardized fundamental morals. Prior to the formation of this ceremony, the social, political, economic and moral systems of Tongan society and its kingly system were already in place since the 9th or 8th Century but in fragmentation. It is an era that Māhina (1992) has called the 'Dark Age Period' of Tonga because of its lack of information. The Tongan dynasty was first formed around the late 8th or early 9th Century under the reign of the first Tu'i Tonga'Aho'eitu, but with no traditional and mythical accounts of an Empire until the time of Momo and the **Ha'a** Lo'au (Gifford, 1929; Bott, 1982; Māhina,1992, 2011b, 2011c; Biersack, 1982, 1990; Herda, 1987, 1990; Helu, 1985, 1999, 2006, Taliai, 2007).

Its formation was unque due to the participation of the **Ha'a** Lo'au with their knowledge and skills that were new to the circumstance of Tonga at the time. Hence there are three different related issues for further consideration while pursuing this section. First, it is dealt with the historical and cultural formation of **kava** ceremony under the leadership of Lo'au Taputoka, the first Lo'au. Next, it explains the place of **fatongia** and its **siate** of **fiefia,** happiness, in **kava** cermony with its resuffle and revival in a new social and political structure at the time. With the third part, its focus unveils the metaphoric and aesthetic beauty, **faka'ofo'ofa**, of **fatongia fiefia**, happy obligation, and its of climax of **tauēlangi** and **'alaha kakala** in the poetical language of chief's orators, **matapule**, in different **kava** ceremonies with their **malanga** of **faiva lea**, art of speech.

4.5. Summary

The previous sections and paragraphs have depicted that **kava** ceremony has been the birth-ground for **fatongia,** obligation, under the advice of the **Ha'a** Lo'au and Tu'i Tonga since the 10th Century. We have witnessed the interaction of culture and history, in which the former deals with the **fuo**, form, changing in a slow rate, whereas the latter with its content, **uho**, evolving in a faster rate over space, **vā**, and time, **tā,** to use Helu, Māhina and Ka'ili's definitions. It shows that **kava** ceremony and **fatongia** have been interacted in a changeable, multiple and compelx ways either in opposing or supporting modes of operation. The Chapter starts by highlighting **kava** as a plant, with its therapeutic and medicinal characteristics in relation to the reasons why the **Ha'a** Lo'au used it in the first place. How **kava** is made and its different dilutions are very material also in this section.

The discussion continues by unfolding the myth, **fananga**, of Kava'onau, and how the **Ha'a** Lo'au used it as a social and political mechanism for preserving the **fuo** of harmony, **maau**, in society. This covers as well how chiefs, **hou'eiki** and their chief's orators, **matāpule**, morally behave in the ritual and society as a whole, with the social energy to promote happy obligation, **fatongia fiefia**. The examination of the notions of sweetness, **melie**, and bitterness, **kona**, in the myth of Kava'onau is one of the hallmarks of such a **fananga**. This comprises the sacrifice by the parents, Fevanga and Fefafa, to fulfil their **fatongia** to Tu'i Tonga Momo. With the *Chant of Kava'onau*, ***Laulau** 'o Kava'onau* by Lo'au Taputoka, this has consequently connected the the **fananga** with the ritual of **kava** and society as a whole since Taputoka and Momo.

Following the **fananga**, the discussion proceeds on and discusses **Ha'a** Lo'au as the Carpenter of Land and People, **Tūfunga Fonua,** and also their relation to the issue of blood relationship, **fekau'aki fakata'ata'a**, social rank, **langilangi,** and political power, **mafaipule**. This was first seen in the Royal wedding of Nua, the eldest daughter of Lo'au Taputoka, and Tu'i Tonga Momo, the 10th Tu'i Tonga. Some interpretations of the **Ha'a** Tu'i Lo'au, or Tu'i Ha'amea, and the Tu'i Ha'atunga help to widen the understanding of the history and geography of Ha'amea, including other interrelated

events to the beginning of **fatongia** in **kava** ceremony. This has directed the Chapter to unveil some information on the word **fonua**, and its definitions. How it was important to **kava** ceremony and **fatongia** in conjunction to the notions of Royal **Kava**, **Tala Hau**, Chiefly **Kava**, **Tala 'Alofi**, and Extended Family **Kava**, **Tala Fatongia** are very central to this sub-section too. How the King, **Tu'i**, **hou'eiki**, and **matāpule**, are seated in the **Tala Hau** is highlighted as well. This has helped to direct the discussion to suggest some definitions of **ha'a**, **Sina'e** and Lo'au. Lo'au therefore was not just a title, **hingoa fakanofo**, of a lineage, **ha'a**, and a person, but it is also referred to any major change in the culture at large, **anga fakafonua**, as well as, any wishes for major changes by the Tu'i Tonga in antiquity and Tu'i Kanokupolu in modern time.

Formal public speech, **malanga**, in **kava** ceremony with its proposed characteristics has brought into account its cultural and aesthetic significance in such a social medium, **vaka**. Apart from its metaphoric-epiphoria, **heliaki**, in fostering the willingness of people to participate in **fatongia**, its other aesthetic side also helps to enhance the divine climax of **tauēlangi** and '**alaha kakala** in psycho-analytic manner. In either way, they can both give strength to the **maau** of the status quo. In addition, the discussion of the concepts of circle, **fuopotopoto**, or curve, **ngaofe** or **'alofi**, interweave, **matalalava** or **matalalanga** and **spirality, vilovilo,** and their relation to words like intersection, **fēlalava'aki**, and interception, **fēhauakitu'a'aki**, further enlightens the **heliaki** nature of Moanan-Tongan language in metaphoric-epiphoric terms. This is followed by the analysis of the related ancient words of food portion, **fono**, and root-cap of **kava**, **fakatomo**, in a **Tala Hau** and **Tala 'Alofi**, as well as, the **fahu** system, and ancient and modern **kava**, which brings the whole Chapter to its end. All of the above have in fact provided answers to the main argument of this dissertation in the propositions of its themes and their conclusion, as well as, the four research questions that I have reiterated in the beginning of this Chapter.

I now continue to Chapter V with its attempt to highlight and illuminate some theoretical outlooks from ancient Western thoughts and civilization regarding obligation, ***deontic*** or **fatongia**, since the 5th Century BC in ancient Greece until 5th Century AD before the

emergence of the Dark Ages. Largely, it is an endeavour to bring into mind the great works on deontic by Greek philosophers up to the Hellenistic scholars with conjunction to happiness, **fiefia,** and its related words like serenity, **nonga,** and satisfaction, **fiemālie**. Importantly, such Western thinkers were the first in the world to study and analyse obligation from scientific and philosophical perspectives. It is therefore fundamental for this dissertation to find out what they had actually conceptualized regarding **deontic**. I now turn and discuss the ***deontic*** in Greek and Roman thoughts and civilizations. (Siosiua Lafitani Tofua'ipangai, PhD Thesis, Doctor of Philosophy in Social Work, Signadou Campus, Australian Catholic University, 2011)."